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(Biographical Sketch Supplement Update 07-2014)

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PREFACE

June 2014

In the last few years the National Institutes of Health has dramatically changed the way that applications for grant support are made to it. Not only did it change to electronic submission, NIH modified the ways that proposals are written and reviewed. This *Workbook*, which is only available through Grant Writers' Seminars and Workshops, LLC (www.grantcentral.com), will be your guide to incorporating all of those changes into the way that you prepare your research proposal to the NIH. You will do so using the *SF424 (R&R) Application Guide for NIH and Other PHS Agencies* and the forms that are related to those instructions. As the title of the *Application Guide* denotes, this *Workbook*, which is based on the Updated July 25, 2013 Adobe Forms Version C edition of the instructions, is also applicable to other Public Health Service agencies, such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ).

Detailed instructions for preparing and submitting a PHS proposal are contained in Part I of the *SF 424 (R&R) Application Guide*. This *Workbook* is meant to complement, not replace, those instructions (refer to <http://grants.nih.gov/grants/funding/424/index.htm> for the latest version). By "complement" we mean that we will help you apply the principles and fundamentals of good proposal writing, as well as the tips and strategies, that kept each of us continuously funded by NIH for nearly 30 years – none of which can be found in the instructions.

This *Workbook* specifically targets NIH's R01 grant mechanism. If you are writing an application that will make use of one of the other grant mechanisms (e.g., R03 or R21) we have provided links in chapter 3 that will give you specific instructions about the mechanism that you have in mind. In general, the principles and fundamentals are largely the same, so this *Workbook* will be helpful to you, regardless of your choice of grant mechanism.

We have included a Supplement to Chapter 12, which describes how to prepare the Biographical Sketch. Extremely important changes in how the Biographical Sketch is written and reviewed are scheduled to be implemented in FY 2016. The Supplement gives you our recommendations on how to prepare to capitalize on the projected modifications.

Many applicants make numerous mistakes in the preparation of their proposals, simply because they don't read and follow the instructions closely enough. Some of those mistakes are of sufficient magnitude (e.g., use of the wrong typeface or font size; exceeding the page limit for a section) that they can cause a proposal to fail its initial compliance review, resulting in the proposal being rejected administratively pending correction of the mistakes. While most mistakes related to not following instructions are not likely to lead to out-and-out rejection of your proposal, it is a fact that, cumulatively, they can negatively influence a reviewer's opinion of your application. Such mistakes clearly reflect inattention to detail, which is what research is all about.

In the theater, often the last encouragement that an actor hears before going on stage is, "Break a leg". We don't know what the equivalent is with respect to writing a grant application — "Break a pen", perhaps? Whatever it is, it would translate as, 'Best of luck'. But, as you will see, luck doesn't play much of a role in this process — unless it's the kind that Thomas Jefferson was referring to when he said, "I'm a great believer in luck, and I find the harder I work the more of it I have." We agree, so let's get cracking!

Stephen W. Russell

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PRINCIPAL CHANGES IN THIS EDITION

The importance of the changes that NIH has made with respect to the preparation and review of grant applications cannot be exaggerated. They collectively represent a true paradigm shift and include:

Switch to a 9-point evaluation scale.

Greater emphasis on quality of content and less on detailed description of what will be done.

Greater emphasis on funding the applications of New/Early Stage Investigators.

Standardization and shortening of reviews.

Greater emphasis on the fastest path to funding: decision to reapply or switch to a new idea.

Shortening of the Research Plan, with elimination of sections for review of literature and presentation of preliminary data.

Linkage of sections of the application to each of the five core review criteria.

Switch to Adobe Forms C

Increase in title length to 200 characters, including punctuation and spaces

Policy switch permitting new submission after either a failed first submission or a re-submission.

Supplement to Chapter 12 offering recommendations regarding how to prepare for modifications in the Biographical Sketch that will be likely be implemented in early 2015

These changes have greatly altered how NIH research-grant proposals are written and reviewed, not only technically, but philosophically. We are not usually given to hyperbole, but in this case it is warranted: In our opinion, these changes are – without question – the most important and positive ones NIH has made in the writing and review of grant applications since we first began submitting grant proposals there in 1972. Let us guide you in using these changes to your competitive advantage.



OVERVIEW: PART ONE

BEFORE YOU BEGIN TO WRITE

In our opinion, most applicants fail to merit research funding primarily because they don't do what is necessary up front to position themselves for success. Chapters one through six of this *Workbook* are designed to help you avoid that trap.

Chapter one, "Finding NIH Funding Opportunities and Responding to Them" will familiarize you with how the National Institutes of Health sets its priorities and creates funding opportunities to help attain its goals. This chapter will also introduce you to the Center for Scientific Review – the part of NIH that receives all applications and refers most of them for review.

Chapter two, "How to Develop an Irresistible Idea for Your Grant Application," will assist you in developing the centerpiece of your proposal – an idea that will make a significant, vertical difference in your field once it is acted upon.

Chapter three, "How to Find the Appropriate Program and Grant Mechanism for Your Idea," will help you target the part of NIH that is most appropriate for your idea and make certain that you package and present it in the appropriate grant mechanism.

Chapter four, "Influence of the NIH Review Process on Writing for Success" will familiarize you with how to select the most appropriate scientific review group for your proposal and how to optimize your presentation to that review panel. In particular, it will introduce you to the wealth of resources that NIH provides to help applicants prepare grant proposals. Finally, it will detail the role of the Center for Scientific Review in the receipt and referral of your application for review.

Chapter five, "Response to Prior Review," will help you to avoid the mistakes that so often undermine resubmitted applications.

Chapter six, "Create a Writing Schedule," will help you set up a developmental schedule for your proposal and will guide you to a part of our website that will assist you in doing so. The recommended approach will allow you to manage all of your other, competing priorities while, at the same time, you develop the best application you are capable of writing.

We strongly urge you to read and follow the recommendations that constitute Part One of this *Workbook* before you begin to write. From years of experience helping investigators prepare research proposals to NIH, we can tell you that those who read and follow this first part of the *Workbook* enter the writing phase with a distinct edge over their competitors. We encourage you to be among them.

CHAPTER 1

FINDING NIH FUNDING OPPORTUNITIES AND RESPONDING TO THEM

To be successful, a grant application submitted to the National Institutes of Health must be concordant with its mission. Translation: one of the awarding components that comprise NIH must be convinced that funding your proposal will help the Institute/Center advance its mission. It is important, therefore, that applicants understand NIH's mission and goals, i.e., what its investments in medical and behavioral research are meant to accomplish.

THE MISSION OF THE NATIONAL INSTITUTES OF HEALTH

(<http://www.nih.gov/about/mission.htm>)

"NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life and reduce illness and disability. The goals of the agency are as follows: 1) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health; 2) develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease; 3) expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and 4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."

"In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research: in the causes, diagnosis, prevention, and cure of human diseases; in the processes of human growth and development; in the biological effects of environmental contaminants; in the understanding of mental, addictive and physical disorders; in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists."

NIH is part of the Executive Branch of our government. Thus, the director is a political appointee of the President. The organizational chart on the next page depicts how NIH is structured.



The Center for Scientific Review is highlighted in this organizational chart because of its importance to the application process. Its role in the receipt, processing and review of your proposal is summarized in the next paragraph and detailed in chapter 4.

THE CENTER FOR SCIENTIFIC REVIEW (CSR)

NIH supports both intramural ('within the walls' of NIH) and extramural (outside its walls) research programs. Members of the extramural community are the ones who make grant applications to NIH. The Center for Scientific Review (<http://public.csr.nih.gov/Pages/default.aspx>), as can be seen from the preceding organizational chart, is independent of the Institutes and other Centers. Its role is pertinent to all of the awarding components, making it a so-called 'cross-cutting' part of NIH. CSR is responsible for the receipt and referral of all grant applications submitted to NIH and oversees the peer review of most of them (~70%), regardless of the Institute or Center to which they are assigned. Approximately 90% of CSR's efforts and resources are focused directly on peer review, which is conducted under the auspices of its six scientific divisions (AIDS, Behavioral and Population Science; Basic and Integrative Biological Sciences; Neurosciences, Development & Aging; Physiological and Pathological Sciences; Translational and Clinical Sciences; and Receipt & Referral).

THE NIH COMMON FUND

The Common Fund (<https://commonfund.nih.gov/about.aspx>), which is administered through the Director's Office, was enacted in 2006. Its purpose is to support research that cuts across at least two of NIH's Institutes/Centers. In other words, its intent is to foster collaboration across NIH's Institutes and Centers that will help to overcome roadblocks that "impede basic scientific discovery and its translation into improved human health. In addition, these programs capitalize on emerging opportunities to catalyze the rate of progress across multiple biomedical fields. Common Fund programs are expected to transform the way a broad spectrum of health research is conducted. Initiatives that comprise Common Fund programs are intended to be catalytic in nature by providing limited term investments in strategic areas to stimulate further research through IC-funded mechanisms."

The range of programs sponsored by the Common Fund can be viewed on the right side of the Fund's home page (<https://commonfund.nih.gov/index.aspx>).

FUNDING OPPORTUNITY ANNOUNCEMENTS

All grant applications to NIH must be submitted in response to a Funding Opportunity Announcement. The *Application Guide* describes "Funding Opportunities" that are available to members of the extramural community (section 2.4). There are three generic kinds of research-grant funding opportunities: 1) ones that are described in a Parent Announcement (previously referred to as "investigator-initiated" or "unsolicited" proposals); 2) ones that are described in a Program Announcement (PA); and 3) ones that are characterized in a Request for Applications (RFA). NIH also offers contract-research opportunities, which are in a separate category from research grants. Contract opportunities are announced through Requests for Proposals (RFP) and will not be considered in this *Workbook* for research-grant proposals (see http://www.ninds.nih.gov/funding/areas/contracts_management_branch/contract_process.pdf for an overview of the contract process).

Parent Announcements sponsor research that is investigator initiated, i.e., there is no specific solicitation of the application. The applicant generates an idea that is programmatically relevant to NIH, prepares an application, and submits it on or before one of the deadlines that are listed at <http://grants.nih.gov/grants/funding/submissionschedule.htm>.

Parent Announcements are listed at: http://grants.nih.gov/grants/guide/parent_announcements.htm.

Program Announcements (PA, PAR or PAS). A Program Announcement is used by awarding components at NIH to communicate particular interest in a research area to members of the extramural community. They are relatively general in nature. Responses to them are considered to be investigator-initiated projects within the specified area. PAs – the most common kind of Program Announcement, are reviewed by standing review panels through the Center for Scientific Review. PARs are reviewed by an Institute. PAs and PARs compete for the same pool of money that funds Parent Announcement applications. PASs are supported by set-aside funds. Program Announcements that publicize research opportunities are usually active for approximately three years. Those currently available can be found at: http://grants.nih.gov/grants/guide/search_results.htm?year=active&scope=pa. Because Program Announcements often seek applications in priority areas, Program Staff at a Center / Institute may elect to fund applications that fall short of the pay line, especially those of New/Early Stage Investigators.

In addition to soliciting research in a specific area, Program Announcements are also used by NIH to remind the extramural community that a given area is of continuing interest to NIH, as well as to modify an activity or grant mechanism.

Request for Applications (http://grants.nih.gov/grants/guide/search_results.htm?year=active&scope=rfa) are quite different. Research of a very specific kind is solicited. There is a single, specified deadline or set of deadlines that must be met. The review panel is a specially convened Scientific Review Group, not a standing study section. Set-aside funds are used to fund successful applications, the estimated number of which is stipulated in the RFA. In other words, applicants responding to a RFA are competing for a different pool of money than those who have written investigator-initiated (i.e., Parent Announcement) applications or responses to a PA or PAR. If you can provide the kind of research that is being sought, writing an application in response to an RFA is a great way to get funded. On the other hand, if you have a 'square peg' and contrive to make it look like it will fit in the RFA's 'round hole,' you are almost surely wasting your time. Such applications rarely succeed and are often sent back administratively, without review, as unresponsive to the RFA.

HOW TO FIND THE FUNDING OPPORTUNITY THAT IS RIGHT FOR YOU

Program Announcements and Requests for Applications are published in five places: 1) the *NIH Guide for Grants and Contracts* (<http://grants.nih.gov/grants/guide/description.htm>); 2) the *Federal Register* (<http://www.gpoaccess.gov/fr/index.html>); 3) Grants.gov at "Search Grants" (<http://www.grants.gov/web/grants/search-grants.html>); 4) the NIH website <http://grants.nih.gov/grants/guide/index.html>; and 5) the websites of the individual awarding components. At the third, "Search Grants" choice, above, you can search manually for relevant funding opportunities by key word, Funding Opportunity Number, or CFDA (Catalog of Federal Domestic Assistance) number. You can also search by "Funding Instrument Type", "Category" or "Agency". You can and should sign up for the Grants.gov e-mail alert service at <http://www.grants.gov/search/email.do>. You can also subscribe to a listserve for the *NIH Guide for Grants and Contracts* by accessing <http://grants.nih.gov/grants/guide/listserv.htm> and/or to an RSS feed (<http://grants.nih.gov/grants/guide/newsfeed/fundingopps.xml>). After subscribing to either of these you will regularly receive a list of all Notices, Program Announcements and Requests for Applications as they are issued by NIH.

GRANTS.GOV AND ELECTRONIC RESEARCH ADMINISTRATION (eRA)

The vast majority of NIH funding opportunities require electronic submission, either through Grants.gov or your institution's NIH-authorized system-to-system means of submitting proposals electronically. Each applicant organization must register with Grants.gov and designate an Authorized Organizational Representative (also known as the Signing Official) – the only person who can sign and submit applications for the applicant organization. All Principal Investigators/Program Directors must register individually. A common mistake on applications with multiple PDs/PIs is registration of the contact PI, only.

The eRA Commons (<https://commons.era.nih.gov/commons>) is exceptionally important to the application process and for monitoring your proposal after it has been submitted. Become familiar with it. An excellent overview is located at <http://era.nih.gov/commons>. You can additionally take advantage of the YouTube eRA Tutorials that are provided at http://era.nih.gov/era_training/era_videos.cfm or the "Demo Account" at <https://public.uat.era.nih.gov/commons/public/createDemoAcct.do?mode=create>. The latter will provide opportunities for you to learn about how to navigate the eRA Commons in a demonstration environment.

SOFTWARE REQUIRED

To access, complete and submit a grant application, you must have a Grants.gov-compatible version of the Adobe Reader software and use the Adobe C version of the SF 424 (R&R) forms. NIH will no longer accept applications prepared using the previous Adobe B forms. Attachments to the Adobe forms must be in Portable Document Format (PDF), which requires PDF-creation software (i.e., Adobe Reader software is not sufficient). The relevant Adobe software is recommended at <http://www.grants.gov/web/grants/support/technical-support/recommended-software.html> or Planet PDF's "Find PDF Software" feature at http://planetpdf.com/find_software.asp. The *Application Guide* strongly discourages creating the required PDF documents by scanning the text – unless your scanner is equipped with the proper Optical Character Recognition (OCR) process.

UNDERSTANDING THE 'LANGUAGE' OF NIH

As with many governmental organizations, NIH uses a bewildering array of acronyms and abbreviations, as well as codes and definitions for its programs and grant mechanisms. Activity codes (e.g., R01 or U50) are deciphered and defined at http://grants1.nih.gov/grants/funding/ac_search_results.htm and http://grants1.nih.gov/grants/funding/funding_program.htm. NIH's *Glossary and Acronym List* (<http://grants.nih.gov/grants/glossary.htm>) is additionally helpful in navigating the language of NIH, as is a separate *Acronym List* that can be found at (http://grants.nih.gov/grants/acronym_list.htm). NIAID's *Glossary of Funding and Policy Terms and Acronyms* (<http://grants.nih.gov/grants/acronymhttp://www.niaid.nih.gov/researchfunding/glossary/pages/n.aspx>) is also helpful.

DEVELOPMENTAL STEPS FOR CHAPTER ONE:

1. Understand NIH's mission and goals and how these influence the focus that your proposal must have if you expect to be successful.
2. Familiarize yourself with the Center for Scientific Review and its role in receiving, referring and reviewing your application. Plan to develop detailed knowledge of this important part of NIH after reading chapter 4 of this *Workbook*.
3. Appreciate that all research-grant applications to NIH must be made in response to one of three kinds of Funding Opportunity Announcements.
4. Sign up for either NIH's funding-opportunity listserv or RSS feed.
5. Familiarize yourself with Grants.gov, the clearinghouse for all Federal competitive grants and the means of submitting grant applications to NIH.
6. Enroll with Grants.gov for e-mail alerts of funding opportunities.
7. If your institution has its own NIH-authorized electronic submission system, become familiar with it.
8. Assure that your institution is registered with Grants.gov. Identify your Authorized Organizational Representative (Signing Official).
9. Become familiar with the NIH eRA Commons and the electronic submission and tracking of your grant application. Do so by exploring the Overview of the eRA Commons website and by making use of the YouTube tutorials that the eRA Commons makes available.
10. Assure that your institution is registered with the NIH eRA Commons.
11. Register with the eRA Commons through your institution.
12. If you plan a multiple PD/PI application make certain that each of the other PDs/PIs is registered with the eRA commons.
13. Download Adobe Reader and PDF-creation software, both of which are needed to create and electronically submit a grant application through Grants.gov.
14. Review and bookmark the following resources as a means of better understanding NIH's 'language'.

CHAPTER 2

HOW TO DEVELOP AN IRRESISTIBLE IDEA FOR YOUR GRANT APPLICATION

The application you write can only be as good as the idea with which you start: If you don't have a compelling, novel idea that will drive your field vertically, you're unlikely to be funded. It's that simple! No amount of 'window dressing' — grantsmanship — can overcome a bad idea. Therefore, you (and we) must do everything possible to ensure that your starting point — your idea — is nothing short of outstanding.

The best preliminary idea that you can generate is usually the product of a step-by-step developmental process, i.e., it will rarely occur as a spontaneous event. We recommend that you take six steps in the developmental process: 1) define the niche area that you want to systematically develop; 2) collect and critically analyze background information that pertains to the proposed area of investigation; 3) generate a preliminary idea that is pertinent to the problem you have chosen; 4) assess your preliminary idea's potential for success and modify it, if necessary; 5) seek constructive criticism from knowledgeable colleagues; and 6) refine the idea to maximize its potential for impact on your field.

1. Define The Niche Area That You Want to Systematically Develop. Your application is unlikely to be fundable if what is proposed only confirms or marginally extends the work of others. Therefore, you must identify an area of research in which you can make contributions that will drive your field vertically. This translates into identifying a niche area within the scope of your overall research interest that is not overworked, i.e., a subdivision of your broader interest that you can systematically develop as your own.

Once you have done so, identify the long-term goal you have within that niche area. It should be more than what could be accomplished under the auspices of a single grant, but not so ambitious that it would be seen as unrealistic within the context of your career. Next, conceptualize the continuum of research that would be required to attain the long-term goal you have identified.

Finally, identify the next logical step that must be taken along the continuum of research that you have conceived. In contrast to the long-term goal, the problem you select here should be one that can be resolved under the auspices of a single award. It will become the subject of your proposal.

2. Collect and Critically Analyze Background Information That Pertains To The Proposed Area Of Investigation. A comprehensive review of the literature is the next step in generating a fundable idea. This is necessary for at least three reasons. First, you need to determine what is already known — published — in the area. Second, the extent to which that body of knowledge

is reliable needs to be critically examined. And, third, you need to determine who is actively working and publishing in the field.

There are many different ways to explore the current and past literature of a field. Examples of some of the databases and services that may be helpful to you are included in the text box, below.

Literature Databases and Services

Highwire Press (<http://highwire.stanford.edu>)

1,939,665 full-text articles are free, with about 3,000 more free each month, making HighWire the largest archive of free life science articles in the world. Includes the biological, medical, physical and social sciences. A free e-mail alert service is available.

PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>)

A service of the National Library of Medicine, PubMed includes over 15 million citations for biomedical articles back to the 1950s. These citations are from MEDLINE and additional life science journals. PubMed includes links to many sites providing full text articles and other related resources. PubMed also has a free e-mail alert service.

Thomson Reuters Web of Knowledge (<http://wokinfo.com>)

This subscription service covers the 'hard' sciences, social sciences, arts and humanities. Individual subscriptions are beyond the resources of most individual investigators, so consult your reference librarian to determine whether or not your institution is a subscriber. In all likelihood, it will be.

Determining the extent and reliability of current knowledge requires more than reading abstracts; *detailed, critical analysis* of the pertinent past and current literature is required. One helpful approach to organizing the results of your review is to photocopy the first page of any journal article that you evaluate. The first page will almost always contain the authors' abstract. As you read the paper, annotate the photocopy with any important information that was not included in the abstract. Also include remarks about the quality of the work, as well as of the conclusions that were drawn from it. The annotated photocopy can then be filed / catalogued for future reference.

TIP: During the course of your literature review, create a list of key words that describe the field, as well as the names of investigators who have been active in the area during the last ten years.

3. How To Generate A Preliminary Idea That Is Pertinent To The Problem You Have Chosen. As you work your way through the literature, invariably, ideas will begin to occur to you. Retain such ideas, but continue to conduct your review until it has been completed. Why? Because many of your early ideas will probably prove to be sophomoric as you become more critically conversant with the literature. Also, major shifts in your insight will almost certainly occur as you view your ideas, not individually, but in the context of how they relate to each other. Finally, some of your early ideas may be ones that other investigators have had before you and have used in their own grant proposals. As you will soon see, there is nothing more 'lethal' in this business than writing a grant application that has already been written.

Once you have completed your review, go back to the notes and ideas that you have written down. As you consider them, inspiration may strike. But, if it doesn't, don't be alarmed. Don't become anxious or think that you are somehow deficient. In fact, it is unusual for your best idea to immediately occur to you. Should that be the case, simply put your notes away for a few days and then take another look at them. This time, use a different approach – e.g., try outlining or diagramming to better establish how the ideas and concepts relate to one another. The proverbial light bulb will eventually come on. When it does, you will know it, because you will be genuinely excited by the prospects that become apparent to you. At that point, you need to ask yourself one last, two-part question: *'Will this idea impact significantly on my field and, if so, can I convince others of that fact?'* If your answer to both parts is affirmative, you've crossed the Rubicon and you're on your way. On the other hand, if you find that you can't say with conviction that the idea has the potential to advance your field substantively, you have to accept that you are not yet ready to write a competitive, i.e., successful, grant application. You either need to keep trying to evolve a more novel, important idea in the same area, or shift to a new problem that has the potential to pass this 'impact' test.

4. How To Assess Your Idea's Potential For Success And Modify It, If Necessary. Once you have generated your preliminary idea, as the next step you need to assess its potential for success before you ever put pen to paper. There are three criteria that must be considered:

Your own ability to pursue the idea. Regardless of how good your idea is conceptually, it has to be one that is within your capabilities to pursue, practically speaking. For example, do you and your colleagues have the expertise necessary to accomplish the work? If not, can you mobilize the missing expertise by recruiting either co-investigators, collaborators or consultants? Is this an application that could benefit from a multiple-PD/PI strategy and, if you think so, can you justify that approach? Do you have the resources that will be required? If not, will you be able to obtain them? Will you have the funding and personnel necessary to acquire preliminary data that will convince reviewers that the project is feasible in your hands? If your application will be clinically oriented, will you have access to sufficient patients / clinical material that a statistically valid outcome will be possible? If not, can you collaborate with investigators at other institutions? Will you, as Principal Investigator, have sufficient time to devote to the project? If you are a senior person with many different kinds of scientific, educational, and administrative responsibilities, is it credible to take on more? If you are a New Investigator, can you commit time enough to convince reviewers that you are fully committed to starting a research career? The answers to these and related questions either have to be answered convincingly in your favor or there is little point in going forward, no matter how good your idea may be conceptually.

The competition you will encounter. Good ideas are often generated independently by more than one person. You need to know, therefore, what research has already been funded in the area that you are considering. As noted above, you must avoid writing an application that is similar to one that has already been funded. Also, if such grants are out there, you want to know about them so that you can make use of them to stimulate and extend your own thinking and planning. You can electronically access grants that have been funded by the United States Public Health Service since 1972 by going to the RePORTER (Research Portfolio Online Reporting Tool Expenditures & Results) query form (<http://projectreporter.nih.gov/reporter.cfm>). Most of this database pertains to extramural projects, the vast majority of which have been funded by NIH. A few will be ones supported by the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), and the Agency for Healthcare Research and Quality (AHRQ).

There are similar databases available for the National Science Foundation back to 1976 (<http://www.nsf.gov/awardsearch>); data prior to 1976 is less complete) and the United States Department of Agriculture (Current Research Information System [CRIS]) located at <http://cristel.csrees.usda.gov>. Finally, you can access grants funded by the United Kingdom's Medical Research Council prior to 2011 by going to <http://www.mrc.ac.uk/ResearchPortfolio/index.htm>. Thereafter, go to <http://qtr.rcuk.ac.uk>.

To retrieve information from any of these databases, you can enter the names of individuals who either are, or have been, active in your field during the last ten years (see TIP box, above). Alternatively, you can use key words that are applicable to the idea that you are trying to fund. By using either the search strategy that is specifically recommended for the database (most are accompanied by such recommendations) or one of your own design, you can obtain numerous titles of currently / previously funded applications that are related to your idea. Clicking on a title of interest will bring up that application's abstract, the content of which may trigger useful ideas. In addition, some of the databases contain either key words or indexing terms (NIH calls them ("Project Terms") for each application. These descriptors often will pertain to information that is not covered in the abstract (e.g., a specific method). Careful consideration of these descriptors can lead to additional useful and new thoughts/approaches that will help you to develop and refine your own research design. *A day or more spent screening these databases of already funded grants will be invaluable!!!* We predict that you will be stunned – literally – at how much better the research design of your own application becomes by using what you glean from the abstracts and key words of your competitors to improve your own proposal. Taking this approach is an important way of gaining a distinct competitive advantage.

Your idea's funding potential. Even though you have tentatively decided to submit your application to the NIH, if you haven't done so already, you need to make certain that there aren't other, equally applicable funding opportunities at other agencies. The objective here is to find other agencies that will be helped to accomplish their missions by funding your idea. To find such additional opportunities, you need to search thoroughly one or more of the funding databases that are available to you. If your institution is a member of either COS Pivot (<http://pivot.cos.com> → Funding Opportunities) or InfoEd International (<http://www1.infoed.org> → Grants and Contracts → SPIN Funding Opportunities), you have access to powerful tools that will facilitate your search for additional funding. You can also manually seek other federal funding opportunities through Grants.gov by clicking on the "Search Grants" tab. While you search such databases, note any agencies that have interests that coincide with your own. Even if NIH continues to be your best bet for funding, other agencies that you identify can become important backup sources of support. It is permissible – smart business – to send essentially the same application to other agencies at the same time that you submit it to NIH – with two important exceptions: (i) you cannot submit an application to one component of NIH and simultaneously submit essentially the same application to other components of the NIH or of the U.S.P.H.S. (e.g., Agency for Healthcare Research and Quality [AHRQ], Agency for Toxic Substances and Disease Registry [ATSDR], Centers for Disease Control and Prevention [CDC], Food and Drug Administration [FDA], Health Resources and Services Administration [HRSA], Indian Health Service [IHS], or the Substance Abuse and Mental Health Services Administration [SAMHSA]; see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html>). However, you could submit essentially the same application to some other federal agency, such as the Department of Defense. And, (ii) if you are an established investigator, with rare exceptions, the Biological Sciences Directorate of the NSF. If, however, you meet NSF's definition of a "Beginning Investigator" (individuals who have not been either a Principal Investigator [PI] nor Co-Principal Investigator [Co-PI]

on a federally funded award, with the exception of doctoral dissertation, postdoctoral fellowship or a research planning grant – see the NSF's *Grant Proposal Guide*, section I.A), you would be able to do so. It's not that much extra work to apply to more than one source of funding, because almost all grant applications contain the same basic elements, i.e., title, summary, background, significance, research plan, budget, etc.), which simply must be 'tweaked' to include specifics that are required by the new agency. Given this fact, with competition what it is these days, as noted earlier, sending an application to multiple potential sources of funding is smart business. If you decide to do so, you must indicate that fact in block 8 of the SF 424 (R&R) Cover Component. Check the "Yes" box and list the other agencies to which the proposal has been submitted. If you ultimately have the enviable problem that more than one grantor wants to fund your proposal, you would either have to select one of them (you cannot double fund the same project) or make adjustments that would eliminate overlap between the pending applications.

5. Seek Constructive Criticism From Knowledgeable Colleagues. Because the idea that underlies a grant application is so fundamentally important to its success, you need to do everything possible to ensure that you have the strongest idea – the strongest starting position – on which to build. An essential part of "doing everything possible" is seeking critical feedback from your colleagues; if problems exist with your idea, now is the time to find out about them — not later, from your reviewers. Once you and colleagues on the application with you have developed the idea to the fullest you can, at least two 'experts' should be consulted. Regardless of their locations, they need to be individuals you trust. Most often, they will be investigators who are researching areas somewhat tangential to your own, but close enough that they will be able to give you the critical feedback that you seek. They could, for example, be members of your pre-submission review committee (see chapter 21). Their primary role will be to review the final draft of your draft application for scientific and technical merit before it is submitted. However, using them to obtain constructive criticism of your idea is an additional role that you should consider for them. A *brief* overview (no more than one page) should be prepared that contains the following components: 1) the principal knowns on which the work would build; 2) the gap in the knowledge base that would be filled; 3) the central hypothesis that would be tested (or the need that you intend to meet, if your application will be need driven); 4) the rationale, or underlying reason, for why the work needs to be done; 5) what could be expected from the work; and 6) why the expected outcomes are potentially important in vertically advancing the field. When you present it to them, you should specifically ask your consultants for ways in which you can improve the idea.

An alternative to getting feedback on the idea at this stage is to wait until the template or master plan for your application has been prepared (see the Overview to Part II, page 60). The positive aspect to this alternative approach is that your idea will be presented in a clearer, more complete form. The negative is that the work invested in writing the template or master plan may be wasted if its centerpiece – the idea – is found to be wanting at this later time.

6. Refine Your Idea To Maximize Its Impact. The sixth and final step is to consider critically the feedback that you receive from your colleagues and, *if you concur*, to modify the idea accordingly. If you don't fully concur, this can be a time of painful decision making. In such circumstances, you may want to seek the advice of additional colleagues before you make any changes. The bottom line is that you must have total confidence that the final product – the idea that will drive your research proposal – is completely sound and will make a difference in your field when acted upon. If you don't have that level of confidence, you won't be able to project the kind of enthusiasm and commitment that are necessary to write an outstanding proposal.

DEVELOPMENTAL STEPS FOR CHAPTER TWO:

1. Identify a relatively under-explored niche within the area of your broad research interest.
2. Develop a long-term research goal in the niche area and conceive a continuum of research that will be needed to reach that goal.
3. Conduct a comprehensive, critical review of the related literature.
4. List key words that characterize the subject you have chosen and the names of investigators who have been active in the area during the last ten years.
5. Develop a preliminary idea for your proposal.
6. Search databases of already funded grants and use what you learn to refine and improve your idea.
7. Seek constructive criticism of the idea from knowledgeable colleagues. Further refine your idea, if necessary.
8. Identify alternative / additional granting agencies to target with your application.

EXAMPLE OF E-MAIL MESSAGE TO A PROGRAM OFFICER

Dear Dr. (Program Officer's Last Name),

I would appreciate the opportunity to talk with you briefly about the research proposal that I intend to submit to NIH on October 5 (please see attached synopsis*).

I plan to request assignment to your Institute and program for consideration of funding.

The purpose of our conversation would be to ensure that I maximize the programmatic relevance of what I submit. Please let me know by return e-mail when it would be convenient for me to call.

Thank you for considering my request.

Sincerely,

Your Name and Doctoral Degree(s)

Your academic rank

Your e-mail address

Your telephone number

Your academic Website (if you have one)

* The synopsis should consist of the *Specific Aims* section and the Significance and Innovation subsections of *Research Strategy* – a total of approximately two pages.

CHAPTER 3

HOW TO FIND THE APPROPRIATE PROGRAM AND GRANT MECHANISM FOR YOUR IDEA

HOW TO FIND THE APPROPRIATE PROGRAM FOR YOUR APPLICATION

TIP: Review panels don't fund grant applications! Review panels recommend funding.

Program officials make the funding decisions.

One of the most important misconceptions held by applicants is that review panels fund grant applications. A second common misconception is that program officials are not relevant to the development of grant applications. In fact, nothing could be farther from the truth! While standing review panels (called Scientific Review Groups or Study Sections at NIH) are critically important in evaluating the scientific and technical merit of proposals (i.e., they recommend funding), the person who has the most input into whether an application will be funded, or not, is the Program Officer who is in charge of the specific program being targeted.

It is also not widely appreciated by applicants that each of NIH's programs has its own set of programmatic priorities. Such priorities are set according to current mission goals. To assist in setting priorities, program officials periodically inventory their portfolios of already-funded grants. The purpose is to determine how their funds are distributed. If a given research area is well- or overly represented, they may decide to de-emphasize that area when future funding decisions are made. Mission-relevant research areas that are not adequately represented, along with new programmatic goals, may be given future funding priority. Therefore, to be maximally appealing to Program, your idea should fall within an area of current programmatic relevance.

TIP: What you want to propose is not necessarily what is important. Finding an NIH program that wants to fund what you want to propose is the key to success!

In light of the above, *a critical step in developing a competitive grant application is assuring that your idea will be regarded by the Program Officer as programmatically relevant when it is submitted.* Ideally, you want to 'marry' what you want to do with what a program wants done, so that by funding your proposal the program will take a step toward accomplishing its mission. It is important at this early stage in the development of your application, therefore, to identify the program at NIH that will be the target of your application.

As was noted in chapter one, NIH is organized under the Director's Office into 19 Institutes, the National Library of Medicine, and 7 Centers. Each of these entities has its own set of priorities and provides research grant support as a means of accomplishing its goals. If you will be sub-

mitting a self-initiated application, i.e., one that has not been solicited and will be submitted in response to a Parent Announcement, the first step is to determine which one (or more) of these 27 potential sources of support is most applicable to the idea that you have developed. To do so, go to the "Institutes, Centers and Offices" part of the NIH website (<http://www.nih.gov/icd>), which will give you a brief overview of the interests of each Institute and Center.

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Turning Discovery Into Health

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NIH Home

INSTITUTES, CENTERS & OFFICES

NIH is made up of 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems. NIH leadership plays an active role in shaping the agency's activities and outlook. Learn more about NIH

NIH OFFICES

NIH Office of the Director (OD)
The Office of the Director is the central office at NIH for its 27 Institutes and Centers. The OD is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components. OD's program offices include the Office of AIDS Research and the Office of Research on Women's Health, among others.

NIH INSTITUTES

National Cancer Institute (NCI) — Est. 1917
NCI leads a national effort to eliminate the suffering and death due to cancer. Through basic and clinical biomedical research and training, NCI conducts and supports research that will lead to a future in which we can prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

NCI	NIAMS	NIHES	CIT
NEI	NIHID	NIHMS	CSH
NHLBI	NICHD	NIHAI	FIC
NIHRI	NIDCD	NIHID	NCI/AM
NIA	NIDCR	NIHDS	NCATS
NIAAA	NIDDK	NIHRI	CC
NIAD	NIDA	NLM	OD

See Also
Directors of NIH Institutes and Centers
Mailing Addresses for NIH Institutes and Centers

Scroll down the list and select the one that seems to mesh best with your idea. Click on its name (or click on the appropriate "Quick Link" at the upper right of the page) and you will find yourself at that Institute's / Center's home page. For illustrative purposes, let's say that your idea most closely meshes with those of the National Institute of Allergy and Infectious Diseases (NIAID; <http://www.niaid.nih.gov>). Part of NIAID's home page (as of this writing) is depicted below. At the lower right, denoted by an arrow, is a "Finding People" option. By clicking on it you

NIH National Institute of Allergy and Infectious Diseases
Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases.

Search Advanced Search

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Resources for Researchers
Technology Transfer and Intellectual Property
Find NIAID Researchers
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Staff Scientist
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Global Research
HIV/AIDS
Influenza (Flu)
Immune System
Malaria
Sexually Transmitted Diseases
Tuberculosis
Food Allergy
View all A to Z Topics

News & Events
FDA Study Helps Provide an Understanding of Rising Rates of Whooping Cough and Response to Vaccination—Nov. 27, 2013
NIH Statement on World AIDS Day 2013—Nov. 27, 2013
Media Availability: NIH Funded Scientists Identify Potential Target for Malaria Drugs—Nov. 27, 2013
NIH Launches Trial of Investigational Genital Herpes Vaccine—Nov. 6, 2013
NIH Scientists Develop Candidate Vaccine Against Respiratory Syncytial Virus—Oct. 31, 2013

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Volunteer for Clinical Studies
You can help researchers improve public health by volunteering for NIAID clinical studies
View the NIAID Showcase

Last Updated November 07, 2013

bring up a list of the offices and Divisions that constitute NIAID. You would discover that there are four extramural Research Divisions listed and one for "Intramural Research" programs. Were your interest in the general area of microbiology and infectious diseases you would click the "Division of Microbiology and Infectious Diseases" button, which would take you to its part of the website. There, you would find that the Division consists of six different scientific branches. Again here you would choose the one closest to your idea. Let's say it's the Sexually Transmitted Diseases Branch. By clicking on it you would bring up the list of personnel shown below.

The screenshot shows the NIAID website header with the NIH logo and the text "National Institute of Allergy and Infectious Diseases". Below the header is a navigation bar with links: "NIAID Home", "Health & Research Topics", "Labs & Scientific Resources", "Funding", "About NIAID", and "News & Events". A search bar is located in the top right corner.

The main content area is titled "Finding People" and lists the "Sexually Transmitted Diseases Branch - DMID". The list of staff members includes:

- Dr. Carolyn Dept. Chief
- Dr. Jill Brown, Medical Officer
- Audria Crowder, Clinical Trial Coordinator
- Dr. Hagit David, Vaccines and Immunology Program Officer
- Jonathan Glock, Health Specialist
- Barbara Hahn, Nurse Consultant
- Dr. Thomas Hiltke, Basic Research Program Officer
- Kimberly Murphy, Product Development Project Manager
- Elizabeth Rogers, Medical Technologist
- Peter Wolff, Clinical Trials Specialist

Two arrows point to Dr. Hagit David and Dr. Thomas Hiltke, highlighting them as Program Officers. On the left side of the page, there is a sidebar titled "Finding People" with a list of offices and divisions, including "Office of the Director (OD)", "Office of Biodefense Research Resources and Translational Research (OBRTR)", "Office of Clinical Research Affairs (OCRA)", "Office of Clinical Research Resources (OCRR)", "Office of Genomics and Advanced Technologies (OGAT)", "Office of Regulatory Affairs (ORA)", "Office of Scientific Coordination and Program Operations (OSCO)", and "Bacteriology and Mycology Branch (BMB)".

On the right side of the page, there is a "Website Tools" section with links to "Print this page" and "Order publications". Below this is a "Stay Connected" section with social media icons for Facebook, Twitter, YouTube, and LinkedIn.

Two of the individuals, Drs. David and Hiltke (arrows), are listed as "Program Officer", together with their areas of programmatic responsibility. By clicking on their names you would obtain their complete NIH contact information.

There is no set of rules on how to find the name and contact information for the person at NIH who is responsible for the program that you are targeting. It is an entirely intuitive process and each Institute/Center is different. As a general rule, it is usually helpful to start with the Institute's/Center's "About" button or, if they have one, the "Staff Directory", or the equivalent of the "Find People" button, as was the case for NIAID. You simply have to work out for yourself how to 'drill down' on the relevant website until you find the information that you are seeking. If you can't find a specific individual who is linked to your subject, get as close as you can and then contact that person. S/he will refer you to the correct person if you don't have it right. An alternative approach is to use the PHS Agency Contact Table (section 1.4 of the *Application Guide*), which has a phone number for each of the Institutes and Centers. That number can be used to obtain a referral to the correct Program Officer at the Institute/Center you are targeting.

If you will be responding to either a Program Announcement (PA) or Request for Applications (RFA) (see chapter one), there is an easier way to identify the relevant Program Officer. The solicitation that provides the details of the funding opportunity will contain the name and contact information of the relevant individual for each Institute / Center participating in that program.

Once you have identified the Program Officer who is in charge of the program you want to target, you need to query him/her at this stage to assure that your idea will be of programmatic interest. Now is the time to find that out, so that you can either modify what you are planning to

propose to make it more programmatically relevant or, if it is not, you can switch to an alternative source of funding that will regard your idea more positively. Your query should be submitted by e-mail, if at all possible. If you use the telephone and are lucky enough to catch the Program Officer in his/her office (they are exceptionally busy), s/he won't know why you are calling and won't be ready to answer your questions. In addition, s/he may be busy at the time and not interested in holding a substantive conversation with you. Last but not least, you don't want to leave the impression inadvertently that you are a pest - a 'black hole of need'. By using the e-mail approach you avoid those problems. *In your e-mail query you should include three very important words: "maximize programmatic relevance."* For example, 'I would like to make an appointment to speak with you by telephone so that I can maximize the programmatic relevance of the proposal that I am planning to submit.' When you use that approach, you distance yourself greatly from being a 'black hole of need'. Instead, you become someone who is being considerate of the Program Officer's job; you are offering to help him/her assure that what you submit is maximally relevant to his/her programmatic priorities. Believe us: Program Officers (and reviewers) do not want to spend time considering projects that are programmatically irrelevant. If you package and present your case as we have suggested you will almost always get the kind of substantive feedback you are seeking, because you will have made it in the best interest of the Program Officer to help you.

You don't have to worry that you are overstepping your bounds by making such a query. On page I-5 of the *Application Guide*, under section 1.4, there is the following invitation: "The PHS agencies encourage applicants to communicate with staff throughout the entire application, review and award process." On page I-6 NIH specifically points out that you can contact program staff to learn more about whether your proposed topic meshes with an Institute's/Center's (or non-NIH agency's) programmatic areas of interest (priorities).

FIND THE CORRECT RESEARCH-GRANT MECHANISM FOR YOUR PROPOSAL

This *Workbook* is specifically written to support the development of a Research Project (Basic Research) Grant (R01) application – the most common kind of grant proposal that is made to NIH. As can be appreciated from the resources presented earlier at the end of Chapter 1, there are many research-grant mechanisms, each with its own purpose. To be successful, an idea must be packaged and presented in such a way that it meets the purpose and requirements of the chosen grant mechanism. No matter how good the idea is – no matter how programmatically relevant it is – if you package and present it using the wrong grant mechanism you will fail. It's that simple! *Choice of the grant mechanism that is appropriate to your idea and its stage of development is, therefore, one of the most important decisions you will make in the development of your proposal.*

TIP: Understand the purposes of the common grant mechanisms that NIH uses to support research – especially the R01, R03, R15, R21, R34 and P01. Make certain that the proposal you write meets the purpose of the research-grant mechanism that you choose to use.

1. R01 Research Project Grant (<http://grants1.nih.gov/grants/funding/r01.htm>). As noted earlier, this *Workbook* is focused on the R01 research-grant mechanism, because it is the one that funds the majority of research projects in the extramural program. This mechanism funds definitive studies for up to five years and is renewable. All Institutes and most Centers support this grant mechanism. Most are investigator initiated, i.e., submitted in response to the related Par-

ent Announcement. At this writing, it is PA-13-302 (<http://grants.nih.gov/grants/guide/pa-files/PA-13-302.html>). R01s are also submitted in response to specific Program Announcements and Request for Applications solicitations. Applications for R01 funding must be supported by a substantial amount of preliminary data that establish the feasibility of its aims. Preliminary data must also support formulation of the focusing central hypothesis and the subordinate hypotheses that focus research under the aims if the proposal is hypothesis-driven. In addition, there must be credible evidence of institutional commitment to the applicant in terms of resources. Without such data and commitment, the likelihood of a proposal being funded at the R01 level is remote, in our experience. New/Early Stage Investigators are being encouraged by NIH to write R01s at the earliest possible time. Compared to established investigators, reviewers require less of applications from New/Early Stage Investigators, particularly with respect to the INVESTIGATOR, APPROACH and ENVIRONMENT criteria (SIGNIFICANCE and INNOVATION are handled the same). However, this should not be taken to mean that the standards for review have been lowered that much; the bar is still set very high with respect to what it takes to merit funding. This point should be kept firmly in mind when making a decision regarding which grant mechanism to select as a New/Early Stage Investigator, especially now that applicants are allowed only one resubmission of a failed application.

2. R03 Small Research Grant (<http://grants1.nih.gov/grants/funding/r03.htm>). The purpose of the R03 is usually sponsorship of pilot investigations/generation of preliminary data / development of a method or technology. Some Institutes and Centers accept investigator-initiated R03s, which must be submitted in response to the R03 Parent Announcement, currently PA-13-304 (<http://grants.nih.gov/grants/guide/pa-files/PA-13-304.html>). The length of the Research Plan is 1 page for the Specific Aims section and 6 pages for the Research Strategy section. Preliminary data are not required for an R03. However, in our experience, a small amount of preliminary data in support of feasibility in your hands is essential. Institutes/Centers that accept unsolicited R03s are listed in the Parent Announcement. Other NIH Institutes / Centers and other U.S.P.H.S. awarding components offer the R03, but under their own definition of this research-grant mechanism. Such specifics can be obtained by investigating Program Announcements or Requests for Applications that are listed on the awarding components' websites. R03 grants are limited in terms of time and budget (currently up to \$50K in each of 2 years) and are not renewable. Why? Because this research-grant mechanism is usually meant to be a steppingstone to subsequent R01 funding. Although NIH is discouraging New/Early Stage Investigators from applying for an R03, if you qualify as a New/Early Stage Investigator and need to develop preliminary data in order to be competitive at the R01 level, we recommend that you consider this grant mechanism (if the awarding component you are targeting offers it). Properly written, i.e., as a steppingstone to a subsequent R01, use of the R03 grant mechanism can be an important and successful first step along the R01-sponsored continuum of research that follows.

3. R21 Exploratory/Developmental Grant (<http://grants2.nih.gov/grants/funding/r21.htm>). This funding mechanism allows more time and money than an R03, but, like the R03, is not renewable. Like the R03, some Institutes and Centers allow investigator-initiated R21s to a Parent Announcement, currently PA-13-303 (<http://grants.nih.gov/grants/guide/pa-files/PA-13-303.html>). Like the R03, the length of the Research Plan is restricted to 1 page for the Specific Aims section and 6 pages for the Research Strategy section. The budget/duration of support for R21s are capped at \$275K and 2 years, respectively. Preliminary data are not required. Again, in our experience, regardless of what is specified in the Announcement, a moderate amount of preliminary data (more than an R03 but less than what would be needed for an R01) greatly increase chances of success. The R21 research-grant mechanism most often has the purpose of supporting high-risk (of failure) / high-impact research. In our experience, the most successful

R21s are those that propose the least amount of investigation that is needed to prove a concept, establish feasibility and/or remove risk that would otherwise undercut the competitiveness of an R01 proposal. In other words, this grant mechanism should also be written as a steppingstone to an R01, which is what would support subsequent definitive studies. That is why R21s are not renewable. The purpose of the R21 grant mechanism becomes crystal clear when it is combined with the R33 (a so-called Phase II grant, which is the equivalent of an R01). This approach is used by the National Cancer Institute to more quickly reach definitive studies when there is a significant component of risk. The applicant in essence writes two grant applications at the same time – an R21 and an R33. The R21 describes the least amount of research that is necessary to reduce the risk of failure and provides clear benchmarks that can be used by Program Staff to corroborate that the applicant has been successful in doing so. The R33 describes what will be done, once such risk has been removed. Both proposals are reviewed and approved for funding at the same time, but only the R21 is activated. As soon as the R21's benchmarks have been reached, Program Staff can terminate the R21 and, without additional review, immediately activate the R33, which then sponsors the definitive studies. The attraction of this approach is that no time is lost between successful completion of the R21 and initiation of subsequent definitive studies, as there would be if an R01 proposal had to be written as a second step. As with the R03, NIH is discouraging use of the R21 grant mechanism by New/Early Stage Investigators. However, if there is component of risk associated with your project that would be highly likely to undermine the prospects of an R01 application, we strongly recommend that you consider using an R21 as a means of removing that risk. When written for the purpose the grant mechanism is intended to have, there is no question, in our opinion, that the R21 has a place in the application process, even for New/Early Stage Investigators.

TIP: The R03 and R21 grant mechanisms can have a particularly important place strategically in responding to the streamlining ('triage') of a prior submission – see chapter 5.

4. R15 Academic Research Enhancement Award (AREA) (<http://grants1.nih.gov/grants/funding/area.htm>). The purpose of this mechanism is stimulation of NIH-supported research at educational institutions/units that provide baccalaureate and/or advanced training and are not currently major recipients of NIH grant support. Most of the awarding components at NIH support the R15 grant mechanism. Each has its own set of objectives for this grant mechanism, however, which are listed at: http://grants.nih.gov/grants/funding/area_grant_objectives.htm. It is important for applicants to consult these before developing an R15 proposal. Eligibility of units within an institution is also an issue that must be considered (http://grants.nih.gov/grants/funding/area_ineligible.htm). For example, the medical school at an institution may be ineligible because of extensive NIH research support, but other colleges and schools on the same campus may be eligible to apply. The Parent Announcement for investigator-initiated R15s is (<http://grants.nih.gov/grants/guide/pa-files/PA-13-313.html>). The Research Plan for an R15, like an R01, is limited to 1 page for the Specific Aims section and 12 pages for the Research Strategy section. The budget and duration of support for R15s are capped at \$300K and 3 years, respectively. Unlike R03s and R21s, R15s are renewable. Thus, R15 applications can and should propose small, complete research projects. They can be a steppingstone to a subsequent R01, but don't have to be, because they are renewable. In other words, they can be used to support a continuum of small complete research projects. In addition to scientific and technical merit, R15s are also evaluated on the basis of what the award will do to: (i) strengthen the recipient institution's capacity to compete for future NIH research support, and (ii) to expose undergraduate and graduate/professional students to biomedical research.

5. R34 Clinical Trial Planning Grant (<http://grants1.nih.gov/grants/funding/r34.htm>). Details pertinent to this funding mechanism can be found in its Parent Announcement (<http://grants.nih.gov/grants/guide/pa-files/PA-09-186.html#SectionIV>). Only 6 of NIH's awarding components support the Parent Announcement, and each of the 6 has its own view of what it will support. Some of the other awarding components (NCCAM; NIAID; NIBIB; NCI; NIDCR; NIDDK; NIEHS; NIGMS; NINR; NHLBI; NHGRI; NIMH NLM; NCRR., NINDS, NIDCD, NCMHD, FIC) offer R34 planning support under their own program announcements. Regardless of the awarding component being targeted it is very important to consult the relevant Program Officer before an R34 proposal is developed. Generally, the purpose of the grant mechanism is to provide a steppingstone to a subsequent Phase III clinical trial. That is why support is currently capped at \$100K for 1 year and renewal applications are not permitted. Basically, the R34 exists to help investigators pull together all of the disparate parts that must be put in place before a complex Phase III trial can be proposed. The activities supported are primarily logistical, conceptual and/or technical in nature, to include development of a detailed Manual of Procedures. In other words, it is a Phase III 'planning grant'. The grant mechanism is not meant for the purpose of acquiring preliminary data or performing pilot studies that would be the basis for a Phase III clinical trial.

6. P01 Program Project Grant (http://grants.nih.gov/grants/funding/funding_program.htm) The purpose of this grant mechanism is to bring together three or more independent investigators around a common theme and shared resources. Key to success is unity and interdependence of the projects, each of which has to be of high quality. P01s usually support large groups that undertake problems which are more complicated than a single individual could address. Although not stated in the NIH description of the grant mechanism, in our experience Program Projects should be written to reflect that they will demonstrably increase productivity of the participating investigators over what would have been the case with each of them working independently. Not all Institutes and Centers sponsor P01s. Those that do sponsor this grant mechanism offer their own version of it. It is critical, therefore, that applicants discuss their intention to develop and submit a P01 application with the relevant Program Officer before going forward with such a proposal. P01 applications are almost always reviewed within the sponsoring Institute/Center and not through the Center for Scientific Review.

All of the grant mechanisms described above, excepting the R01, will be the subjects of supplements to this *Workbook*. As noted in the Preface to this *Workbook*, many of the principles and fundamentals of grantsmanship are transposable from the R01 to the preparation of other kinds of applications. There are specifics, however, that need to be considered in the development of each. The supplements will address those specifics. In addition to the ones for research granting mechanisms, supplements will be available for the preparation of Career Development (K) and National Research Service Award (NRSA) applications. If you have an interest in any of these research / training supplements, please watch for their announcement on Grant Writers' Seminars and Workshops' website, www.grantcentral.com.

DEVELOPMENTAL STEPS FOR CHAPTER THREE:

1. Understand that what you want to do is not necessarily what's important. What is important is finding a program within NIH that wants to fund what you want to do.
2. Appreciate that review panels recommend the funding of grant applications. Program officials are the ones who fund grant proposals.
3. Identify the programmatic area within NIH that will be the target of your proposal.
4. Identify the Program Officer who is responsible for the programmatic area you will target. Obtain his/her contact information from the NIH website.
5. Understand and appreciate that your Program Officer is an important ally and resource in developing your grant proposal.
6. E-mail the Program Officer regarding your desire to "maximize the programmatic relevance" of your idea/application.
7. Based on feedback you receive from the Program Officer refine your idea to maximize its programmatic relevance.
8. Understand the differences between Parent Announcements, Program Announcements and Requests for Applications. Appreciate that all applications to NIH must be made in response to one of these.
9. Understand the purpose of each research-grant mechanism that you are considering for your application.
10. Appreciate that, in spite of NIH's instructions to the contrary, R03s and R21s are most often successful when accompanied by small or moderate amounts of preliminary data, respectively.
11. Identify the research-grant mechanism that is most appropriate for your research project and its stage of development.

CHAPTER 4

INFLUENCE OF THE NIH REVIEW PROCESS ON WRITING FOR SUCCESS

HOW TO WRITE FOR SUCCESS – COMPLIANCE REVIEW

As noted earlier, all grant applications submitted to NIH are received and distributed for review by the Center for Scientific Review. Upon receipt, each application is given a compliance review to ensure that it is responsive to the relevant instructions. Both automated (computer validation) and manual (NIH staff) reviews are conducted. If your application fails this initial screening, it may be sent back to you without being reviewed. The decision to do so is not subject to appeal.

Obtain All of the Current Instructions. As the first step in the preparation of your proposal, you must obtain the most current version of the *SF 424 (R&R) Application Guide for NIH and Other PHS Agencies* (hereinafter referred to as the '*Application Guide*'). The latest instructions can be downloaded from <http://grants.nih.gov/grants/funding/424/index.htm>.

Be aware that there are instructions that are generic, i.e., that pertain to use of the forms for applications to any U.S.P.H.S. agency that uses the SF 424 (R&R) application kit. There are also agency-specific instructions, however. The latter instructions are denoted in the *Application Guide* by the logo of the Department of Health & Human Services, which is reproduced to the right. These must be adhered to carefully, because they modify and/or supplement the generic SF 424 instructions to make your proposal acceptable to NIH.



If you are responding to a specific solicitation (Program Announcement or Request for Applications) there will be additional instructions associated with it. Those should be downloaded from Grants.gov, along with the appropriate application kit, using the approach that is described in section 2.4.3 of Part I of the *Application Guide*.

Format Specifications. There are several formatting instructions (section 2.6 of Part I of the *SF 424 (R&R) Application Guide*) that must be adhered to or, in all likelihood, your application will be returned to you. For example:

- **Page Limits and Size:** The length of the Research Plan (combination of the Specific Aims and Research Strategy sections) is strictly regulated. There are different limits for different research-grant mechanisms (e.g., 1 page for the Specific Aims section of all R-series applications plus either 12 pages for the Research Strategy section of R01s, R15s and R34s or 6 for R03s and R21s). Determine how long the Research Strategy section can be for the research-grant mechanism you plan to use, because that limit cannot be exceeded without risking rejection during the compliance review. Other parts of the application that are restricted in length include the Introduction (no more than 1 page

for all R-series resubmissions) and the Biographical Sketch (no more than 4 pages). All pages of your application must be 8.5 X 11 inches in single-column format.

- **Typeface:** There is no flexibility regarding the typeface that can be used in an NIH grant application. It must be black and either Arial, Helvetica, Georgia, or Palatino Linotype. We prefer Arial, which is the typeface used in this *Workbook*.
- **Font Size:** The required typeface must be 11 points or larger. Smaller font can be used in figures, figure legends, graphs, diagrams, charts, tables and footnotes to tables. In these places the only restrictions are that one of an allowed typeface be used and that the print be legible.
- **Type Density and Line Spacing:** There must be 15 or fewer characters and spaces per linear inch, and line spacing must be 6 lines or fewer per vertical inch.
- **Page Headers and Footers** cannot be used. Page numbers will be system-generated automatically when NIH concatenates your proposal.
- **Color** can be used in figures, but not for text. We recommend that, if you use color in your figures, you choose shades that have distinct grayscale differences when printed in black and white. When a color is referred to in the legend it should be followed by the corresponding grayscale shade, e.g., 'dark blue (grayscale = black)'. This assures that color differences can be interpreted even when a reviewer downloads and prints a figure in black and white.
- **Margins:** While it is permissible to use a minimum of 0.5 inch for top, bottom, left and right margins, we recommend that you use 1-inch margins for all uploaded text files, with the exception of the Project Summary. It should have left and right margins of 0.5 inch (see chapter 19 for the reason why). Wider margins are aesthetically more pleasing and, therefore, more reviewer friendly. For the same reason, we recommend that you open a line between each of your paragraphs.

HOW TO WRITE FOR SUCCESS – SCIENTIFIC AND TECHNICAL REVIEW

TIP: The bottom line in writing a successful proposal, regardless of funding agency or discipline, is knowing how to identify the 'hot buttons' that are of importance to the targeted funding agency, and then having the grantsmanship skills needed to 'punch' those buttons.

Your objective should be to create advocacy for funding your application, not only through the quality of the science, but also by the way that you present the science. In our opinion, more applications fail because of poor packaging and presentation of the proposed research than because of flawed science. How you write for reviewers makes a BIG difference, therefore. The tip given above is an important part of the equation. The remainder of this chapter focuses on some of the ways that you can optimize your grantsmanship.

Resources Available to You. There is a great deal of NIH-based help available to you if you want to avail yourself of it. There are many helpful hints and examples on its website designed to help you. Most of these can be found at <http://www.niaid.nih.gov/researchfunding/grant/Pages/newpiportal.aspx> and http://grants.nih.gov/grants/grant_tips.htm. Among other sources of help you will find sample applications and Summary Statements. Other examples of funded grants can often be obtained by directly approaching the Principal Investigator. Simply go to the RePORTER database query form (<http://projectreporter.nih.gov/reporter.cfm>) and search for the kind of grant or contract you are interested in (e.g., one of the Research series, such as R01, R03, R15, R21, etc.). To do so, select the activity code of the grant mechanism, e.g., R01, in the dropdown for the "Activity Code:" field on the right side of the form, the year(s) you want to query, and any other criteria that you want to use in your search. After receiving the results of your query click on the title of each grant of interest. That will bring up a "DETAILS" page that is comparable to the one below. Note that the Principal Investigator's e-mail address is at the left above-middle of the page (see arrow, below). Simply write the investigator a note asking whether s/he would mind sharing a copy (or a partial copy) of his/her funded grant. Indicate in your note that your purpose is to obtain an example of a successful application of that kind, not to compete. In our experience, many investigators, especially those at your own institution, will respond positively to such a request.



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Project Information

2R01AR054326-06

Project 1 of 160

PI PROFILE LINKS

DESCRIPTION DETAILS RESULTS HISTORY SUBPROJECTS SIMILAR PROJECTS NEARBY PROJECTS LINKS NEWS AND MORE

Project Number: 2R01AR054326-06
Title: MOLECULAR MECHANISMS UNDERLYING TAX1 FUNCTION IN OSTEOCLASTS

Contact PI / Project Leader: ABU-AMER, YOUSEF
Awardee Organization: WASHINGTON UNIVERSITY

Contact PI / Project Leader Information:  Program Official Information: Other PI Information:  Profile Exists  No Profile

Name: ABU-AMER, YOUSEF
Email: Click to view Contact PI / Project Leader email address
Title: ASSOCIATE PROFESSOR OF ORTHOPAEDIC

Name: CHEN FAYE H
Email: Click to view PO email address

Not Applicable

Organization: Name: WASHINGTON UNIVERSITY
City: SAINT LOUIS Country: UNITED STATES (US)

Department/ Organization Type: ORTHOPEDICS
SCHOOLS OF MEDICINE

Congressional District: State Code: MO
District: 01

Other Information:

FOA: PA-11-260
Study Section: Skeletal Biology: Structure and Regeneration Study
Section (SBSR)
Fiscal Year: 2013 Award Notice Date: 12-MAR-2013

DUNS Number: 068552207
Project Start Date: 1-DEC-2006
Budget Start Date: 1-APR-2013

CFDA Code: 846
Project End Date: 31-MAR-2018
Budget End Date: 31-MAR-2014

The National Institute of General Medical Sciences (NIGMS) has on its website 25 "Tips for New NIH Grant Applicants" (see <http://www.nigms.nih.gov/Research/Application/Tips.htm>). As another example of help that is available, the National Cancer Institute (NCI) offers a 12-page "Quick Guide for Grant Applications" (<http://deainfo.nci.nih.gov/extra/extdocs/qntapp.pdf>), which walks an applicant through the preparation of an NIH proposal.

Hierarchical Formatting. Reviewers should be able to see at a glance what is subordinated to what in a grant application. Again, this is another part of taking a reviewer-friendly approach. We recommend that you choose a format and use it consistently throughout the text of your proposal. One that we particularly like is a combination of different heading / subheading / sub-subheading styles coupled with corresponding levels of indention. For example:

SECTION HEADINGS

Section headings are presented at the left margin entirely in bolded, capitalized letters. The first line of each paragraph that is subordinated to a section heading is indented one tab. Subsequent lines return to the left margin, as is shown here.

Subsection Headings

Subsection headings are in bolded *italics*, with the first letter of each main word capitalized. The first line of each paragraph is indented two tabs, with subsequent lines returning to the left margin.

Sub-subheadings

This level of subordination is indicated by putting the sub-subheading in underlined *italics*. The first line of each paragraph is indented three tabs. Subsequent lines in each paragraph return to the left margin, thereby preventing an expanse of white space from developing as indentions progress to the right.

By adopting a system similar to the one shown, above, you make it easy for the reviewer to grasp the relationships that exist in what you are presenting.

Apply Strategies Employed by Writers of Newspaper Articles. Newspaper writers are taught to write in such a way that the reader will want to read what has been written. By contrast, reviewers have to read what is written in grant applications. The ideal application should be written so cleverly and compellingly that it will convert its reviewers from a 'have to' to a 'want to' mode. Some of the tricks and strategies used by newspaper journalists can effectively be transposed to facilitate such a conversion.

- A newspaper headline is a conceptual distillation of the related article into the fewest words that will inform the reader of the article's content while, at the same time, it 'hooks' the interest of the reader and makes him/her want to read the article. Although we don't have the exact equivalent of headlines in grant applications, we can apply the principle. For example, the title of your proposal should have the characteristics of a headline. It is the first impression that your application will make on reviewers. It should immediately generate interest in your proposal. The same holds true for your specific aims, section headings and paragraph headings. They should be brief, informative, conceptual 'headlines' that will make the reviewer want to read what follows.
- The introductory paragraph in a newspaper article usually complements the headline as a broad, conceptual overview of the content of the article. The headline and subordinate headline, if there is one, is/are designed to 'stop' the reader and make him/her begin to read the article. The first paragraph is designed to set the 'hook' embedded in the headline by increasing interest in the content of the article. We will apply exactly the same approach, using introductory paragraphs in association with each major section and sub-

section to increase interest in the details that follow. A common mistake made by grant applicants, in our opinion, is that they bury reviewers too quickly in extensive detail.

- **Paragraphing.** Practically every sentence in a newspaper article is a new paragraph. That is because newspaper journalists are taught to make each sentence a stand-alone thought. Then, they are taught to present the stand-alone thoughts in an order that creates a progression of logic which leads readers through the newspaper article. We can't paragraph each sentence in a grant application. But we can apply the same strategy: every paragraph in your application should make one point and one point, only. The ordering of your paragraphs then helps to set up a progression of logic that leads the reviewer through your application. *The ideal grant application, in our opinion, is one that leads reviewers through it without them knowing that they are being led.*
- **Style of Writing.** Newspaper journalists write with a simple, direct style that emphasizes brevity and is easily read and comprehended. This approach is highlighted by one of USA Today's commercials: "It's not the most words, just the right words." This is so pertinent to the writing of grant applications that we have devoted the entire next section of this chapter to developing an appropriate style of writing.

Adopt a Spare, Clear, Direct Style of Writing. Writing grant applications is not unlike writing short stories. The similarity between the two genres is that, in each case, every component of the 'story' must have a reason to be there and must be contained within a limited number of pages. To achieve this, every word must be the right word and must relate meaningfully to its neighbors. Every sentence must be crafted to convey exactly the message that you want it to impart. Every paragraph must flow logically out of the ones that have preceded it, so that the story builds clearly and vividly in the mind of the reader/reviewer. It takes time and effort to write this way. However, there is no alternative but to make the necessary investment, because poorly written proposals are almost always preordained to fail. Why? *Because reviewers rarely will take the time to decipher badly written, unclear material.*

The following considerations are ones that you should keep in mind. By doing so, you will avoid many of the compositional mistakes that are made by unsuccessful proposal writers.

First, write in clear, simple declarative sentences. By doing so you will avoid hard-to-understand, tortuous, syntactically difficult, compound sentences that go on forever. A reviewer should be able to read from the first to the last word without having to re-read anything to understand it. Therefore, when you have the urge to use a comma and keep on writing, stop and ask yourself whether it would be clearer to use a period, instead. Breaking things up into smaller 'bites' increases comprehension and is, therefore, very reviewer friendly.

Second, brevity is saintly, especially in this era of the shortened Research Plan. Twenty-five pages are no longer allowed for an R01 or K-Award application. Approximately half that number is now allowed. The same is true for other members of the R series: approximately half the number of pages is allowed for the Research Plan. As noted earlier, writing succinctly by including only what is absolutely necessary to make your points is essential. For example, the first three sentences in this paragraph could be distilled, as follows, without losing anything of value: '**Second,** brevity is saintly. Approximately half the number of pages is now allowed for the Research Plan of R-series applications, compared to what was allowed in the past.' That revision cut 3.5 lines to slightly less than two. All of us are guilty of verbosity when we write. That is no longer a luxury that can be afforded.

Third, avoid the use of clichés and 'empty generalities'. These are words and statements that, at first, look great, but when analyzed critically, convey little or nothing. For example, 'The proposed state-of-the-art research is expected to advance the field significantly.' What does the cliché, "state-of-the-art", mean in an objective sense? What makes the research "state-of-the-art"? What does "advance the field significantly" mean? That's a good start, but it is meaningless to a reviewer unless additional explanatory detail follows. We can't underscore enough that 'Be specific!' is one of the cardinal rules of good grantsmanship. Specificity and precision are what build credibility with reviewers. Meaningless clichés and generalities almost always do the opposite.

Fourth, avoid the use of nouns as adjectives. This is a particularly prevalent problem among writers of grant applications. Consider: 'lower respiratory tract iron burden' or 'total parenteral nutrition catheters'. What is actually meant in these two examples is 'burden of iron in the lower respiratory tract' and 'catheters for administering total parenteral nutrition,' respectively. *It doesn't add that much more text to make things maximally clear.* The gain in understanding is well worth it. As will be noted in detail later, the same comments can be made about the use of non-standard acronyms. You don't gain that much space by using them. You do risk loss of comprehension, however. A related point pertains to compound adjectives (two or more words that form a phrase that modifies another word). The modifying words in the phrase must be linked with hyphens; otherwise, they modify independently. Exceptions include adverbs and words that are capitalized, e.g., African American women.

Fifth, avoid the use of 'weak' qualifying words, i.e., ones that unnecessarily convey doubt in your ability to do something. By weak words we mean ones like: if (if we can do X, then we will be able to do Y); try (we will try to overcome the problem that is caused by X); hope (we hope to obtain Y); believe (we believe [pray?] that we can obtain X); might (we might be able to prepare the antiserum); could/should (we could/should obtain); and may (we may be able to extend our understanding to). In every one of these examples, the word 'expect' could have been substituted (e.g., we expect to obtain, instead of we hope to obtain). Use of 'expect' is a much more positive and confident way of asserting confidence that you can do what you propose. Another example is: 'it is our conviction that we can ...' Both examples avoid the trap of guaranteeing an outcome, as 'will' would, but leave little doubt in your ability to get the job done.

Sixth, the word 'whether' can create serious problems. Why? Because it always means whether or [something else], even when used alone. Usually, it means whether or *not*. Just as in the case of weak words, use of 'whether' can inadvertently cause doubt in the mind of a reviewer. Therefore, the next time that you find yourself about to use 'whether [or not],' try 'the extent to which' as a substitute. 'Whether or not' is black and white, one way or the other, yes or no. 'The extent to which' ranges from 0 to 100%. Thus, the use of this phrase can avoid the problem of 'not' (i.e., failure) being the only alternative outcome.

Seventh, make certain that you use the correct word when there is a choice between two that are closely similar in spelling and/or meaning. Words that are commonly misused by applicants include: affect vs. effect; alternative vs. alternate; because vs. since; complement vs. complement (complementary vs. complimentary); led vs. lead; principal vs. principle; rationale vs. rational; and which vs. that. If you need to do so, consult a dictionary or style manual to make sure that you use these (and others like them) correctly. This suggestion also pertains to use of singular and plural forms of the same word. Examples of words that are commonly misused in this way include: data (plural) vs. datum (singular); sera (plural) vs. serum (antiserum vs. antiserum); criteria vs. criterion; media vs. medium; and phenomena vs. phenomenon. Use of the correct word can make a big difference in the clarity of your writing and, equally important, can influence how your attention to detail is perceived by a reviewer.

THE NIH REVIEW PROCESS SHOULD INFLUENCE HOW YOU WRITE

Recommendation. View the very helpful presentations that NIH has provided at http://enhancing-peer-review.nih.gov/application_changes_video.html, which are designed to familiarize applicants with the new approach to review of grant applications. They include: ENHANCING PEER REVIEW: *What Applicants Need to Know* (slides and text transcript), Overview of Peer Review Enhancements, and What Reviewers Need to Know. To keep abreast of future enhancements of peer review, become a member of the Enhancing Peer Review LISTSERV: <http://nexus.od.nih.gov/all/subscribe>.

While your proposal will ultimately be funded by one of NIH's Institutes, Centers or Offices, it will first be evaluated by a review panel (i.e., a Scientific Review Group or, as most review panels at NIH are called, a 'study section') for scientific and technical merit. Thus, the application must be written to appeal to the panel members, who will be the 'consumers' of the grant application that you create. Your proposal will be read by individuals who are assigned this task by panel's Scientific Review Officer (SRO), usually in collaboration with its Chairperson. In most cases, three persons – a primary, secondary and tertiary reviewer – will be assigned to review your application. Their job will be to identify the strengths and weaknesses of your proposal. The primary reviewer will usually be the person on the panel who is judged by the SRO to be the most qualified to review your application. If not an expert on the subject you are proposing, s/he will be close. The secondary reviewer will be the next most knowledgeable person, and so on.

Become Aware of How Study Sections Operate. Understanding the NIH review process is very important to your success. A YouTube video of a mock study section meeting can be found at <http://www.csr.nih.gov/Video/Video.asp>. We strongly recommend that you view it because it will give you a very good impression of what goes on during the meeting of a study section. Understanding the dynamics of the process and knowing what panel members have to contend with will help you to make your application more reviewer friendly. We also recommend strongly that you view the video, "NIH Tips for Applicants", which is located at the same URL.

Understand the Criteria Reviewers Must Use. Applications are evaluated for scientific and technical merit using (1) a set of five core review criteria (a reviewer must address and score each one in preparing his/her critique – see below); (2) an overall impact score (see <http://grants.nih.gov/grants/guide/notice-files/not-od-09-025.html>); and additional, unscored criteria that are applied, as applicable.

1. Core Review Criteria. Five mandatory core review criteria are used to evaluate applications. They were updated in December 2008 and include the following:

- a. **Significance:** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?"
- b. **Investigator(s):** "Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing re-

cord of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?"

- c. **Innovation:** "Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?"
- d. **Approach:** "Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?"
- e. **Environment:** "Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?"

Of the five evaluative criteria, Significance is the most important, in our opinion. Even if there were all the money in the world, who would want to invest any of it in a project that lacks or has little significance? That is why it is essential to invest the up-front effort required to generate an idea that will make a vertical difference in your field, once it has been acted upon.

2. Overall Impact Score. Overall impact is the second (and, in our opinion, the most important) means of assessing scientific and technical merit. According to NIH's referenced URL, above, it reflects reviewers' assessment of the *likelihood* for the project to exert a *sustained powerful influence* on the research field(s) involved. It is not necessarily the arithmetic mean of the five core-criteria scores, nor should it be considered a sixth core criterion. It encompasses the five core review criteria, which are unequally weighted, plus any additional review criteria (as applicable for the project proposed). "Likelihood" is assessed primarily on the basis of the Investigator(s), Approach and Environment core criteria, while "sustained powerful influence" is assessed primarily on the basis of Significance and Innovation.

3. Additional, Unscored Criteria and Considerations. The following will be considered, when applicable, in the evaluation of scientific and technical merit but will not be scored: Protections for Human Subjects; Inclusion of Women, Minorities, and Children; Vertebrate Animals; and Biohazards. When applicable, the following additional considerations will also influence evaluation of your proposal, but not in terms of assigning the overall impact score: applications from foreign organizations, select agents, resource sharing plans, and budget / requested period of support.

Understand the Scoring System Used to Evaluate Your Proposal. Each of your assigned reviewers will be required to give a score to each of the five core-review criteria using a range of 1-9. S/he will do this before the meeting without discussion with other assigned reviewers. As is illustrated in the table, below, the format of the proposal is designed to help reviewers find the information that they need to make such judgments. *This is a very important point to remember when writing your proposal.*

RELATION OF SECTIONS OF PROPOSAL TO REVIEW CRITERIA

REVIEW CRITERION	RELATED SECTION OF PROPOSAL
Significance	Research Strategy: Significance subsection
Investigator(s)	Biographical Sketch: Personal (Well-Prepared) statement
Innovation	Research Strategy: Innovation subsection
Approach	Research Strategy: Approach subsection
Environment	Facilities & Other Resources: Environment subsection

In an effort to standardize and maximize the quality of critiques by individual reviewers, NIH now provides critique templates and guidelines on how to use them for each grant mechanism (see http://grants.nih.gov/grants/peer/reviewer_guidelines.htm). We have reproduced the template for R-series applications at the end of this chapter. Note that the reviewer is required to formulate his/her critique on the basis of strengths and weaknesses. Second, the title of each core criterion on the template is a hyperlink to the related definition for it, thereby allowing reviewers to optimize the relevance of their comments. Another important innovation that contributes to standardization of critiques is "clustering" (grouping together) of New/Early Stage Investigator R01 applications for review at the beginning of the meeting. Doing so helps to ensure that standards appropriate to the review of established investigators' proposals will not be applied to the evaluation of those from New/Early Stage Investigators.

Only assigned reviewers rate each of the review criteria; other members of the panel do not. Each assigned reviewer's numerical ratings will appear in the Summary Statement at the beginning of his/her critique. *This provides you with the opportunity to see at a glance (1) where your application's greatest strengths and weaknesses were, and (2) what the range of opinion on each criterion was among the assigned reviewers.*

Each assigned reviewer is also required to give a preliminary impact score to your application before the meeting, again using a scale of 1-9. These preliminary impact scores will be used by the SRO to rank applications with respect to how they will be considered at the review-panel meeting. Those in the upper half of the rank order will be discussed, along with any in the lower half that are singled out by reviewers. The remainder in the lower half will be streamlined (i.e., triaged; see discussion of *Streamlined Review* later in this chapter).

Applications that are discussed at the meeting will be assigned a final impact score (1-9) by each member of the panel (excluding any member who has a conflict of interest). The overall impact score for your application, which you receive as part of your Summary Statement, will be

the average of these secret-ballot votes multiplied by 10. Thus, the best overall impact score is 10 and the worst 90. Only applications discussed and voted on at the meeting receive an overall impact score, i.e., applications that are streamlined ('triaged') do not.

For standardization purposes NIH has created a set of adjectival descriptors that reflect specific numerical scores (see table, below). Such adjectives connote various levels of strength/weakness, which, in turn, relate to level of impact (taken from NIH's Guidelines to Reviewers at http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf).

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Additional Information for Scoring Guidance Table	
Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed	
Minor Weakness: An easily addressable weakness that does not substantially lessen impact	
Moderate Weakness: A weakness that lessens impact	
Major Weakness: A weakness that severely limits impact	

Depending on the funding opportunity, decisions to make an award are based on either the overall impact score or the percentile rank of your application in comparison with other applications. Overall impact score is used in situations where variability in scoring, panel to panel, is not a consideration, e.g., when the award of funding is based on the one-time-only meeting of a single panel. Percentiling (<http://nexus.od.nih.gov/all/2013/06/21/more-on-percentiling>) is used to award funds when there is likely to be variability in how overall impact scores are assigned. The need to do so stems from the fact that applications reviewed by various standing study sections compete for the same pool of money. Each study section has its own 'personality.' Some are very tough, while others are relatively easy and assign many low scores. Thus, were funds to be awarded **only** on the basis of the overall impact score, most awards would go to applications that were reviewed by 'easy' panels. It is necessary, therefore, to normalize raw overall impact scores to minimize differences between the various panels. To do so, a distribution of overall impact scores is created for the current and last two meetings. The 10th percentile on the distributions would be closer to equivalency, for example, than the raw, overall impact scores would be.

Because the current approach to scoring applications has a tendency to produce 'ties,' i.e., the same final impact score or percentile rank, Program Staff at the awarding unit apply additional criteria to break such ties and make their funding decisions – for example, mission relevance. One of the most important of these additional criteria is 'portfolio balance' – how already-funded

grants in their portfolio are distributed across the range of their priorities. This fact reflects why it is so important to determine, up front, how your idea relates to the priorities of the Institute/Center that you plan to target (see chapter 3).

Streamlined Review. When Harold Varmus was Director of NIH his concern that too much time was being spent at review-panel meetings discussing non-competitive applications was acted upon. The solution that he and his colleagues implemented was to eliminate from discussion applications that were deemed at a given meeting to be in the lower half, competitively speaking. As noted above, this is now done by ranking the proposals, from best to worst, before the meeting based on the preliminary impact scores of the assigned reviewers. Eliminating non-competitive applications effectively doubles the time that can be spent at a meeting discussing the applications in the upper half that actually have a chance of being funded.

As noted above, applications discussed and voted on at the meeting receive a final overall impact score. Assigned reviewers' preliminary impact scores are not reported to the applicant for either discussed or streamlined ('triaged') applications. The latter receive only the scores the assigned reviewers gave to the five core criteria.

The primary objective of this *Workbook* is to get its readers funded on their first try. However, in these highly competitive times, that isn't realistic. The secondary objective, therefore, is to help applicants avoid triage. As you will see in chapter 5, triage puts the applicant at a serious disadvantage when resubmitting a proposal.

Review of New Investigators' Grant Applications. You qualify as a New Investigator by NIH's definition if you have never served as a Program Director/Principal Investigator on a PHS-supported research project other than an R00 (Pathway to Independence Award), R03 (Small Research Grant), R15 (Academic Research Enhancement Award [AREA grant]), R21 (Exploratory / Developmental Grant), R34 (Clinical Trial Planning Grant), R36 (Dissertation Award), R55 (Shannon Award), R56 (NIH High-Priority, Short-Term Project Award), SC2 or SC3 (Competitive Research Pilot Projects) or any Fellowships (F series awards) or mentored K Awards (K series awards). Instrumentation, construction, education, health-disparity endowment grants and meeting awards are also exempt. Historically, this definition did not prevent established investigators who were applying to NIH for the first time from representing themselves as New Investigators. For that reason, and for the purposes of reducing prolonged periods of postdoctoral training and improving the chances of true New Investigators for R01 funding, NIH created a new subcategory of New Investigator in 2008, called an Early-Stage Investigator (ESI). This subclass is defined as anyone who meets the original definition of a New Investigator AND who is within 10 years of either their terminal research degree or of their medical residency. The period of eligibility can be extended to accommodate investigators whose careers have been interrupted by such things as medical problems, military service or pressing family-care responsibilities (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-034.html>). NIH's intent in creating the ESI subclass is to ensure that career stage is considered more effectively than it has been in the past at the time of review and award.

To qualify as an ESI information regarding date of completion of the terminal research degree or medical residency must be entered in the individual's eRA Commons personal profile (http://era.nih.gov/services_for_applicants/apply/personal_profile.cfm). The submission system will automatically assess ESI eligibility thereafter. In other words, there is no longer a "New Investigator" check-off box in the application. When a multiple PD/PI proposal is submitted, all of the PDs/PIs must have ESI eligibility in order to claim ESI status for the application. Once an ESI competes successfully for his/her own R01, eligibility as a New Investigator / ESI is lost, even if

the individual is still within the 10-year post-degree/residency window.

The value in being an ESI is considerable. For example, reviewers are instructed to put more emphasis on the research that is proposed and less on the individual's track record. To help reviewers apply this mandate and, thereby, increase the likelihood that ESIs will be funded at the R01 level, ESI R01 proposals are clustered for review at the beginning of the meeting. This step is intended to overcome the problem of reviewers forgetting to apply appropriate, New Investigator criteria when such applications were interspersed with those of established investigators. This approach is not taken with the review of other grant mechanisms in the R series, such as the R03 and R21.

If you qualify as a New Investigator, there are additional 'hot buttons' that you should punch, compared to what an established investigator would do. For example, you should stress the feasibility of the approach *in your hands* when you write your Research Plan. You should make certain that you underscore in the Personal Statement of your *Biographical Sketch* (chapter 12) that you are *independent* in your current position, and that the quality of your training is commensurate with a career in biomedical research. Finally, the issue of space / time for research should be emphasized in the *Facilities & Other Resources* section (chapter 15).

Identify the Most Qualified Review Panel for Your Proposal. Unlike most granting agencies, NIH gives you the opportunity to recommend which study section should review your application; you will do so in the Cover Letter attachment. There are four different kinds of study sections that are managed by the Center for Scientific Review (<http://www.csr.nih.gov/committees/rosterindex.asp>): (1) regular standing study sections and continuing special-emphasis panels; (2) fellowship study sections; (3) SBIR/STTR study sections; and (4) special emphasis study sections that meet for one-time only. The first of these four categories is usually the you will select.

With some exceptions, such as K Award applications (reviewed by Institute/Center-based study sections) and responses to RFAs (reviewed by a mandated special-emphasis panel), NIH allows you to recommend in the application's Cover Letter attachment which study section should review your proposal. If you are not already certain which study section would be most appropriate for the review of your application, we recommend that you identify it using one of the following two approaches.

The first of these involves use of the RePORTER database. Enter into the Query Form (<http://projectreporter.nih.gov/reporter.cfm>) either key words that are related to the subject of your application or the names of active researchers in the area during the last ten years. This will produce a list of funded grants in the area of your interest. By clicking on the title of a grant you will bring up its "Description" page, which will be similar to the one shown at the top of the next page. Click on the "Details" tab at the top, next to the one titled "Description." At the left of that page (see figure at the bottom of the next page) the name and acronym of the review panel that recommended the funding that grant can be found (arrow). If most of the applications that are similar to the subject of your proposal were reviewed and recommended for funding by the same one or two study sections, they are almost surely the ones that are most applicable to your needs and, accordingly, they are the ones that you should consider first.

Project Information

2R01AR054326-06

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Project Number: 2R01AR054326-06

Contact PI / Project Leader: ABU-AMER YOUSEF

Title: MOLECULAR MECHANISMS UNDERLYING TAK1 FUNCTION IN OSTEOCLASTS

Awardee Organization: WASHINGTON UNIVERSITY

Abstract Text:

DESCRIPTION (provided by applicant): Bone development is tightly regulated by bone forming cells, osteoblasts, and bone resorbing cells, osteoclasts. Therefore, understanding the mechanisms governing **osteoclastogenesis** is crucial for addressing bone loss pathologies. Differentiation of osteoclasts is governed by RANK ligand which activates several signal transduction pathways, including MAP kinases and NF- κ B pathways. Proximal activation entails recruitment of **TRAF6** and other key **Proteins** including TGF- β -activated kinase-1 (TAK1) to the receptor RANK. **TRAF6**, TAK1 and other signaling partners undergo extensive post-translational modifications aimed at stabilizing RANK signaling and enabling precise regulation and execution of proper downstream signals, primarily NF- κ B activation. Precise regulation of NF- κ B activity is crucial to maintain normal osteoclast activity and bone homeostasis. Conversely, abnormal activity of this transcription factor causes deleterious inflammatory osteolysis. In fact, we discovered recently that constitutive activation of IKK2 is sufficient to induce RANKL-independent **osteoclastogenesis** in vitro. More convincingly, we reported that knock-in of constitutively active IKK2 causes severe bone loss in mice. Given that IKK2 phosphorylation and activation is governed by TAK1, a MAP kinase heavily implicated in poly-ubiquitination and stabilization of RANK-TRAF6 complexes and downstream signaling, we decided to investigate its molecular role in **osteoclastogenesis**. Thus, we generated mice harboring myeloid-specific deletion of TAK1. These mice displayed all hallmarks of osteopetrosis primarily defective **osteoclastogenesis**. Mechanistically, we observed that Tak1-null precursors fail to generate osteoclasts. More importantly, we discovered diminished expression of key osteoclastogenic **Proteins** including **TRAF6**, NEMO and Notch-NICD. This phenomenon was associated with accumulation of NUMBL, a previously described neuron protein. Consistent with these observations, we established that exogenous expression of NUMBL induces degradation of **TRAF6**, NEMO, NOTCH1-NICD, and inhibits **osteoclastogenesis** in vitro. Inhibition of NUMBL using a dominant negative PTB-phosphotyrosine binding of NUMBL and shRNAs knockdown of NUMBL enhanced expression of **TRAF6** and NEMO and did not inhibit **osteoclastogenesis** in wild-type cells. In addition, inhibition of NUMBL using a dominant negative PTB of NUMBL and exogenous expression of NOTCH1-NICD restored **osteoclastogenesis** in TAK1 null cells. Based on these observations we hypothesize that "NUMBL is a repressor of **osteoclastogenesis** and its expression is regulated by TAK1. Deletion of TAK1 leads to accumulation of NUMBL protein which induces degradation of **TRAF6**, NEMO and NICD **Proteins**, and subsequently blocks **osteoclastogenesis**." To test this hypothesis, we propose to investigate the following specific aims: 1) Determine the mechanism by which TAK1 regulates NUMBL expression. 2) Determine the mechanism by which TAK1 deletion regulates and impedes expression of **TRAF6**, NEMO and NICD. 3) Determine the effect of Genetic ablation of NUMBL on the osteopetrotic phenotype of TAK1-null mice.

Public Health Relevance Statement:

PUBLIC HEALTH RELEVANCE: Osteoclasts are the bone resorbing cells and their normal function is crucial to maintain bone homeostasis. Differentiation and function of osteoclasts is regulated by the factors **M-CSF** and RANK-ligand which induce crucial signal transduction pathways including MAP kinases and NF- κ B. These signaling pathways are activated by the upstream kinase TGF- β -activated kinase (Tak1). The direct role of Tak1 in osteoclasts is not fully clear. We provide evidence that myeloid-specific deletion of Tak1 leads to osteopetrosis in mice. We discovered a novel mechanism whereby deletion of Tak1 leads to accumulation of the protein NUMBL, previously described in neurons. NUMBL in turn mediates degradation of key **Proteins** of the osteoclast machinery including **TRAF6**, NEMO, and Notch1-NICD resulting with arrest of **osteoclastogenesis**. We propose to decipher the molecular mechanism underlying the role of Tak1-NUMBL signal in osteoclasts and its implications to bone development. Our studies are expected to unravel an entirely new area in osteoclast biology.

Project Information

2R01AR054326-06

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Project Number: 2R01AR054326-06

Contact PI / Project Leader: ABU-AMER YOUSEF

Title: MOLECULAR MECHANISMS UNDERLYING TAK1 FUNCTION IN OSTEOCLASTS

Awardee Organization: WASHINGTON UNIVERSITY

Contact PI / Project Leader Information:

Program Official Information:

Other PI Information:

[Profile Exists](#) [No Profile](#)

Name: ABU-AMER YOUSEF

Name: CHEN FAYE H

Not Applicable

Email: [Click to view Contact PI / Project Leader email address](#)

Email: [Click to view PO email address](#)

Title: ASSOCIATE PROFESSOR OF ORTHOPAEDIC

Organization:

Department/ Organization Type:

Congressional District:

Name: WASHINGTON UNIVERSITY
City: SAINT LOUIS **Country:** UNITED STATES (US)

ORTHOPEDICS
SCHOOLS OF MEDICINE

State Code: MO
District: 01

Other Information:

FOA: PA-11-280

DUNS Number: 068552207

CFDA Code: 846

Study Section: Skeletal Biology Structure and Regeneration Study

Project Start Date: 1-DEC-2006

Project End Date: 31-MAR-2018

Section (SBSR):

Budget Start Date: 1-APR-2013

Budget End Date: 31-MAR-2014

Fiscal Year: 2013 **Notice Date:** 12-MAR-2013

Administering Institutes:

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Project Funding Information for 2013:

Total Funding: \$323,000

Direct Costs: \$12,500

Indirect Costs: \$110,500

Year	Funding IC	FY Total Cost by IC
2013	NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES	\$323,000

Confirm applicability of the selected study sections to the research you intend to propose by going to http://www.csr.nih.gov/Roster_proto/sectionI.asp and then scrolling down the list of study sections until you come to the appropriate identifying acronym in the left column. Clicking on that panel's title in the center column will bring up its subject charge, as is illustrated in the figure, below. If you can't find the acronym listed in the left column it is probably because the related study section was eliminated/consolidated with another during a prior reorganization of NIH's peer-review panels.

Rosters

SBSR Membership Roster

SBSR Meeting Rosters

Topics

- ▶ Molecular and cell biology of bone, cartilage, tendon and ligament injury and repair.
- ▶ Gene expression, gene regulation, and gene therapy in the processes of injury and repair of musculoskeletal tissues.
- ▶ Mechanobiology and biomedical mechanics at the molecular, cellular, tissue and organ level.
- ▶ Nature of musculoskeletal injuries, and selected disorders and/or diseases of infectious, degenerative, traumatic and/or age-related etiologies (this includes sports-related and repetitive motion disorders, and the wear, injury-induced and degenerative changes manifest in articular and meniscal cartilage).
- ▶ Characterization of the intrinsic capacity of musculoskeletal tissues/joints to repair and regenerate; development and application of strategies to enhance repair (using biomolecular, biomaterial, mechanical and/or cellular approaches [tissue engineering], limb lengthening techniques, and/or targeted physical rehabilitation programs).
- ▶ Joint mechanics (including forces and kinematics) and joint replacement (including design, materials, fixation, wear, and other modes of failure).

Closely Related

Skeletal Biology Development and Disease [SBDD]

Musculoskeletal Tissue Engineering [MTE]

Arthritis Connective Tissue and Skin [ACTS]

Musculoskeletal Rehabilitation Sciences [MRS]

Bioengineering, Technology, and Surgical Sciences [BTSS]

Medical Imaging [MEDI]

As a second, amplifying approach, use the list of closely related study sections conveniently provided beneath the Topics list to expand your search. They will be rank ordered from most to least related. Clicking on the title of each will bring up the list of topics for which it is responsible. You should evaluate each closely related study section to determine whether or not it offers a better match for the subject of your application than your primary choice.

Characterize the Expertise Held by Potential Reviewers of Your Application. After narrowing the list of candidate study sections to one or two, you should investigate the range of expertise held by its members. NIH allows you to know who sits on the various panels. The easiest way to determine study-section membership is to click the "Membership Roster" link that is located above and to the left of the Topics list (see example on previous page). Almost no other agency allows you to know who sits on which panels. NIH reviewers are appointed for terms of 4 years, each. Thus, when you look at each study-section roster, barring absences for personal reasons, at least 75% of those individuals will likely be sitting at the table when your application is reviewed. The 25% who may have rotated off the panel (or who might be absent for personal reasons) will be replaced by reviewers who have equivalent expertise. Reviewers rotate off on June 30 of each year; the year in which a reviewer will leave appears to the right of his/her name (see roster, below).

SKELETAL BIOLOGY STRUCTURE AND REGENERATION STUDY SECTION

Center For Scientific Review

(Terms end 6/30 of the designated year)

ROSTER

CHAIRPERSON

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CHU, CONSTANCE R, MD, (14)
PROFESSOR

Some of the individuals you will know of – or even know personally – because their research areas are close to yours. Most, however, will not be known to you. But now you have their names and institutions. Run a PubMed search (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>) on any of its members with whom you are unfamiliar. Also, identify each individual's current NIH funding by using his/her name to probe the RePORTER database. Making these searches will give you each individual's specific expertise, allowing you to better understand the 'consumer group' that will be sitting in judgment of your proposal. The information you obtain in this way will help you write your application to be maximally appealing to members of the targeted panel.

A second reason that you should characterize the members of the selected study section is to assure that, even though the targeted panel is the most appropriate one, there isn't a kind of expertise that is missing, without which your application could not be reviewed fairly. If you discover that there is such a lack, you should, first, justify in the Cover Letter component why the study section you have chosen is the most qualified to review your application. A second part of the Cover Letter should then point out that, even though this is the most qualified panel, a kind of expertise is missing without which your proposal cannot be reviewed fairly. Then, request that an *ad hoc* (temporary) reviewer be added to the panel for the purpose of evaluating your application. If you adequately justify such a request, in our experience, it will almost always be granted; NIH is very committed to making sure that applications are reviewed fairly. After receiving your study-section assignment you should follow up your Cover Letter request with a telephone call or e-mail message to the Scientific Review Officer. Repeat your written request to him/her.

There is a third reason why you should investigate who sits on the targeted study section. If there is a member who you think would not review your proposal fairly, you have the right in your Cover Letter to request, with justification, that that person not be involved in the review of your application. You also have the right to name individuals with a conflict who are not permanent members of the study section, just in case either a temporary member is needed to stand in for a permanent member or outside, written opinions are sought by the SRO. The Cover Letter is never seen by the reviewers, so you don't have to worry about offending anyone who is named. Regardless, your justification shouldn't hang out 'dirty laundry'. All you have to write is that the person is a close competitor. Even though you have the right to make such a request, you should consider making it to be a two-edged sword. Who would be more qualified to recognize the significance of the contribution you propose to make than a close competitor? Thus, if you feel that you can trust the person to be fair, you may decide to retain him/her on the panel.

A final reason for determining who will be sitting on the review panel is to assure that the work of any member of the study section who has contributed to your subject area is included when the literature for your proposal is reviewed.

TIP: After your application is submitted it will be assigned by the Division of Receipt and Referral to an Institute(s) or Center(s) and a scientific review group. If you disagree with any of these assignments you should immediately contact the SRO of the review group to which your application has been assigned. S/he can be identified either by referring to your eRA Commons account or by looking up the review group at either <http://www.csr.nih.gov/Roster/proto/section1.asp> or http://www.csr.nih.gov/Roster/proto/allother_sep.asp. In either case, when the SRO's name is clicked on it will set up an e-mail message to him/her.

Two Audiences on the Scientific Review Group

KEY POINT: You must appreciate that you are writing your proposal for *two distinctly different audiences*: 1) your assigned reviewers and, 2) everyone else on the panel.

It is an unfortunate fact that reviewers read the proposals to which they are assigned. Rarely do they do much more than glance at other proposals at the meeting until they come up for review. Thus, review panels consist of two audiences: a minority audience – the primary, secondary and tertiary reviewers who are assigned to review your proposal – and a much larger audience –

everyone else on the panel. Members of the minority group will have read every word of your proposal. Members of the majority group, each of whom has an equal vote on the fate of your proposal, will be relatively / completely ignorant of its content until the very moment that it comes up for review at the meeting. Because each member of the panel – i.e., both assigned and unassigned reviewers – has an equal vote, *it is absolutely critical that you write your proposal in such a way that members of the majority group can become just as enthusiastic about your proposal as your assigned reviewers will be.*

At the meeting (see <http://www.csr.nih.gov/Video/Video.asp>), the primary reviewer – your principal spokesperson – will present your application orally to the rest of the panel. S/he will describe what you propose to do and then follow with his/her critique. The secondary and tertiary reviewers will then present anything about the application that was not described by the primary reviewer and offer their critiques. While these oral presentations are being made, the remaining members of the study section – the ones who haven't seen your grant application before it comes up for review at the meeting – will be trying to 'catch up,' so that they can make an informed vote in the 15 or 20 minutes they have to invest in your application. To become informed they will be doing two things: listening to the oral presentations of your three assigned reviewers and, at the same time, they will be reading parts of your application in an effort to corroborate or refute what they are hearing. That is why the parts they will read – the Title, the Project Summary/Abstract, the Specific Aims section, and the Significance and Innovation subsections of the Research Strategy section – must be written in such a way that they can be comprehended by the reviewers while someone is talking to them at the same time. The strategies for doing so are covered in later chapters that are devoted to those parts of your application.

Requesting Assignment to More Than One Awarding Component. If the subject of your proposal has relevance to the missions of two or more of NIH's Institutes and Centers, you can request that your application be assigned to more than a single awarding component. You should provide justification for your request using the Cover Letter component. Primary assignment should be requested to the part of NIH that is most relevant to the subject of your proposal. Should that entity decide not to fund your application, if the Center for Scientific Review has honored your request for two or more assignments, your proposal will automatically be sent to the other awarding components for consideration there. In other words, you get more than a single chance at funding. For this reason, if you have a so-called cross-cutting subject, you should definitely make a request for multiple assignments in your Cover Letter.

DEVELOPMENTAL STEPS FOR CHAPTER FOUR:

1. Obtain and read all of the instructions that are pertinent to the preparation of your application. Read them thoroughly several times.
2. Obtain the current Adobe C SF 424 forms from the Funding Opportunity Announcement to which you will be responding. If your application will be an unsolicited one you should obtain the forms from the relevant "Parent" announcement (http://grants.nih.gov/grants/guide/parent_announcements.htm).
3. Understand that you will have to pass an initial compliance review and all that it entails before your application will be reviewed for scientific and technical merit.
4. Understand the formatting requirements for NIH applications that pertain to typeface, font size, type and line density, margin widths, and the various sections and subsections that required in the application.

5. Develop a hierarchy of headings, subheadings, sub-subheadings, etc. for your application that will allow reviewers to discern at a glance what is subordinated to what.
6. Become proficient at applying the strategies that are used by newspaper journalists to make readers want to read what they write.
7. Appreciate the importance of grantsmanship – the packaging and presentation of your idea and the related research – in developing advocacy for funding your proposal.
8. Concentrate on developing a clear style of writing that emphasizes brevity and ease of comprehension.
9. Take full advantage of the resources that are available to you through the NIH website.
10. Download and view NIH's videotape of the meeting of a mock study section. Understand how reviewers approach review, including the template that they are required to use in formulating their critiques.
11. Know the definitions of New and Early Stage Investigators and whether or not you qualify as either one of these. Update your eRA Commons profile to include the date of completion for your terminal research degree and/or medical residency.
12. Understand the review criteria for NIH grant applications and what parts of the grant application are most relevant to them.
13. Know how applications are scored by reviewers and how the percentile rank of your proposal (if applicable) is derived.
14. Identify the most qualified study section for review of your proposal.
15. Investigate the scientific backgrounds of the members of the panel you have identified, using both their publications (PubMed database) and the abstracts of their current NIH grants (RePORTER database).
16. Understand the concept that review panels consist of two audiences and appreciate what that means with respect to the way that your application must be written.

EXAMPLE OF TEMPLATE-BASED R01 CRITIQUE

(Provided to reviewers by NIH)

#

Application #: 1R01HL123456-01

Principal Investigator(s): Doe, Jane

Overall Impact

Overall Impact

Please limit text to ¼ page

Strengths

- High potential impact in clinically important area of safe blood transfusion.
- Highly qualified investigators with complementary expertise ensure likely success.
- Novel application of incident reporting methods now in use in other fields could lead to improved public confidence in blood supply.
- The study will bring a rigorous, systematic approach to the current error reporting process, which is empiric and lacking in evaluation.

Weaknesses

- Lack of representation of non-academic transfusion medicine practitioners may make incident reporting less effective in non-academic hospital setting.
- Not enough time is allotted for aim one work and aims two and three too dependent on success of aim one work lessens confidence that work can be successfully completed.

Scored Review Criteria

1. Significance

Please limit text to ¼ page

Strengths

- An effective incident reporting system should greatly increase confidence of the public in safety of the blood supply.
- Models developed for other error-critical fields have been effectively adapted in the development of an incident-reporting system for transfusion medicine.
- Identifies and incorporates limited and appropriate range of human error patterns—will be easily transferable to practice.
- Could be generally applicable to understanding influence of incentives/disincentives on behavior.

Weaknesses

- Premise that human error follows limited range of patterns in diverse situations may not hold true.
- Unclear how incident reporting system would be utilized to reduce human error.
- Unclear whether public perception or clinical need is target of model application.

2. Investigator(s)

Please limit text to ¼ page

Strengths

- Investigators are well recognized for their expertise in blood banking.
- The PI has a strong publication record in field of HIV analysis in the context of blood transfusions.
- Collaborators have expertise in error-critical fields and are complementary in expertise to PI.

Weaknesses

- Levels of effort proposed by investigators are unlikely to be sufficient for scope of project, raising doubts that goals will be accomplished.
- There is not sufficient expertise in the area of transfusion medicine. Research plan would benefit from input from someone with expertise in collection & transfusion in non-academic hospital setting.

3. Innovation

Please limit text to ¼ page

Strengths

- Adaptation of incident reporting systems used in other error-critical fields (aviation, nuclear power, anesthesiology) to transfusion medicine is highly innovative.
- Use of positive reinforcement to address disincentives associated with self reporting of errors.

Weaknesses

-

4. Approach

Please limit text to ¼ page

Strengths

- The experiments are well designed with appropriate controls proposed.
- Potential problems are anticipated and alternative approaches are presented.
- Conceptual framework for the entire project is well developed and supported.
- Use of ubiquitous computer platform to manage information is sound and generates confidence in the potential expandability of the system across the country.

Weaknesses

- Time allotted for aim one work is likely to be insufficient.
- Aims two and three are less well developed because they are dependent on outcome of aim one.
- It is unclear which test site will provide gold standard against which results from other sites are compared.
- Test sites are all academic institutions and thus lack real world diversity; hospitals/ community health centers should be included so that results are more generalizable.

5. Environment

Please limit text to ¼ page

Strengths

- Outstanding scientific environment in each participating institution.
- Strong commitment of support from each institution.
- Opinion leaders in transfusion medicine field will participate.

Weaknesses

- Notable omission is the absence of non-academic hospital settings.
- Better plan to ensure uniformity across sites is needed.

ADDITIONAL REVIEW CRITERIA

The following review criteria are not scored individually, but should be considered when determining the overall impact/priority score.

Protections for Human Subjects

Acceptable Risks and/or Adequate Protections

Comments (Required Unless Not Applicable):

- Plans for sample anonymity are inadequate

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Comments (Required Unless Not Applicable):

○

+

Inclusion of Women, Minorities and Children Applicable Only for Human Subjects Research

G1A - Both Genders Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

Comments (Required Unless Not Applicable):

- There is no need to include children in this study.

Vertebrate Animals

Not Applicable (No Vertebrate Animals)

Comments (Required Unless Not Applicable):

•

Biohazards

Acceptable

Comments (Required Unless Not Applicable):

- The use of biohazards is acceptable.

Resubmission

Please limit text to ¼ page

Comments (if applicable):

- 

Renewal

Please limit text to ¼ page

Comments (if applicable):

- 

Revision

Please limit text to ¼ page

Comments (if applicable):

- 

ADDITIONAL REVIEW CONSIDERATIONS

The impact/priority score should not be affected by the following considerations.

Budget and Period of Support

Recommend as Requested

Recommended budget modifications or possible overlap identified:

- 

Select Agents

Not Applicable (No Select Agents)

Comments (Required if Unacceptable):

- 

Applications from Foreign Organizations

Not Applicable (No Foreign Organizations)

Comments (Required Unless Not Applicable):

- 

Resource Sharing Plans

Not Applicable (No Relevant Resources)
--

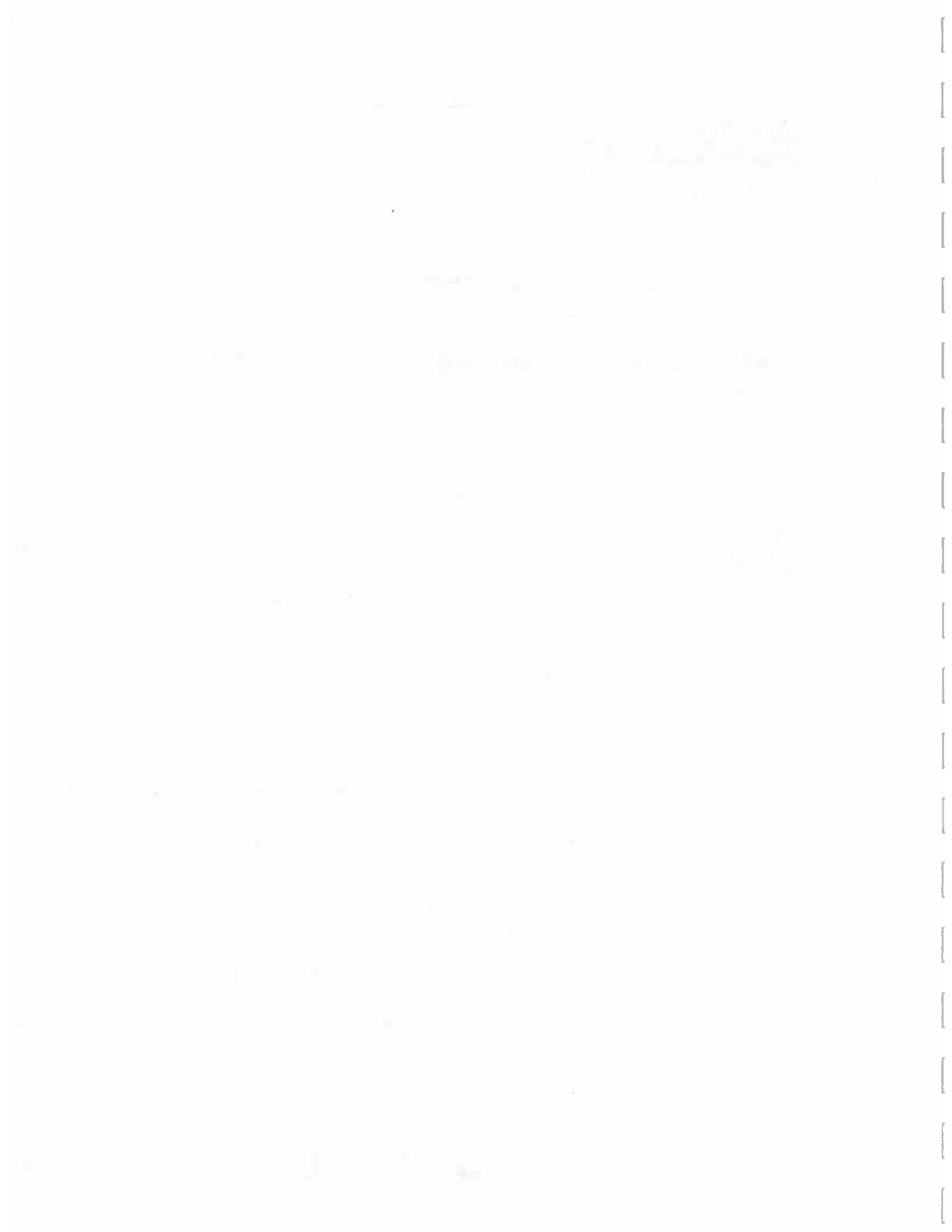
Comments (Required if Unacceptable):

- [REDACTED]

ADDITIONAL COMMENTS TO APPLICANT

<u>Additional Comments to Applicant</u> (Optional)
--

- It is likely that more time will be required between the two workshops planned for the second year.



CHAPTER 5

RESPONSE TO PRIOR REVIEW

TIP: The single most important reason for failure of resubmitted applications, in our opinion, is lack of full and substantive response to all of the constructive criticism offered by prior reviewers.

This chapter will help you avoid the trap of selective response to prior review.

NIH has two approaches that help applicants decide at the earliest possible time whether or not their idea is fundable. The first of these we hope won't pertain to your application: Not Recommended for Further Consideration (NRFC; see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html>). The NRFC rating is applied to proposals that have something fundamentally wrong with them. Either the science proposed is without significant/substantial merit or there is an ethical problem with what is proposed. Applications designated as NRFC cannot be funded and cannot be resubmitted.

The second approach allows only one resubmission (A1) of a previously rejected A0 application (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html>). As originally conceived, subsequent rejection of the resubmitted A1 application would result in the applicant having to wait a minimum of 37 months from the date of the original (A0) submission before the idea could be proposed again. The intent was to force applicants to make earlier decisions regarding whether or not an idea is fundable. What no one foresaw was that, because so few proposals are being funded in these tough economic times, the one-resubmission approach would cause many good ideas to be lost – ideas that only needed to be tweaked a bit more to become fundable. Accordingly, on April 16, 2014, NIH's resubmission policy was changed (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>) to allow a rejected A0 or A1 to be immediately re-proposed as a new, A0 application with little or no change in the basic idea. In our opinion, this change will help greatly in terms of applicants ultimately meriting funding.

FORMAT OF THE SUMMARY STATEMENT

Parts of the Summary Statement have changed dramatically, compared to what applicants received in the past. (Examples are provided by NIAID at <http://www.niaid.nih.gov/ncn/grants/app/default.htm#rpindex>). There were many reasons for the changes. Among them were the needs to: 1) better communicate reviewers' constructive criticisms to applicants; 2) provide more detail to investigators whose original submission was unscored (streamlined or 'triaged'); 3) enhance the uniformity of reviews; and 4) reduce administrative burdens on reviewers and Scientific Review Officers.

The name of the responsible Program Officer is still in the upper left corner of the Summary Statement. Administrative information regarding the review panel that reviewed the proposal is still supplied, along with an impact/priority score (if the proposal was scored), a percentile rank (if applicable) and information about the budget. The impact/priority score is the average of all of the final impact scores awarded by eligible reviewers (those without conflicts of interest), multiplied by 10. There is still a Description, which is usually a combination of the Project Summary and Project Narrative (statement regarding relevance to public health) that were written by the applicant. And, if the proposal was scored, there is a Résumé – a summary by the Scientific Review Officer of the discussion that took place during the consideration of your application at the review-panel meeting. Up to this point, things are pretty much the same as they were with the previous approach.

Big changes begin with the critiques of the (usually) three reviewers.

1. The order in which the five core review criteria are addressed by each reviewer (and discussed at the review-panel meeting) has changed. The difference is that APPROACH has dropped from second to fourth in the sequence, with SIGNIFICANCE, INVESTIGATOR(S) and INNOVATION preceding it. This change has been made to put less emphasis on how the project will be done and more on the quality of the idea and of the investigator(s) who will pursue the research, as well as on the impact that the work is likely to have. Switching the order may seem like a small change, but it is actually a major one that addresses one of the root problems in the previous system: nitpicking of the proposed approach by reviewers, both in their written critiques and during discussion of applications at the meeting of the review panel.
2. The score that each assigned reviewer gave each of the five core review criteria is presented in a table that precedes his/her critique. This is exceptionally important to applicants who decide to resubmit an initially rejected application. It allows them to see at a glance where their application was strong and where it was weak. Such scores are provided for unscored (streamlined/triaged), as well as scored, applications. This is very useful in terms of helping applicants decide whether to resubmit an application (especially one that was streamlined/triaged initially) or switch to a new idea (see next section regarding Analysis and Interpretation for details).
3. Greater standardization is promoted by requiring reviewers to use templates for their critiques (see example at the end of chapter 4). Each assigned reviewer's completed electronic template is uploaded into the Summary Statement. This approach has greatly decreased the administrative burden on Scientific Review Officers, who in the past had to write each applicant's critique from reviewers' comments.
4. Reviews are shorter and more to the point of evaluation, rather than description of what will be done and how. The new template approach forces reviewers to make their points more concisely. First, with rare exceptions, the template limits discussion of each of the five core criteria to a quarter-page or less. Second, reviewers are required to write bullet-ed points or, if absolutely necessary, short narratives. This has eliminated the long, rambling discussions that were often seen in the past. Third, reviewers now must focus primarily on major strengths and weaknesses, i.e., the ones that contributed most to the reviewer's scoring of each criterion. This requirement has gotten rid of a lot of the extraneous and often confusing comments that were included in the past. Any succinct comments to the applicant that pertain to either additional review criteria/considerations or other issues are provided by reviewers in the final "Additional Review Criteria," Additional

Considerations,” or “Additional Comment to Applicant” fields, respectively, which are found at the end of the template.

Finally, as in the past, the Summary Statement concludes with the meeting roster – the names and institutional affiliations of all reviewers who participated in the meeting, both permanent and temporary members, if any, along with the names of the relevant Scientific Review Officer and Grants Technical Assistant.

ANALYSIS AND INTERPRETATION OF THE SUMMARY STATEMENT

Essential Point: the primary purpose of analysis and interpretation of the Summary Statement is identification of the quickest route to funding – resubmit or switch to a new idea.

If you weren't funded on your first try, your first priority should be to decide whether to resubmit or not. Is it a quicker path to funding to revise and resubmit the same application or switch to a new project? To make that decision we recommend that the PD/PI make photocopies of the Summary Statement immediately after it is received. The copies should then be distributed to Senior/Key members of the research team. Each should independently read the Summary Statement several times. With each reading, new insights will likely be acquired. During a final reading, anything that can be interpreted as constructive criticism should be highlighted. The Principal Investigator should collect the independently highlighted copies of the Summary Statement, together with each member's independent 'go/no-go' recommendation. Then, we suggest that the PD/PI call a meeting of the research team to discuss and collectively decide what should be done. For scored applications the decision is usually straightforward: Resubmit if the strengths identified in the critiques outweigh the weaknesses and no 'fatal flaws' are apparent. The decision is more problematic for unscored (triaged) applications. If four-of-the-five core review-criteria scores are reasonable, for example, and each of the assigned reviewers saw it that way, one could easily argue that the proposal should be resubmitted after strengthening the weak area and responding to the constructive criticisms offered on the others. By contrast, an unscored application with uniformly poor core-criteria scores would probably be a poor investment of time and effort.

If the collective decision is to resubmit, using the highlighted Summary Statements collected from members of the research team, the PD/PI should make a list of all criticisms that were lodged against the previous proposal. Once the list of all criticisms has been created, the Principal Investigator and other Senior/Key members of the research team should decide how to respond to each. If the decision is made to reject a recommendation made by the previous reviewers, strong and logical justification for doing so should be formulated.

TIP: You are missing a very important means of improving your response to the previous review if you do not consult your Program Officer during analysis of your Summary Statement.

At this point, for a scored application (one that wasn't triaged), the Principal Investigator should contact the relevant Program Officer, a step that is encouraged in the letter that accompanies

the Summary Statement, as well as by the *Application Guide* (see section 1.4 of Part I). After you and your colleagues have gleaned everything that you can from the Summary Statement, send the Program Officer an e-mail message asking for the opportunity to talk to him/her by telephone. Good Program Officers – and that's most of them – or their representatives attend review-panel meetings and listen to the review of applications that are relevant to their program. Therefore, s/he will likely know what took place during the discussion of your proposal. What you are seeking in the conversation is information that is hidden 'between' the lines of the critique, e.g., what the greatest problems will be in converting reviewers to your side. You also want to make sure that the Program Officer concurs with your decision to resubmit. Information from this telephone conversation can be very helpful in refining the Introduction to your resubmission.

There is no point calling your Program Officer about a triaged application because no discussion of it was held at the meeting. S/he won't know any more about its review than you know from reading the Summary Statement.

The Scientific Review Officer who managed the review should not be contacted unless you have a specific question or concern that pertains to the process of review. For example, if you think that your proposal was treated unfairly (and have objective evidence to support that assertion) you would take that up with the SRO. Submit your concern via an e-mail message that can be created after scrolling down to the relevant acronym in the left column and then clicking on the SRO's name in right column of the table at http://www.csr.nih.gov/Roster_proto/sectionI.asp; his/her contact information will be part of what appears on the screen.

WRITING THE INTRODUCTION TO YOUR RESUBMITTED APPLICATION

TIP: The Introduction should not be a stand-alone section. To be maximally effective it must be written as a complement to changes made in the rest of the application.

The response to prior review takes the form of the first, "Introduction" section of the Research Plan. You are allowed only one page, regardless of the grant mechanism. It is a great challenge to fit everything that needs to be covered onto a single page. A succinct writing style is required here, therefore, to an even greater extent than it is elsewhere in the application. Here are five tips regarding how to maximize your utilization of the space, which are detailed below.

1. Set up the page to maximize available space.
2. Do not waste space by calling attention to strengths listed by the previous reviewers.
3. Concentrate on overall impact, the five core criteria and any "Additional Comments to Applicant."
4. Proportion the size of your responses to the relative importance of weaknesses.
5. Minimize detail here with respect to changes that have been made.

1. Set up the page to maximize available space. Use the minimum for margins, 0.5 inch all around. The smallest allowable font – 11 points – should be used. Single space after each sentence. Full justification will save a little space. A small amount of additional space can be conserved by auto-hyphenating the document, which brings up short lines at the end of paragraphs and tightens word-spacing problems that can sometimes develop when full justification

is used, especially when text is wrapped around tables. Avoid the use of manual hyphenation. Word placement can change when what you have written is converted to a PDF file, which can cause manually hyphenated words to appear inappropriately within a line. If you prefer to write with left-margin justification, auto-hyphenation will save space by additionally making the right margin less ragged. Paragraph as infrequently as possible, e.g., only after each section (see #3, below), but without open lines between them.

2. Do not waste space by calling attention to strengths. The Introduction should be restricted to responses to criticisms of the earlier application. These will usually be the weaknesses that were flagged by the previous reviewers and any of their Additional Comments that could be construed as negative. The introduction should not be used to call attention to things that the prior reviewers identified as strengths. First, there isn't room to do so. Second, calling attention to strengths can backfire, because new reviewers may think that doing so constitutes a not-so-subtle attempt to influence their thinking.

3. Concentrate on overall impact, the five core criteria and any "Additional Comments to Applicant." There are five core criteria and three reviewers. Even if each reviewer were to offer only one weakness per criterion, there would be 15 items if you were to respond to each individually. One weakness per criterion is an unrealistically low number, so what we are really considering here is how to respond in one page to 30 or more individual constructive criticisms. We recommend that you do so by beginning the Introduction with a simple table that reflects each reviewer's scores for the five core criteria. Wrap brief opening general comments around the table. Then, subdivide the rest of the page into up-to-eight sections that correspond to the score for overall impact (if the application was scored), each of the core criteria, Additional Review Criteria/Considerations (if any) and the Additional-Comments-to-Applicant (again, if any).

Create the table as a separate document. Copy and paste it into a text box, as shown at the right. Place the text box at the upper right margin of the Introduction

REVIEWER	SIG.	INVEST.	INNOV.	APP.	ENV.
One	2	1	6	3	1
Two	2	2	3	5	1
Three	4	5	5	6	2

and then wrap text around it, as is shown here. To do so, reset the right margin to the left of the text box. When you come to the last line adjacent to the table, paragraph and reset the right margin to 0.5 inch. Complete your general remarks, which should include how changes in the rest of the Research Plan have been marked (see below). Then set up the subsections for the Introduction. Do not waste space by opening a line between them. The subsections should be:

OVERALL IMPACT: (if the application was scored)

SIGNIFICANCE:

INVESTIGATOR(S):

INNOVATION:

APPROACH:

ENVIRONMENT:

ADDITIONAL CRITERIA / CONSIDERATIONS: (if weaknesses were identified)

ADDITIONAL COMMENTS TO APPLICANT: (if weaknesses were identified)

4. Proportion your responses based on the relative importance of weaknesses. In the example given in the text box, above, one would expect the most important expressions of

weakness to be found under INNOVATION and APPROACH for all reviewers and under each of the other core criteria for reviewer #3. Thus, INNOVATION and APPROACH would likely get the most space. One of the reviewers, #2, was concerned about APPROACH but not to the extent that it caused him/her to downgrade the IMPACT score. That observation would be useful to include in the response. By contrast, reviewer #1 was generally positive but the IMPACT score was apparently dragged down by perceived serious weakness in INNOVATION. It would be important to make that point and respond to it.

5. Minimize detail in the Introduction. There isn't enough space to describe your responses in detail. That is why the Introduction cannot be written as a stand-alone document. It must be written as a summary of the responses that have been made, with specifics given elsewhere in the application. Referring the reviewers to changes that have been made in the application takes thought and creativity because the complete document will not be sequentially paged until after it is submitted, i.e., you can't refer to where a change has been made by providing a page number. You have to use some other kind of locator. The sections of the Research Plan, not including the Introduction, consist of the *Specific Aims* section, the *Research Strategy* section, and, if applicable, other sections, including *Inclusion Enrollment Report*, *Progress Report Publication List*, *Human Subjects* sections, and 'Other' sections that pertain to *Vertebrate Animals*, *Select Agent Research*, *Multiple Principal Investigator Leadership Plan*, *Consortium/Contractual Arrangements*, *Letters of Support*, and *Resource Sharing Plan(s)*. Other parts of the application also have titles, such as *Facilities & Other Resources*. Section titles should be the primary locator of changes. If the section referred to has subsections, the title of those becomes the secondary locator, and so on. For example, a response to a perceived weakness in the ENVIRONMENT criterion might be followed by '(see *Facilities & Other Resources-Clinical*).' For a response to an APPROACH criticism the referral might extend to a sub-subsection: '(see *Research Strategy-Approach: Source of Subjects*).

As a specific example of what the response to a major weakness would look like, let's say that the INVESTIGATOR criterion for an Early Stage Investigator's application was cited as weak because of perceived lack of independence. The response and referrals might be something like:

INVESTIGATOR: The lack of independence perceived by Reviewer #2 and Reviewer #3 has been addressed by upgrading the applicant's academic appointment, assignment of new resources to her, and provision of evidence of full separation from her former mentor (see *Biographical Sketch-Personal Statement*; *Facilities & Other Resources-Laboratory and Equipment* sections; and *Chair's Letter of Support*, respectively).

But that response takes up a little over four lines. Accordingly, the next step is to edit it down to the fewest words that are required to make the point clearly. Anything extraneous should be eliminated. For example:

INVESTIGATOR: Perceived lack of independence (Reviewers 2 & 3): appointment upgraded (*Biographical Sketch-Personal Statement*); resources assigned (*Facilities & Other Resources-Laboratory and Equipment*), and full separation from former mentor (*Chair's Letter of Support*).

Almost 1.5 lines were cut without losing any information. Granted, the edited version doesn't read as smoothly. But that's not a consideration here. You must provide responses to all – or at least all important – criticisms in the very little space you are given. After meeting that mark you can always smooth things out later, if you have the room to do so. Clever editing is an essential skill needed to convey all that's required within NIH's shortened application format. Changes in

the revised application must be marked so that reviewers can find them easily. NIH prohibits shading or underlining text as a means of delineating what has been changed. *The approach used to indicate changes in the revised application should be described at the beginning of the Introduction.* "Bracketing, indenting, or changing typography" are recommended by NIH (see Part I, section 2.7 of the *Application Guide*). Of the three choices, we recommend that you mark changes with **bolded** brackets. The remainder of our recommendation here is denoted that way. [This approach is subtle, to the extent that marking changes is unlikely to be an aggravation to reviewers. Brackets are seldom used for other purposes, so they will be highly specific for the changed parts of your Research Plan. Another very important advantage is that brackets are searchable. Thus, if the reviewer only wants to read what has been changed, s/he can set up a search for the right-facing bracket and find all of your changes quickly and easily. That is likely to be perceived as very reviewer-friendly. The bracket-search strategy should be suggested to reviewers at the beginning of your Introduction, where you tell them how you have marked changes.] If changes have been so extensive that almost everything is different, you should not mark changes in the text. Simply note that at the beginning of the Introduction.

As will be seen in chapter 21, we **strongly** recommend that grant applications be reviewed by knowledgeable colleagues prior to their submission. For revised proposals, it is critical that such review focus particularly on the Introduction and the changed parts of the application. It is important, therefore, that pre-submission reviewers receive **both** the Summary Statement and the complete application (or, at least, all of the parts in which changes have been made in response to the previous review). The pre-submission reviewers should be asked to comment, specifically, on whether the response to the previous review is clear, full and substantive. If it is not, why isn't it? What are their suggestions for improving it?

After preparing your Introduction you must upload it into field 1 of the PHS 398 Research Plan form, as shown below. Clicking on "Resubmission" in field 8 of the Cover form will activate the "Introduction to Application" field here.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001



1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment
Human Subjects Sections				
5. Protection of Human Subjects		Add Attachment	Delete Attachment	View Attachment
6. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Children		Add Attachment	Delete Attachment	View Attachment

RESUBMISSION OF STREAMLINED (TRIAGED) APPLICATIONS

If your original, A0 submission was triaged, by definition, there was a lot wrong with it. Taking such a proposal to funding is not impossible, but it will certainly be very difficult. *That is why every step presented in Part I of this Workbook should be taken to maximize the competitiveness of your application and, thereby, avoid having to deal with recovering after triage.*

If your proposal was triaged and the decision to revise has been made, there are three approaches that are available to you: (i) respond to the Summary Statement and resubmit the application to NIH as an A1 proposal; (ii) send it back as a new, A0 application; or (iii) switch to a new agency. The third option requires no explanation. As to the first two:

The danger with the first option is that the previously assigned reviewers may not have included everything in their critiques that was wrong with the original proposal. To save time and work, they may have focused only on major problems that justified the low scores that they awarded; they are not obligated to do more than that. Thus, when responding to such a review, the applicant may not have all of the constructive criticism needed to be fully responsive to the full range of problems that existed. As a result, previously unrevealed problems compromise the A1 resubmission. Fortunately, the change in NIH policy that allows a failed A1 application to be re-proposed as a 'new', A0 application reduces the importance of this concern. We caution, however, that resubmitting the same proposal over and over again may greatly delay funding success. To help cope with this problem we recommend that, when you resubmit to NIH, you submit the same application to some other agency or agencies. That strategy is permitted under NIH rules. Should both agencies want to fund the revised application – and we hope that you have that problem – you would only be allowed to accept one of the offers (probably the one that comes with the most time and money).

The second option, send the proposal back as a new, A0 application, has merits. You would be able to use all of the constructive criticism received during the first round of review, but you wouldn't have to write an Introduction for the revised proposal – i.e., how you responded to the criticisms of first set of reviewers. Therefore, you would avoid calling attention to the many problems that your original proposal had. For example, the next group of reviewers would not be given the Summary Statement for the triaged A0, as they would be if you were to submit an A1. In other words, your application would start over with a clean slate – helped by your responses to the constructive criticisms that you received from the first round of review. We also strongly recommend here that, if you take this approach, you send the revised application to other agencies at the same time that you send it back to NIH.

SHORTENED REVIEW CYCLE FOR NEW/EARLY STAGE INVESTIGATORS

NIH is doing everything possible to accelerate the pace with which New/Early Stage Investigators are funded at the R01 level. One strategy is to shorten the review cycle (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-083.html>), providing that the original R01 proposal was submitted to a standing review panel on a standard receipt date, i.e., February 5, June 5 or October 5. Eligible applicants receive their Summary Statements about 4 months later, usually within 7-10 days of the review panel's meeting (no later than July 1, November 1 or March 1, respectively), allowing them to resubmit to the next round of review. This approach saves at least four months. The study section targeted can be the same or a different one. If a switch to a different panel is desired, that must be communicated in the Cover Letter component which accompanies the resubmitted proposal. The Center for Scientific Review's Division of Receipt & Referral has the last word on whether such a request is granted, or not.

While this approach has great potential benefit associated with it, the risk of failure is also potentially increased. Even though resubmission deadlines have been extended 15 days beyond the standard dates, i.e., to July 20, November 20 or March 20, there is less time than with the standard approach in which to correct problems and revise the application. We highlighted in a text box at the beginning of this chapter why resubmissions usually fail: lack of full and substantive response to all of the constructive criticism offered by the previous reviewers. If you are eligible as a New/Early Stage Investigator and can be fully responsive, even though the time available to correct problems is short, you should take advantage of this opportunity to be funded earlier. About 13% of eligible applicants have been able to do so. But, if trying to meet the accelerated deadline is going to force submission of selective responses to the prior criticisms, the shortened review-cycle program is a scenario for disaster. Our recommendation, therefore, is to stick with a comfortable regular resubmission deadline (July 5, November 5 and March 5) that will allow you to submit the best revision you are capable of offering.

DEVELOPMENTAL STEPS FOR CHAPTER FIVE:

1. Appreciate that selective response to reviewers' previous criticisms is the commonest cause for the failure of resubmitted applications.
2. Understand that NIH now allows either a failed A0 or A1 application to be resubmitted immediately as a new, A0 proposal.
3. Know what the parts of a Summary Statement are and the relevance that each has to developing a resubmitted application.
4. If your New/Early Stage Investigator R01 proposal was not funded when originally submitted, appreciate that your resubmission is eligible for a shortened review cycle. But also appreciate the potential for increased risk if this option is taken, due to less time to formulate your responses to the criticisms your proposal received..
5. Understand that resubmitting an application should not be a knee-jerk reflex. The route to funding may be shortened by switching to a new project.
6. The resubmit/switch decision should be based on careful analysis of the Summary Statement. Distribute copies to Senior/Key members of the research team.
7. Each member should read the Summary Statement several times, highlight weaknesses/constructive criticisms and then independently decide whether to resubmit the proposal as an A1, send it back as a revised A0, or switch to a new project.
8. Convene a meeting of the research team to discuss the pros and cons of sticking with this project vs. switching. Then, collectively decide what the course of action should be.
9. Know that triaged applications can be sent back to NIH as either A0 or A1 proposals.
10. If the decision is to resubmit (A1), understand that the Introduction should not be written as a stand-alone document. It must be a complement to bracketed changes in the body of the application.
11. To begin preparing the Introduction, the Principal Investigator should use the research team's highlighted Summary Statements to make a list of all weaknesses/constructive criticisms that were lodged against the previous proposal.
12. Create a table of the assigned reviewers' numerical scores for each of the five core review criteria.
13. Set up the single-page Introduction – response to prior review – with the table of scores at the top right, followed by headings for overall impact, the five core review criteria, Additional Criteria/Considerations, and Additional Comments to Applicant, if any.
14. Proportion the length of responses in the Introduction to the importance of weaknesses identified by the previous reviewers.

15. Edit out any words that can be eliminated from responses without affecting their clarity and impact.
16. For scored applications (those that were not streamlined), contact the Program Officer using the contact information in the upper left corner of the first page of the Summary Statement.
17. Do not contact the Scientific Review Officer unless you have questions or concerns that relate to the process of the prior review.
18. Write the Introduction. Edit what you have written to fit within one page using 0.5-inch margins, 11-point font, auto-hyphenation and full justification.
19. Mark changes made in the revised application with bolded brackets. If changes are so extensive that it would be impractical to mark them individually, note that fact at the beginning of the Introduction.
20. Before submitting your revision, have members of your Pre-Submission Review Committee (see chapter 21) read your Summary Statement and evaluate the changes you have made to assure that a full and substantive response to all constructive criticism has been made.
21. Convert your Introduction into a PDF file. Check to make sure that it still is a single change after the conversion. Give it the file name, "Introduction."
22. Upload your PDF Introduction file into the PHS 398 Research Plan form (Field 1).

EXAMPLE (TRUNCATED) OF AN INTRODUCTION

The text box (right) contains reviewers' scores for our previously submitted proposal. Responses to critiques are

REVIEWER	SIG.	INVEST.	INNOV.	APP.	ENV.
One	2	4	6	4	2
Two	2	4	5	5	1
Three	2	8	6	5	2

summarized below, with referrals to details in the body of the application. Changes in the Research Plan have been marked using searchable, bolded brackets.

OVERALL IMPACT: Concerns related to lack of creativity/originality and the research team's relative lack of immunological experience elevated scores here. These issues are addressed, below (see INVESTIGATOR, INNOVATION and APPROACH).

SIGNIFICANCE: The minor concern that we were inappropriately regionalizing our focus, thereby limiting the potential positive impact of our outcomes, was expressed by all 3 reviewers. This has been addressed by nationalizing the scope of our outreach programs through new collaborations (see Biographical Sketch-Howard, -Hanks and -Cantor; also see Research Strategy-Significance and -Approach).

INVESTIGATOR: The research team's relative lack of immunological expertise has been overcome by adding a formally trained immunologist (see Biographical Sketch-Hopkins) who will have primary responsibility for design and oversight of studies in this area. Her influence on research design is evident in this revision (see Research Strategy-Approach).

INNOVATION: Outdated, antiquated immunological approaches that limited creativity and originality created weakness in the earlier proposal. This weakness was seen as compounded by lack of appreciation for recent immunological advances. As will be seen in this revision (Research Strategy-Innovation & -Approach),etc.

CHAPTER 6

CREATE A WRITING SCHEDULE

Availability of time is one of the most important factors that influences the success or failure of an applicant's proposal-writing efforts. No one has an excess of time! Your competitors who are also writing NIH grant applications will be confronted by this same problem.

TIP: Efficient time management while writing your grant application is one of the most important ways that you can gain an edge over your competitors.

Two kinds of time are needed to write a competitive grant application: (1) lead time before the deadline, and (2) quality time while you are preparing the proposal.

LEAD TIME PRIOR TO THE DEADLINE

There are two kinds of deadlines at NIH, ones that recur on a regular basis (see section 2.15 in Part I of the *Application Guide*) and ones that are set by specific solicitations (e.g., Requests for Applications [RFAs] and Program Announcement [PAs]). Applicants have no control over the latter deadlines. Therefore, the way to maximize the amount of lead time between formal announcement of such a funding opportunity and its deadline is to have a strategy – a system – that will assure that you discover such opportunities at the earliest possible time. Thus, it is smart business, in our opinion, to subscribe to listserves and e-mail alert services that will help to assure such early discovery.

Listserve. Examples of useful listserves include the one for the NIH Guide for Grants and Contracts (<http://grants.nih.gov/grants/guide/listserv.htm>). Subscribers to it are notified each Friday of every Notice, RFA, and PA that has been issued during the preceding week. Greater specificity can be gained by additionally consulting one of the specialized listserves listed at <https://wiki.nci.nih.gov/display/COREtraining/Subscribe+to+NIH+Mailing+Lists+and+List+Server>. NIH also offers the opportunity to subscribe to an RSS feed (<http://grants.nih.gov/grants/guide/newsfeed/fundingopps.xml>) that is updated more frequently.

E-mail alert services are very useful means of assuring early notification of a funding opportunity. We recommend the one at Grants.gov that provides daily notification (also by RSS feed) (<http://www.grants.gov/web/grants/manage-subscriptions.html>) and those sponsored by COS Pivot and InfoEd. Both of the last two require that your institution be a subscriber in order to use them; most universities and other research institutions are members of one or the other or, in some cases, both. See your reference librarian for help.

QUALITY TIME WHILE PREPARING THE PROPOSAL

When you have the luxury of planning ahead to meet a recurring deadline, we estimate that four-to-six months are needed to develop the best proposal of which you are capable while, at the same time, you contend with all of your other competing professional and personal priorities. In our opinion, most applicants cannot write a competitive NIH proposal within the 22-hour "paperwork burden" that is estimated in the *Application Guide* (section 1.8 of Part I), not including development of the Research Plan and the Human Subjects parts of your application.

Why are four-to-six months needed to optimize the developmental process? Because few of us can drop all other competing priorities and do nothing else than work on a grant proposal. In addition, time is required to thoroughly review the literature and the already-funded grants that are contained in the RePORTER database. These are critically important steps. Additional time is needed to maximize the programmatic relevance of your idea with respect to the priorities of the agency that you plan to target. Significant time must be invested in writing every aspect of the proposal – not just the Research Plan. And finally, time is required to obtain pre-submission review of your application by knowledgeable colleagues – one of the most important steps in the development of a proposal.

We recommend that you start by freeing up as much time as you can. Conduct an inventory of both your professional and private obligations. Anything that can be dropped, deferred and/or delegated (the three Ds) should be eliminated from your schedule. Discuss with your unit leader and supportive colleagues how they can help you. For example, with appropriate planning and coordination, you may be able to find temporary stand-ins for committee assignments, swap clinical rotations with colleagues, and/or find short-term substitutes for teaching responsibilities. The operational words in the previous sentence are "planning" and "coordination." Such arrangements can't be made at the last minute.

For any responsibilities you can't drop, defer or delegate we suggest that you deal with them in blocks of time. For example, while you are writing a grant application, telephone (including cellular) calls should be accumulated by an assistant or by an answering machine / voice-mail service. Return the calls during a scheduled block of time. E-mail messages should be handled similarly: respond to them during a single time during the day. If you are teaching, set up office hours and require that students stick to them. By using these strategies, you can minimize disruptive influences that would otherwise degrade the quality time that you need for development of your grant proposal.

The most efficient approach to writing your grant application also involves blocking off time for that purpose. Set aside one-to-two hours or more per day. Protect that time by making it a formal entry in your calendar, and then have the discipline to keep that appointment with yourself. If you are a 'morning person,' set the time aside in the morning. If you are more efficient at some other time of the day, set the time aside then. To optimize the efficiency with which you utilize this block of time, we recommend that you set up a writing schedule – a timetable – that allows you to accomplish a little bit on your application each day. Consistent writing of a little bit every day results in development of the application without it being that daunting, intimidating process that we all think about in association with writing a grant application. You can do your best on your grant proposal while, at the same time, you attend to all of the other competing priorities that you couldn't drop, defer or delegate.

The writing process is facilitated, in our opinion, by writing the parts of your application out of the order that they appear in the Table of Contents, i.e., the order in which you will submit them. By

doing so, you will use the momentum that you have developed while writing one section to help write the next one, and you will minimize the potential problem of having internal inconsistencies develop between related sections that would be written widely separated in time if the 'Table of Contents' order were followed. The many applicants who have used this approach and given us feedback have uniformly found it positive. The following timetable, which is available in electronic form on our website (www.grantcentral.com/downloads.html), is the one that we recommend you use to guide the writing phase of the proposal-development process.

Complete By:

Set up your Pre-Submission Review Committee (see chapter 21)	
Seek constructive criticism of your idea from the expert members of your Pre-Submission Review Committee	
Refine the idea further, if necessary, using the constructive criticism(s) received from members of the Pre-Submission Review Committee	
Complete <i>Specific Aims</i> section, Significance and Innovation subsections of the <i>Research Strategy</i> section.	
Final refinements of <i>Specific Aims</i> section, Significance and Innovation subsections of <i>Research Strategy</i> section; prepare <i>Cover</i> form (except title and Cover Letter Attachment) & <i>PHS 398 Cover Page Supplement</i> form; complete upper 6 sections of <i>Other Project Information</i> form.	
Send the finalized <i>Specific Aims</i> section, Significance and Innovation subsections of <i>Research Strategy</i> to Pre-Submission Review Committee and to Institute/Center Program Officer	
Prepare <i>Research Strategy-Approach</i> subsection for specific Aim 1 minus Justification & Feasibility; complete <i>Project/Performance Site Locations</i> form.	
Prepare <i>Research Strategy-Approach</i> subsection for specific Aim 2 minus Justification & Feasibility; develop <i>Senior/Key Person Profile (Expanded)</i> form and <i>Biographical Sketch</i> for each Key Person and Other Significant Contributor.	
If applicable, prepare <i>Research Strategy-Approach</i> subsection for specific Aim 3 minus Justification & Feasibility; if applicable, develop Multiple PI Leadership Plan and Resource Sharing Plan of <i>PHS 398 Research Plan</i> form, as well as International Collaborations and Environmental Impact sections of <i>Other Project Information</i> form.	
Develop Justification & Feasibility sub-subsection for each specific aim; prepare Bibliography & References Cited section of <i>Other Project Information</i> form	
If applicable, develop the Human Subjects sections and Vertebrate Animals section of the <i>PHS 398 Research Plan</i> form; <i>Planned Enrollment Report & Cumulative Inclusion Enrollment Report</i> .	
If your proposal is a renewal, develop the Progress Report subsection of <i>Research Strategy-Approach</i> and the Progress Report Publication List of the <i>PHS 398 Research Plan</i> form.	
Develop <i>Budget</i> component (Modular or R&R breakout, whichever is applicable) and applicable Budget Justification(s).	
Prepare Facilities & Other Resources and Equipment sections of the <i>Other Project Information</i> form; prepare section on Consortium/Contractual Arrangements of the <i>PHS 398 Research Plan</i> form or <i>Subaward Budget Attachment(s)</i> form, if one or the other is applicable	
Prepare Project Summary/Abstract and Project Narrative sections of the <i>Other Project Information</i> form; Title and Cover Letter Attachment of <i>Cover</i> form; if needed, obtain Letters of Support and prepare Appendix (both sections of <i>PHS 398 Research Plan</i> form).	

Assemble final draft. Proof and make final adjustments	
Send draft to members of Pre-Submission Review Committee for review of scientific and technical merit:	
Respond to constructive criticisms of members of Pre-Submission Review Committee:	
Send completed proposal to Sponsored Programs Office 3-5 working days prior to agency deadline (Obtain exact number of days needed from Sponsored Programs Office):	
Submit application to meet deadline – not later than:	

Be realistic when you set up your schedule. Take into account all of your professional and personal obligations. It is of no value whatsoever – and is actually detrimental to the process – to set up deadlines that you can't meet. Generally, the span of time should be 16-18 weeks. If you have a deadline that doesn't allow that amount of time, we recommend that you either compress the writing and pre-submission-review schedule proportionately or move some elements into other weeks where there is available time. Whatever you do, NEVER eliminate pre-submission review as a means of recovering time. As you will see in chapter 21, in our opinion, obtaining pre-submission review is the *single most important step* that you can take to increase the likelihood that your proposal will be funded.

Finally, we recommend that you not try to write your first draft perfectly. Don't agonize over every word. The initial goal should be to just get your thoughts down on paper. If you are like most investigators, you're much better at rewriting than you are at getting it right the first time. If you can't find exactly the right words the first time, don't let it throw you. Simply write down whatever comes to mind at the time and go on. You'll find the inspired wording later – during the rewrite.

DEVELOPMENTAL STEPS FOR CHAPTER SIX:

1. Maximize the amount of quality time that you will have for writing your grant proposal by, first, inventorying all of the professional and personal obligations that you will have during development of your application. Then, drop, defer, or delegate as many of those obligations as you can in order to free up time in your schedule to write your application.
2. Identify the part of the day when you can spend one-to-two hours of quality time working on your grant proposal every day. Set that time aside in your formal appointments calendar.
3. Download the timetable from www.grantcentral.com/downloads.html. Use it to set up a realistic writing and pre-submission review schedule, taking into account all other professional and personal commitments that you can't drop, defer or delegate.
4. Have the discipline to stick to the schedule that you set for yourself. Don't allow yourself to get behind because, if you do, a little behind will rapidly become a lot behind.

OVERVIEW: PART TWO

THE TEMPLATE FOR YOUR RESEARCH PLAN

Once you have completed all of the activities that are summarized in Part One, you will be positioned well to begin development of the Research Plan. It will consist of these sections for new applications (for renewal applications there would be an additional, "Progress Report" as the first sub-subsection under "Approach" – see page 98 for details):

- Specific Aims (limited to 1 page)
- Research Strategy (limited to 12 pages for R01, R15 & R34; 6 for R03 & R21)
 - Significance
 - Innovation
 - Approach
 - Each Specific Aim (same format for each):
 - Introductory Paragraph
 - Justification & Feasibility
 - Review of Relevant Literature
 - Preliminary Studies
 - Research Design
 - Expected Outcomes
 - Potential Problems & Alternative Approaches
 - Timetable
 - Future Directions (optional)

The developmental process should begin with the all-important *Specific Aims* section and the first and second subsections of the *Research Strategy* section, Significance and Innovation. These parts of your proposal have great importance in terms of both its writing and review. With respect to the former, they constitute the 'template' that will be used to write the rest of the proposal. In terms of review, they introduce reviewers conceptually to everything that is important and exciting about your proposal, thereby 'hooking' their interest and making them want to read the details that are provided in later sections.

Chapter seven, "*Specific Aims* Section: Conceptual Overview & Creating a Bullet Outline," addresses the conceptual approach that underlies formulation of the *Specific Aims* section and introduces you to the specific purpose for each of the components that collectively comprise this section. It will also direct you to a part of our website where you will find an interactive template that will help you develop the bullet outline that will facilitate the drafting of your *Specific Aims* section.

Chapter eight, "Writing the *Specific Aims* Section," will take you, step-by-step, through the development of text for your *Specific Aims* section. This will begin with expansion of the bullet outline generated by your response to chapter 7, which will then be refined to provide an integrated overview of everything that is important about your proposal.

Chapter nine, “Significance and Innovation Subsections of the *Research Strategy* Section,” will focus on development of the parts of your proposal that are arguably the most important ones in the entire grant application. NIH places great importance on these two subsections, which is where reviewers get most of the information needed to score two of the five core-review criteria.

These are the parts of your application that will provide the ‘blueprint’ – the template or master plan – for development of the rest of your Research Plan. If these sections are written well, the rest of the Research Plan, as well as other parts of the application, become relatively easy to conceive and write. Thus, we encourage you to make an investment in them that will maximize the positive impact that they can have on preparation of the rest of your proposal.

CHAPTER 7

SPECIFIC AIMS SECTION: CONCEPTUAL OVERVIEW & CREATING A BULLET OUTLINE

CONCEPTUAL OVERVIEW

TIP: Strategically, the *Specific Aims* section should be written to create a 'partnership' with the assigned reviewers who will represent you at the review-panel meeting. You will provide the conceptual framework on which they will orally hang the details of what will be done.

The *Specific Aims* section is critical to writing a first-class NIH grant application. It is the most important section related to the development of your proposal, in our opinion, because as noted earlier, it becomes the template or master plan for the rest of your Research Plan; if this section works well, everything else will fall naturally into place.

The *Specific Aims* section has an equally important role in the review of your proposal: recruiting reviewers to vote a fundable priority score for it. The majority of reviewers – those who were not assigned your application – in all probability will not have read your proposal before it comes up for evaluation at the review-panel meeting. Regardless, these reviewers have an equal vote in establishing your proposal's priority score. You need to appreciate that they will want to make an informed vote, not a directed one. Therefore, at the meeting, while your assigned reviewers are presenting your proposal to other members of the panel the vast majority of the others will be playing catch up – reading parts of your proposal to determine whether or not they agree with what they are hearing. In other words – and this is what you must understand – they will be doing two things at the same time: listening to your spokespersons – the primary, secondary and tertiary reviewers – while, at the same time, they will be reading parts of your proposal – the title, the *Project Summary/Abstract*, the *Specific Aims* section and the Significance and Innovation subsections of the *Research Strategy* section. If you have ever tried to read and comprehend something that is filled with detail at the same time that someone is talking to you, you know that it is impossible; either comprehension of what you are reading or of what you are hearing suffers. This fact is what informs our approach to writing the *Specific Aims* section.

The *Specific Aims* section must include everything about your application that is important and exciting – *but without a lot of detail*. It must provide a *conceptual* framework on which your assigned reviewers can orally hang the details of what is proposed. Thus, in this section you are 'partnering' with your assigned reviewers at the review-panel meeting. The flow of logic has to be even more compelling than it is elsewhere in the proposal – so compelling that reviewers can follow it at the meeting while someone is talking to them at the same time. Together with the Significance and Innovation subsections, it is one of the most important parts of the application in terms of capturing the affirmative vote of the majority of reviewers.

TIP: The secret to creating a compelling flow of logic in this section is to appropriately link its components, one to another, which requires in-depth understanding of what each component is meant to convey.

Just as each grant mechanism exists for a purpose, and just as each section of the application has a purpose, each component of each section exists for a reason. The reason is to contribute something important to the understanding of what is proposed. To optimize their ability to create a flow of logic, components need to relate to each other in very specific ways, i.e., they need to be linked one to another. Such linkages are best established, in our opinion, by starting this section, not by writing everything out in full, but by creating a bullet outline.

CREATE A BULLET OUTLINE

TIP: Outlining is your key to developing linkage and to avoiding unnecessary detail!

One of the most important tips that we can give you regarding development of this section is to begin by creating a bullet outline. When extra verbiage is removed and you are dealing only with brief bullets you can see better how the various components relate to each other and can recognize and eliminate extraneous detail. Without the interfering clutter of unnecessary words, the outline approach also allows you to see whether or not the logic and the concepts flow, as they must in a competitive application. To help you create your bullet outline, in this chapter we will ask you to make a series of responses in a set order. An interactive template is available on our Website (www.grantcentral.com/downloads.html) in which you can make your responses. Those responses will become the bullets in your outline. Once you are satisfied with the bullets you have written and how they link to each other, we will help you to expand them into sentences that will collectively become the first draft of your *Specific Aims* section. You can then modify, amplify, re-write and otherwise refine your first draft to produce the version that will become the template for writing the rest of your application.

The explanations that follow will give you a strong working knowledge of the purpose of each component, as well as how it must be linked to other components. When you create your bullets we recommend that you do so in four, distinct paragraphs. The first three are meant to gradually ratchet up detail the deeper into the section the reviewer reads, while the last is included to tell reviewers what they will get for their investment if they decide to invest in your proposal.

Introductory Paragraph

Opening Sentence. Begin with an interest-grabbing sentence that immediately establishes the relevance of your proposal to human health. You want to convey that, by supporting your proposal, the reviewers will be helping NIH accomplish its goals, which are to improve the control of disease, enhance human health, and advance understanding of biological systems. For example, were you writing an application about a biochemical defect you suspect is the cause of manic-depressive illness, what you write here should not focus on fundamental biochemistry. Instead, you should create one that makes clear how important manic depression is in this country, both from the standpoint of numbers of people affected and the cost of caring for such persons. Be careful not to open with something that the audience you are targeting would obviously know. Now, write a bullet that conveys the medical importance of your area of interest.

Current Knowledge. This component has two purposes. The first of these is to help the less expert members of the review panel get up to speed with respect to what is currently known about the topic of your proposal. A few cleverly written sentences are needed that bring reviewers from the most important, older knowledge to the edge of the field as it exists today. Only key citations should be provided using the reviewer-friendly 'author/year' approach that is described in chapter 11, i.e., not numerals. The current-knowledge component has the additional purpose of setting up presentation of the gap in the knowledge base or unmet need that your application will address. Write bullets that flow logically, one into the next, in such a way that they will lead the reviewer to the 'jumping-off point' for your application, i.e., what needs to be done next.

Gap in the Knowledge Base / Unmet Need. This component is one of the most important in creating the Specific Aims section, because *all of the logic downstream flows from it*. It should be simple and direct. It should very specifically identify either the gap in the knowledge base or the need that will drive your application. Furthermore, it must link back to the 'current knowledge' component as the next logical step that is required to advance the field.

Gap in the Knowledge Base to be Addressed: Now that your reviewers have an appreciation for what is known, you need to introduce them to what is missing and, therefore, holding back the field. The gap in the knowledge base that you highlight should be the one that you will address with this research proposal. Write a bullet that clearly defines the gap that you want to fill.

Statement of Need and Objective Evidence for Its Existence: If you are writing an application that will be driven either purely by need or one that will be a 'hybrid' – a proposal that offers both a statement of need and, later, a central hypothesis – you should write a single bullet that denotes the need. We want to emphasize that, even though most kinds of applications to NIH should not be driven purely by a statement of need, there are some that must be. For example, a proposal to renovate space (a construction grant) would have to be driven by a statement of need for the renovation. An application to purchase a piece of equipment (equipment grant) would, likewise, have to be driven by need for the equipment. If you are going to use a statement of need to drive a research-grant proposal, in most cases you should take the hybrid approach, i.e., provide focus for the application with a subsequent central hypothesis (see below).

Follow the bullet for the statement of need with one or more bullets that provide objective evidence for existence of the need (e.g., your own assessment of need and/or the publications of others that corroborate existence of the need).

At the conclusion of the first paragraph, the reviewers should understand that the research area is medically relevant, they should be up to speed with respect to current knowledge in the field, and they should understand that there is a gap in the knowledge base that constitutes an important problem.

'What, Why, Who' Paragraph

The first three components in this paragraph must create a focusing progression that takes the reviewer from the broadest to the narrowest focus that is relevant to this application.

Long-Term Goal. The purpose of this component is to project the continuum of research that you will pursue over the course of multiple periods of grant support. In other words, this component should tell reviewers what the 'big picture' of your research program is. It must be relevant to public health, i.e., to NIH's mission and must be broad enough to encompass the gap or unmet need that you delineated in the first paragraph. It should reflect the niche area that you intend to systematically develop as your own – the area in which you will become the acknowledged expert, if you are not that person already. Also, it must be realistic, i.e., something that is clearly achievable over a finite period of time. For example, if you were a cancer researcher, it would *not* be credible to write that your long-term goal is to cure cancer. Now, write a single bullet that denotes what your long-term goal is.

Objective of this Application. This component defines the purpose of your grant application, i.e., what it seeks to accomplish, *which must be either to fill the gap or meet the need that you delineated in the first paragraph*. Thus, this component must link back to the gap/need. It also must link to your long-term goal as the next logical step along the continuum of research that was projected by that component. Be certain that your objective emphasizes the product of the research, not the process that produced it. For example, "to study" something would not be an appropriate goal; what you want is what the study will produce. In addition, "to study" is temporally indeterminate; how would you know when you had studied enough? Write a single bullet that projects your objective for this application.

Central Hypothesis and How Formulated.

The central hypothesis must link to the objective, because the objective will be accomplished by objectively testing the central hypothesis. The purpose of the hypothesis is to provide focus for your research project and, therefore, your grant application. Thus, your hypothesis must be 'directional,' i.e., it is what gives direction – focus – to the research. In other words, it must be your 'best bet' as to how to attain the objective, which must be to either fill the gap or meet the need (the latter for a 'hybrid' application). A good hypothesis must be objectively testable and cannot project a predetermined conclusion. And, very importantly, it should be crafted to have readily identifiable 'parts' that set up the specific aims, which will test those parts. Now, write a single bullet that conveys what your central hypothesis is.

How formulated. Write additional bullets that tell your reviewers how the central hypothesis was formulated – how you focused on this starting point from among all others as your 'best bet.' Your own preliminary data are the most important basis for formulating the hypothesis. That bullet should be first, therefore. Published work of others, if any, that guided formulation should be highlighted in additional bullets.

Rationale. The purpose of this component is to convey to reviewers why you want to undertake the proposed research. In most cases, you want to because doing so will yield new knowledge that will advance the field. Thus, *your rationale should tell reviewers what will become possible after the research is completed that is not possible now*. It must pass that litmus test! The gap / unmet need delineated in the first paragraph represents a problem because its continued existence blocks the next step in the field from being taken. Once the proposed research has been completed you will be able to take the blocked step – that is why you want to do the research. You get few opportunities in a grant application to excite reviewers. This is one of them. Cleverly written, the rationale – why you want to do the research – can truly be exciting because it conveys that the expected outcomes will clearly advance the field vertically. Now, write a bullet that delivers that message.

At the conclusion of the second paragraph, the reviewers should understand: 1) what the continuum of research is that you are following; 2) what the next step along that continuum is; 3) why you want to take that next step; and 4) what your 'best bet' is regarding how to take that next step.

Specific Aims 'Paragraph'

As the name implies, this component conveys specifics about the research. The approach to creating the aims differs for hypothesis- and need-driven proposals.

Hypothesis-Driven Applications. Although there are disciplinary exceptions, as noted above, *most reviewers of NIH grant proposals demand hypothesis-driven research.* The aims are probably the most difficult components of the section to write. They must clearly grow out of your central hypothesis because their purpose is to objectively test its parts. Thus, with respect to linkage, there must be complete concordance between the aims and the parts of your central hypothesis. The aims need to be brief, informative, attention-getting 'headlines' that will attract a reviewer's attention and whet his/her interest. Each aim should convey why that part of the research is being proposed, not what will be done. Under no circumstance in a hypothesis-driven application should your aims be descriptive, i.e., project what is best referred to as 'look-to-see' research (I will do something, look to see what happens, and then describe whatever that outcome is – the antithesis of hypothesis-driven research.). For this reason you should avoid using words in your aims that connote a descriptive approach, such as (but not limited to) compare, correlate, describe, catalog, or investigate. Neither should they be statements regarding 'what' will be done, i.e., the process that will be involved should not be emphasized. What you want them to project is 'why' — conceptually, why is this part of the research necessary? They should deliberately be broad and open-ended, but then focused by a working hypothesis.

The aim must be written globally to ensure that it encompasses any alternative to which you might have to turn in the unlikely event that the primary hypothesis tests invalid. 'Identify the mechanism that is responsible for macrophage activation.' is an example of an aim that is written at a broad, open-ended level. If the purpose of the aim is to "identify the mechanism," then the working hypothesis must be the 'best bet' as to what the mechanism is. It might read something like, 'The *working hypothesis* for this aim is that the mechanism entails binding of IFN- γ to its receptor, which activates STAT-1 α and then, in concert with other transcription factors, up-regulates the expression of genes that result in activation. It is based on preliminary data that will be presented later (see Preliminary Studies under Aim #1, *Research Strategy-Approach*).' By narrowing the focus to a specific entity with the working hypothesis, the applicant avoids criticism that the aim is unfocused and open-ended. Later in the application, under Potential Problems and Alternative Strategies (*Research Strategy-Approach*), the fall-back position – a viable alternative to which the applicant would turn in the event of hypothesis invalidity – will be offered. That assures the reviewers that, regardless of how the primary hypothesis tests, the applicant will still land on his/her feet and attain the application's overall objective. The trap of writing an aim like, 'Determine whether STAT-1 α initiates macrophage activation.' is avoided. With such an aim, if it is STAT-1 α , there's no problem. However, if it's not – and the aim really should be interpreted to read 'Determine whether or not STAT-1 α initiates macrophage activation.', the applicant (and the reviewer) is left with nothing other than a negative outcome, which is rarely enough to satisfy NIH reviewers.

The example below will illustrate further how to avoid the trap of writing descriptive aims. It should clarify why well written aims in hypothesis-driven proposals are most often an answer to the question, "Why am I proposing this part of the research."

**CONVERSION OF DESCRIPTIVE SPECIFIC AIMS ('WHAT' WILL BE DONE) TO ONES
THAT ARE CONCEPTUAL ('WHY' THE WORK IS PROPOSED)**

- 1. *Determine the genotypic allele frequencies of the AAA and BBB genes in a closed, unselected, drug-naïve population.***
- 2. *Determine the genotypic allele frequencies of the AAA and BBB genes in a population that has been highly selected by frequent long-term drug treatment.***
- 3. *Select for alleles that convey resistance by comparing gene expression in the naïve population with the frequently treated population.***

Note that each of the above is a detailed description of 'what' will be done. The first two set up different populations – untreated and treated. The third aim seeks to determine what the difference is by comparing the two populations. Were we to ask the investigator why s/he wants to make the comparison, s/he would respond without hesitation, 'To identify the alleles that most likely cause resistance.' Thus, all three of the aims, above, could better be combined into a single, 'why' aim, such as:

- 1. *Identify candidate resistance alleles.***

That aim, if left uncomplemented, would be criticized as unfocused and open ended. Thus, a working hypothesis is required to bring focus – your 'best bet,' based on preliminary studies to date, as to what the resistance alleles are most likely to be. This is one reason why preliminary studies are so important at the R01 level: the data generated allow formulation of a focusing hypothesis for each aim. It isn't necessary that the research proposed be already completed, as some would contend. However, enough has to have been done to allow the applicant to formulate a strong working hypothesis that provides direction – focus – for the proposed studies. The research design presented later would be structured to test that working hypothesis and would offer an alternative to which the applicant would turn in the unlikely event that the working hypothesis tests invalid. We want to re-emphasize again here that the combination of the broad aim, focused by a working hypothesis, which is then complemented later by an 'escape-hatch' alternative, is a powerful way of assuring reviewers that, regardless of how the original working hypothesis tests, the objective of the aim will be attained.

The aims you present must test all of the parts of your central hypothesis, nothing more and nothing less. Ideally, the reviewer should be able to see easily that each aim links to a specific part of your central hypothesis. If an aim isn't clearly related to testing some aspect of the central hypothesis, it is likely to be rejected by reviewers as superfluous.

No more than three-to-four aims should be offered; the page limitation on the *Research Strategy* section precludes developing any more aims than four substantively. Each aim should be of

approximately equal weight, i.e., equal in importance to the other aims and projects a similar amount of work. The first aim must flow logically into the second, and so on; *however, none of them can be absolutely dependent on an expected outcome of an earlier aim.* Why? Because, should the critical aim either not be achieved or yield an unexpected outcome the subsequent, dependent aim(s) could not be pursued as proposed. For example, consider an application on gene regulation that has as its first specific aim, 'Clone the promoter [regulator] for gene X.' Examination of the subsequent aims reveals that all of them are dependent on availability of the promoter. Such an application would be fundamentally and fatally flawed because, if the promoter couldn't be cloned, the rest of the work couldn't be done. The applicant should have realized that fact and cloned the promoter as part of his/her preliminary studies. Alternatively, an R21 could have been written to accomplish that part of the study, which would remove the risk that the promoter couldn't be cloned. In other words, it would be a stepping stone to a later R01 that would support the aims that are dependent on having the cloned promoter.

Using these tips, write bullets that summarize your aims. Follow each with another bullet that projects the working hypothesis for that aim. Make sure that the number of aims is concordant with the number of parts that are found in your central hypothesis.

Need-Driven Applications. The aims in a pure need-driven application are 180° different, compared to those in a hypothesis-driven proposal. In other words, they will be – and it is OK for them to be – descriptive. The aims here are the tasks that must be undertaken, in the order that they must be undertaken, to attain the objective. Thus, in contrast to a hypothesis-driven application, it is acceptable in a need-driven proposal for the aims to describe what will be done. The paragraph that is subordinate to a need-driven aim should summarize the approach that will be used to accomplish that particular task.

'Payoff' Paragraph

TIP: The purpose of this last paragraph is to inform reviewers what they can expect for a return if they vote to recommend funding of your application. This paragraph is particularly important in helping to develop advocacy for your proposal among the majority of reviewers who will not, in all likelihood, have read your complete application. It is a paragraph in which a great deal of effort should be invested, therefore.

Expected Outcomes. These are the expected products of the research. In other words, these represent the 'payoff' that reviewers can expect to realize if they vote to recommend funding of your application. We want you to include them here, together, rather than individually under the related aims, because reviewers can more easily see that the outcomes collectively attain the overall objective of the proposal. There should be at least one important expected outcome for each of your aims. There must be clear linkage back to the specific aims that produced them.

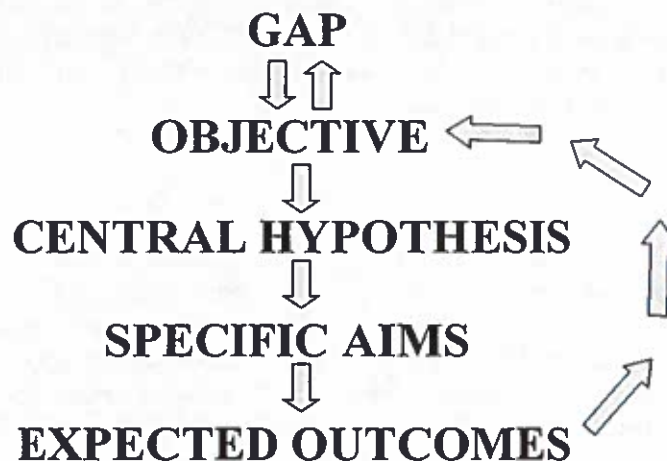
Now, write bullets that tell your reviewers what they can expect from your research as outcomes. As noted earlier, you need at least one important outcome for each aim.

Generality Regarding Positive Impact. This final part of the *Specific Aims* section must summarize the general impact of the expected outcomes. We recommend that you deliberately write a bullet that is a generality that segues into details that will be presented in the next, Significance and Innovation subsections of the *Research Strategy* section. In most cases, your

positive-impact bullet should make clear that, collectively, the outcomes will advance your field vertically, as well as contribute to the mission of the NIH Institute/Center that you are targeting.

After completing your bullet outline, print it and consider carefully how all of the elements relate to each other. Do they relate and link to each other logically and well? Remember that we called attention earlier to how important the phrasing of the gap in the knowledge base is, because that statement sets up everything downstream with respect to the flow of logic. As is shown in the figure, below, if you are proposing hypothesis-driven research, how you present the gap automatically sets up the objective, because the objective must be to fill the gap. When you write your objective, you set up your central hypothesis, because that is what must be objectively tested in order to attain the objective. When you write your central hypothesis, it ordains what the aims will be, because they are the means that will be used to test each part of your central hypothesis. The aims, in turn, dictate what the expected outcomes will be, and those, in turn must collectively result in attainment of the objective, thereby filling the gap. If you

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are proposing a project that is driven purely by a statement of need, the only differences in the figure, above, would be that "GAP" would become "NEED" and the CENTRAL HYPOTHESIS would be eliminated. Otherwise, the progression of logic would be the same. Also, make sure that your long-term goal encompasses the gap in the knowledge base that you plan to fill. Check to be sure that the rationale passes the test of telling the reviewer what will become possible after the project is completed that is not possible now. In other words, it should make clear that, once the research has been done, it will be possible to take the vertical step in the field that is now blocked.

Spend as much time as you need to refine and perfect your bullets, making sure that they are as well crafted as they can be. The better that these work in creating the all-important flow of logic, the easier it will be to write this section, which is the subject of the next chapter.

DEVELOPMENTAL STEPS FOR CHAPTER SEVEN:

1. Appreciate that there are two audiences for whom you are writing: the minority audience (primary, secondary and tertiary reviewers) and the majority audience (those reviewers who, in all likelihood, will not have read your application prior to the time that it comes up for consideration at the review-panel meeting).
2. Realize that this section of the application is written for the second, majority audience.
3. Understand the strategy that underlies this section, which is to provide a conceptual framework that will allow your representatives at the meeting (the primary, secondary and tertiary reviewers) to hang details on it, thereby helping reviewers who are relatively ignorant of your application to reach a point where they can cast an informed vote.
4. Understand the purpose of each component that makes up the Specific Aims section and how each must be written to meet its purpose.
5. Appreciate how the components must be linked to one another in order to create a linear progression of logic.
6. Download the interactive template from our website (www.grantcentral.com/downloads.html) that will facilitate development of your bullet outline.
7. Create a bullet outline that includes each of the ten components that comprise the *Specific Aims* section.
8. After leaving the outline alone for a day or so, return to it to determine whether it can be improved. Continue to do so until you, as the PI, cannot make it any better.
9. Seek constructive criticism of the bullet outline from the Key Persons and Other Significant Contributors who are on your research team.
10. Continue to work on the outline until each component meets its purpose, each is linked to the others in the way(s) that it should be, and the progression of logic is linear. When you reach that point, you are ready to proceed to chapter 8.



CHAPTER 8

WRITING THE SPECIFIC AIMS SECTION

Instructions for PHS 398 Research Plan Component / *Specific Aims* Section:

"State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology." You are limited to one page.

In the previous chapter, we introduced you to the purpose of each of the ten components of the *Specific Aims* section and showed you how to create a bullet outline using them. In this chapter, we will guide you through the process of expanding your bullets, which is the initial step in formulating the first draft of this section. As can be seen from the instructions in the text box, above, this section is limited to one page. Succinct writing will be required, therefore, if you expect to get everything needed into the allowed space. Only the most important, 'linchpin' references should be cited here. Set up the page using some of the same space-saving approaches that are described in chapter 5 for the one-page Introduction: use either Georgia, Palatino Lino-type Arial or Helvetica at 11 points, auto-hyphenate (do not hyphenate manually), use full justification and single space after each sentence. We recommend that you start with one-inch margins, because that is a more reviewer-friendly approach than using the minimum of 0.5 inch. For the same reason, open a line after each paragraph. If clever editing of the first draft still leaves you over the one-page limit, then and only then, go to 0.5-inch margins. The last thing that you should give up, in our opinion, is the open line after paragraphs. You don't want your application to look like pages from a telephone directory! The formatting for this page should be what is used for the other documents that will collectively constitute your Research Plan.

In terms of writing the Research Plan, we recommend that nothing be left to the interpretation of reviewers. If you allow them to interpret what you have written, they may not make the desired interpretation or – worse – they may make the wrong interpretation. To avoid this problem we recommend that you help reviewers make the connections that you want them to make. The approach we have developed allows you to 'tell' reviewers exactly why information has been included without running the risk of being seen as pedantic or condescending while doing so. The approach entails 'labeling' of the components that make up the section in such a way that there can be no question as to why you have included the information. Labeling of key sentences also helps to lead reviewers through what you have written. (A well-written proposal leads reviewers without them knowing that they are being led.) The approach makes comprehension effortless, because no work is needed to appreciate why material has been included. As you expand your bullets we will recommend where and how to use such 'labels.'

We also recommend that you increase reviewer friendliness by highlighting key words that identify components you know reviewers will need to find in order to review your proposal. We will tell you which words to highlight later in this chapter. *Judicious use of subtle highlighting* – we

recommend italics – is the key; overuse causes such highlighting to lose its effect and can even become an aggravation to reviewers. Of the four allowed typefaces, italicized *single words* or *several words* aren't that noticeable with either Arial (which is the typeface for this *Workbook*) or Helvetica. We recommend, therefore, that you also underline with these typefaces to make *single words* or *several words* stand out, as is illustrated in this sentence. More than several words, i.e., phrases or entire sentences, are sufficiently prominent in italics that you don't have to underline. To do so would be overuse of highlighting – to the point that it would be an aggravating distraction. If you are using Georgia, which is what this typeface is, italicized *single* or *several words* stand out adequately and underlining is not needed. The same is true for *Palatino Linotype*, which is what this typeface is. We do not recommend the latter typeface because of the extra room it requires as a result of wider line spacing (evident here) – unless, of course, you change the default setting for line spacing.

EXPANSION OF YOUR BULLET OUTLINE INTO SENTENCES

Once you are satisfied with your outline, the next step is to expand it into your first draft of the *Specific Aims* section.

Introductory Paragraph

Opening Sentence. Expand the bullet that you wrote for your opening sentence. Make sure that it reads well and flows easily into the presentation of what is currently known. Make sure that the sentence is arresting and, as such, will immediately attract the reviewer's interest and attention.

Current Knowledge. Working from the bullets that reflect current knowledge, write two-to-four complete sentences that convey what is known about your subject area. The first sentence should be labeled to signal this component's purpose. For example, "It is well known that ..." or "It has long been appreciated that ..." The series of two-to-four sentences should narrow reviewers' focus from the most important older current knowledge to the edge of the field as it exists today. Cite only the most important references in doing so.

Gap in the Knowledge Base/Unmet Need. Next, expand the bullet that you wrote to delineate the gap in the knowledge base or the unmet need that will drive the application. Label this sentence by beginning with something like, 'What is not known is ...' or 'Thus there is an *urgent [or critical] need* for ...' Note that "*urgent need*" is highlighted in italics. If you are offering a statement of need, next, expand the bullets that provide objective evidence for existence of the need. If publications of other investigators are used to support existence of the need, cite that work.

What, Why, Who Paragraph

TIP: The first 3 components in this paragraph create a focusing progression, which the reviewer must perceive. To help ensure that s/he makes that connection, the long-term goal, objective and central hypothesis should be presented without interposed explanatory information. These three components should be juxtaposed, so that there is a seamless flow of logic from the broadest (the long-term goal) to the narrowest focus (the central hypothesis).

Long-Term Goal. Expand the bullet for your long-term research goal. It should clearly encompass the gap or unmet need that was delineated in the first paragraph. Do so by completing the following: 'Our [My] long-term goal is to' Note that the words 'long-term goal' have been italicized and underlined to make them easier for reviewers to find. Note, also, that there is a hyphen between "long" and "term." It is required because those two words created a compound adjective that modifies "goal."

Overall Objective. Now, expand the bullet you wrote for the overall objective into a single sentence that conveys what you want to produce with this research project. Make sure that what you write here links back to the gap in the knowledge base or unmet need that you presented in the first paragraph; the objective of any grant application must be to either fill that gap or meet that need. Label this sentence by beginning it with something like, 'The overall objective of this application, which is the next step toward attainment of our long-term goal, is to' Note use of the phrase, "which is the next step toward attainment of our long-term goal." Including something like it assures that reviewers will recognize that this application represents the next step along the continuum of research that is projected by your long-term goal. The words "long-term goal" should not be underlined and italicized when they are used the second time. When you have completed this sentence, make certain that it links back to the gap/unmet need component and that it relates clearly to your long-term goal.

Central Hypothesis and How Formulated. This component will not be included if your proposal is purely need driven. It will be included if you are writing either a hypothesis-driven application or a 'hybrid' – one that is driven both by a statement of need and by a central hypothesis. The expanded bullet should convey your 'best bet' as to how the objective can be attained. Ideally, it should have readily identifiable parts that will be used to set up the aims. Make sure that you label this component so that it can be found easily by reviewers. For example, 'Our central hypothesis is that' Be certain that what you have proposed is objectively testable.

Now, expand the bullet(s) that you wrote to describe how your hypothesis was formulated, i.e., why it has been chosen as your 'best bet.' If the work of others is used in addition to your own preliminary data to support formulation of your central hypothesis, the relevant publications should be cited.

Rationale. Next, expand the bullet that summarizes your rationale. 'Label' this component so that it is readily recognizable, e.g., 'The rationale that underlies the proposed research is that ...' Remember that the litmus test is to ask yourself, 'Does this tell the reviewer what will become possible after I have completed the research that is not possible now?' It should convey that you will be able to take the next vertical step in the field that is currently blocked by existence of the gap/need.

Specific Aims 'Paragraph'

Begin paragraph three with a sentence something like, 'We plan to objectively test our central hypothesis and, thereby, attain the objective of this application by pursuing the following specific aims:' Next, expand the bullets for your specific aims and the working hypothesis for each. After doing so, make certain that each clearly links back to a part of your central hypothesis. If you find that doesn't link back, either eliminate it or create a part in the hypothesis that will support its inclusion.

Because the aims are so important, we recommend that you set each off as a separate 'headline,' and that it and its subordinate paragraph be indented one tab. For the same reason, we

recommend that you present them in bolded italics. Nothing in the subordinate paragraphs should be bolded or otherwise highlighted, except for '*working hypothesis*.'

Payoff Paragraph

Expected Outcomes. Continue by expanding the bullets that present your expected outcomes. Label the opening sentence with something like, 'It is anticipated that these aims will yield the following *expected outcomes*. First, _____, Second, _____.' Continue to develop this component using the same approach for each expected outcome.

Generality Regarding Positive Impact. Conclude the fourth paragraph and your *Specific Aims* section by expanding the bullet that you wrote to generalize about positive impact. Make sure that what you write sets up an easy transition into the next section, *Research Strategy*, which will begin with the Significance and Innovation subsections. In those two subsections, you will provide specific detail that validates the general statement about positive impact that you write here. This sentence should also be used to segue into the next section. To accomplish these things, we recommend that you begin and end the sentence with something like, 'These outcomes are expected to have an important *positive impact* because, as will now be detailed in the next, Significance subsection.'

FINALIZING YOUR SPECIFIC AIMS SECTION

As the next step, revise and refine the sentences that you have written until they flow well. Add material, if needed, to link the sentences appropriately and blend them into readable prose. Edit until you have no more than a single page. Convert to a PDF file for upload into the PHS 398 Research Plan form at the site indicated, below.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment
Human Subjects Sections				
5. Protection of Human Subjects		Add Attachment	Delete Attachment	View Attachment
6. Inclusion of Women and Minorities		Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Children		Add Attachment	Delete Attachment	View Attachment
Other Research Plan Sections				

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EXAMPLE OF A HYPOTHESIS-DRIVEN *SPECIFIC AIMS* SECTION

Modulation of a part of the interferon gamma (IFN- γ)-receptor complex on cell surfaces has the potential to deliver both preventive and therapeutic value. This assertion is based on the fact that IFN- γ is central to the maintenance of homeostasis, as well as to host defense against a variety of pathogenic microorganisms and tumor cells. It is also known that IFN- γ has an active role in the pathogenesis of a number of diseases. IFN- γ mediates all of these effects through a single binding protein (the α subunit of the IFN- γ -receptor complex), which is present on the surfaces of all nucleated cell types (Granger & Coe, 1994). While it is known that the binding protein initiates signal transduction (Yu, 2000), and it is understood mechanistically how it does so (Griffin *et al.*, 2004; Campbell, 2008), what is not known is how production of this critically important protein is regulated transcriptionally. Lack of such knowledge is an important problem, because, without it, the likelihood that the protein's presence on cell surfaces can be modulated pharmacologically is remote.

Our long-term goal is to harness the medical benefits that are offered by the IFN- γ -receptor complex. Our overall objective here, which is the next step in pursuit of that goal, is to determine how production of the receptor's alpha subunit is regulated transcriptionally. Our central hypothesis is that both constitutive and stimulated transcriptional regulation are required, involving different sets of *cis*-acting response elements in the gene's promoter. Our hypothesis has been formulated on the basis of our own preliminary data (see Approach subsection of Research Strategy), which were acquired using the promoter that we recently cloned (Galaway *et al.*, 2008). The work of Adams & Seagram (2008) is additionally supportive of the hypothesis. The rationale for the proposed research is that, once it is known how transcription of the alpha chain's gene is regulated, production of the subunit can likely be manipulated either up or down pharmacologically, resulting in new and innovative approaches to the prevention and treatment of a variety of diseases.

We plan to test our central hypothesis and, thereby, accomplish our overall objective for this project by pursuing the following two specific aims:

1. **Identify the DNA response elements that regulate constitutive transcription of the alpha subunit's gene.**

Based on the preliminary data referred to above, our working hypothesis is that one or more Sp1 sites are critical to the regulation of constitutive transcription.

2. **Determine how stimulated transcription of the subunit is up-regulated by different stimuli.**

We postulate, again on the basis of our preliminary data, that cyclic AMP response elements (e.g., CRE and AP-2) regulate stimulated transcription of the subunit's gene, regardless of how stimulated transcription is activated.

With respect to outcomes, the work proposed is expected to identify the full complement of response elements and the cognate transcription factors that regulate constitutive and stimulated transcription of the alpha subunit's gene. Such results are expected to fundamentally advance the fields of receptor biology and immunotherapy by further defining how receptor subunits are produced. Equally important, the results are expected to have positive translational impact because the identified regulatory components will likely provide new targets for preventive and therapeutic interventions, as will now be detailed in the next, Significance subsection.

The 'hybrid approach would be similar, except that the first paragraph would contain a statement of need and a summary of objective evidence in support of its existence. The central hypothesis would be the applicant's best bet as to how to meet the need. Research proposals dri-

ven purely by need rarely succeed at NIH, which is why we do not recommend them for that purpose. Need-driven proposals to NIH are usually for things like equipment.

DEVELOPMENTAL STEPS FOR CHAPTER EIGHT:

1. Set up the page for the *Specific Aims* section to maximize space, with two exceptions: (i) open a line after each paragraph and use 1-inch margins, left and right, if at all possible.
2. Expand the bullets for your *Specific Aims* section into complete sentences.
3. 'Label' them in such a way that reviewers will know precisely why the related information has been included.
4. Cite only key, 'linchpin' references in this section.
5. Highlight key words using either underlined italics (Arial or Helvetica typefaces) or italics alone (Georgia and Palatino Linotype).
6. Unless you change the default line spacing, avoid the use of Palatino Linotype because of the extra space it requires.
7. Present the ten components that make up the *Specific Aims* section in four separate paragraphs.
8. Make your specific aims and the related subordinate paragraphs stand out by indenting them 1 tab and presenting the aims, themselves, in bolded italics.
9. Edit and refine the section until it reads well and occupies no more than 1 page.
10. Convert the *Specific Aims* section into a PDF file.
11. Upload the *Specific Aims* section into the *PHS 398 Research Plan* form.

CHAPTER 9

SIGNIFICANCE AND INNOVATION SUBSECTIONS OF THE RESEARCH STRATEGY SECTION

GENERAL CONSIDERATIONS

TIP: Your commitment to these two subsections should be commensurate with the importance that they have to the review of your grant proposal.

The relative importance of these two subsections cannot be overemphasized. They will be read by most, if not all, of the reviewers at the review-panel meeting – even those who haven't read your proposal before it comes up for review. Their importance is signaled, in part, by the fact that they are the first subsections in the *Research Strategy* section. Another indicator is the fact that they precede the subsection where APPROACH is addressed. Finally, their importance is emphasized by the fact that each has been given its own, distinct subsection. *The latter fact should make evident to you that this is where reviewers will look to find the majority of the information that they need to evaluate these two core criteria.*

In the past, when INNOVATION was not set apart as a separate subsection, reviewers could easily miss the fact that applicants would fail to draw a sharp distinction between innovation and significance. Now that each is addressed in its own subsection, and those subsections are adjacent in the application format, reviewers can easily see and appreciate overlap/redundancy. To avoid this trap, let's begin by generically defining each of these two core review criteria:

SIGNIFICANCE: the [positive] impact something is likely to have on some other thing

INNOVATION: a new and substantively different way of considering/addressing something, which opens new horizons

If those two definitions are kept in mind, and each is used in concert with its purpose in the application (see text box, below), it should be relatively easy to make the two subsections distinctly different, one from the other.

TIP: The purpose of the Significance and Innovation subsections is to help justify the need for what will be proposed. The 'spin' that you put on them should be consistent with that purpose.

The most efficient approach to writing these sections is the one that you used to develop the *Specific Aims* section. First, prepare a bullet outline. Then, expand the bullets into sentences, after which the first draft of the subsection can be created by integrating and linking the sentences appropriately. Edit to refine what you have written. Make sure that the length of each does not exceed 0.5 to 0.75 page. Ideally, both subsections should be on the same page.

SIGNIFICANCE SUBSECTION

An important part of our proposal-writing strategy is to gradually ratchet up detail as the reviewer reads farther into the application. The idea is to get the reader 'hooked' on the conceptual, exciting parts of the proposal to the extent that s/he will want to read the details that are presented later. The Significance subsection is where you begin to increase the level of detail that is included. It is meant to provide specifics and citations that will extend and validate what was written in the *Specific Aims* section. It should be brief. We recommend 0.5-to-0.75 page.

Application Guide's characterization of the SIGNIFICANCE core-review criterion:

"Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how scientific knowledge, technical capability and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?"

Not surprisingly, the *Application Guide's* characterization of the SIGNIFICANCE core-review criterion is virtually identical to its stipulation of what the Significance subsection should contain.

Application Guide's instructions for the Significance subsection:

"Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved."

Given the above information from the *Application Guide*, let's re-visit and revise the general definition of significance on the previous page to be pertinent to NIH:

SIGNIFICANCE: the positive impact that solving an important, NIH-relevant problem will have on some other thing or things that are relevant to NIH and its mission.

To help the reviewer grasp such significance, we recommend that you write this part of your proposal to have three readily identifiable parts:

Part 1 should provide a critical analysis of literature that expands on what was briefly asserted at the beginning of the *Specific Aims* section. Detail existence of the gap/need. Clearly frame why its continued existence represents an important problem that must be resolved. *In other words, this is where you review primary literature that substantiates and validates that there is an important problem.* Conclude this first part of the subsection with a sentence that explicitly describes the contribution that you expect to make. The statement of your expected contribution must link well to what precedes it as the solution to the problem that you have delineated. Without being redundant, the contribution sentence must also link back to the objective in the *Specific Aims* section: your contribution must be attainment of the objective. We recommend that the 'contribution' sentence be 'labeled' with an opening phrase something like, 'The contribution of the proposed research is expected to be'. Complete that sentence by being as specific as possible.

Part 2 is the statement of significance. It should appear approximately in the middle of the subsection and should be a simple, direct statement regarding why the expected contribution is important – why it is significant. In other words, this is the sentence that should reflect the definition given earlier: What is the positive impact that your contribution will have? *This sentence is arguably the most important one that you will write in the application.* Such importance derives from the great weight that SIGNIFICANCE has as a core-review criterion. The preceding point should make clear to you why it is necessary to do the hard work up front that will generate an idea which will advance your field vertically when acted upon.

Because of its importance, we recommend that the statement of significance be written entirely in italics. Even if you are using Arial or Helvetica as your typeface, italics alone for an entire sentence will be prominent enough and, at the same time, unobtrusive. That would not be the case if you were to also underline. We also recommend that you clearly 'label' it and link it back to the just-described contribution: *'This contribution will be significant because'* The resultant sentence should be the kind that, figuratively speaking, knocks the reviewers right out of their chairs. It must be specific and substantive, i.e., neither a cliché nor an empty generality. In almost all cases, the effect that your research results will have should be projected as a vertical step in the field.

Part 3 Remember from the definition that significance requires that there be a positive impact on some other thing(s). Thus, in the context of your application, significance derives from tangible benefits that could credibly be expected to accrue to the contribution you expect to make. *The third part of the subsection should be a discussion of such benefits.* They are what validate your assertion of significance. Vertical advancement of the field will, of course, be a benefit. That point should be made relevant to NIH's mission. How will your contribution inform subsequent thinking and research? If applicable, call attention to decreased morbidity/mortality, improvements in the quality of life and/or medical outcomes, reduction in the cost of medical care, etc. Such claims should be discussed, i.e., not just listed, and be supported by relevant references, if there are any. You don't have to be the direct contributor of the benefits. If it is credible to project that others will build on what you expect to produce, e.g., through an enabling of their research, you are justified to claim such positive impact. Any 'fringe benefits' that might accrue to the research should also be claimed. By fringe benefits, we mean outcomes that would be beneficial when extrapolated to other venues and/or fields, e.g., animal health.

INNOVATION SUBSECTION

In our opinion, INNOVATION is the least understood of the five core-review criteria - by both applicants and reviewers. Therefore, let's reconsider the general definition of innovation in light of NIH's instructions, which are:

Application Guide's characterization of the INNOVATION core-review criterion: "Does the application challenge and seek to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?"

Application Guide's instructions for the Innovation subsection: Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

When viewed in the context of the preceding two text boxes, it can be seen that there are many bases for a claim to innovation, all of which represent new and substantively different ways of addressing an important, NIH-relevant problem. Thus, in our opinion, NIH is seeking your description here of why your project represents a substantive departure from the status quo that opens new horizons that advance a field that is relevant to NIH's mission. Accordingly, the generic definition of innovation given on the first page of this chapter needs to be modified:

INNOVATION: a new and substantive departure from the status quo that addresses an important public-health problem, thereby enabling new, NIH-pertinent horizons that otherwise would likely have remained unattainable.

Given that definition, when thinking about writing this subsection, the two essentials that have to be part of what you write are: (i) departure from the status quo, and (ii) attainment of new, NIH-relevant horizons.

While it is conceivable that a project which is inherently not innovative is fundable – for example, a foundation-laying project that is necessary to reach a later, innovative level – it would be risky, in our opinion, to make that argument in this subsection. *To have the greatest chance for funding, you need to be able to argue here that your project is truly innovative.*

Again here, we recommend that you use a three-part approach to writing this subsection. It should be written to educate reviewers regarding what constitutes innovation while, at the same time, you inform them as to why what you are proposing meets that definition.

Part 1 should use citations of the literature to *diplomatically* frame the status quo. Some of your reviewers may not be able to appreciate why what you are proposing represents a substantive departure until they first have a clear idea of what the status quo is. In other words, you need to *diplomatically* convey why the area you are presenting has been unable to advance. To do so, we recommend that you begin the first sentence of this subsection with the phrase, 'The status quo as it pertains to is' By doing that you assure that the reviewer connects with the fact that you are framing the status quo. So, for example, if you plan to assert that innovation is attributable to a new approach that you will take, you need to *diplomatically* discuss, supported by pertinent references, why previous approaches have been unsatisfactory. Or, if you plan to propose that innovation stems from your alternative interpretation of past work, which has resulted in you having drawn different conclusions on which the present project will be based, you need to back that up with discussion (and relevant citations) that *diplomatically* calls attention to the shortcomings of the earlier interpretations. You would go on to *diplomatically* discuss how those shortcomings have prevented advancement or, less likely, caused misdirection, of the field. Why have we highlighted *diplomatically* in italics throughout this paragraph? Because one or more of your application's reviewers may be 'owners' of the status quo. You shouldn't impugn their prior work by the way that you discuss it.

Part 2 should be a fully italicized statement regarding why your project is innovative, i.e., how it represents a substantive departure from the status quo. It should begin with the phrase, '*The proposed research is innovative, in our opinion, because it represents a substantive departure from the status quo by*' You should include "in our opinion" because you do not want to be perceived as projecting your own subjective opinion onto the reviewers. Complete the sentence by stating what sets your project apart - what makes it different. Most of the time it will be due to a different approach that you are taking or different technology that you have created, compared to past investigators. Whatever it is, remember that it must open new horizons of some kind, which is what will be discussed in part 3 of this subsection. Remember, also, that preliminary data which support of your claim to innovation are essential and should be referred to in part 3 (see example at the end of this chapter).

Part 3 Your job here is to describe how what you are proposing will break down barriers that have prevented others from reaching the new horizons that you envision. Many applicants don't do that; they confuse the new horizons here with the tangible benefits that validate significance. That kind of confusion causes redundancy/overlap between the two subsections that can negatively impact the evaluation of one or both of them. The positive impacts under Significance stem from concrete benefits that are relevant to NIH's mission, such as decreased morbidity/mortality or reduced health-care costs. The new horizons that are linked to innovation are new areas (of research, clinical care, etc.) that probably would have remained unattainable without the innovation you propose. To help you draw that distinction clearly, we recommend that you specifically use "new horizons" in what you write.

Examples of the two subsections are provided at the end of this chapter to further illustrate what the difference is.

DEVELOPMENTAL STEPS FOR CHAPTER NINE:

1. Appreciate that these two subsections are where reviewers obtain most of the information they need to evaluate your application with respect to the SIGNIFICANCE and INNOVATION core-review criteria.
2. Understand that the purpose of each of these subsections is to help justify the need for what you propose in your application.
3. Clearly understand the definition of "significance" and of "innovation."
4. Use a three-part approach to writing each of these subsections.
5. Include a fully italicized, 'labeled' sentence in each subsection that clearly and directly addresses the related core-review criterion.
6. Understand that Significance is attributable to tangible benefits that produce positive impact, while Innovation must open new, NIH-relevant horizons that, in all likelihood, would otherwise have remained unattainable.
7. Make sure that the length of each subsection is no greater than 0.75 page. Ideally, both subsections should be on the same page.

EXAMPLE OF A SIGNIFICANCE SUBSECTION

The alpha subunit of the IFN- γ receptor complex binds this important cytokine to cells (Yang, 1977) and is the initiator of transmembrane signaling (Telifer and Gomez, 1988; Homer et al., 1995). Through it, IFN- γ exerts a wide range of immunologic effects. For example, serious infectious disease problems are experienced by those who become deficient in the cells that produce this cytokine, either because they are lost due to disease (e.g., AIDS; Galbreath, 2002; Toliver, 2003), during chemotherapy (Aikens and Osada, 2000), or as a natural consequence of aging (James and Kary, 1997; Zeleny et al., 2004). In addition to its homeostatic and defensive roles, IFN- γ appears to have a pathogenetic role, either because there is an overabundance of the cytokine (Alcott and Cochrane, 1998; Jones et al., 2000) or because cells become hyper-reactive to normal, physiologic concentrations (Sandoval, 1999). Responsiveness to IFN- γ is related to the number of its receptors that are on a cell's surface (Carlson et al., 2003). This suggests that the effects of IFN- γ could be modulated by altering the number of receptors that are available to bind it. How to effect such modulation is not known. Our contribution here is expected to be detailed understanding of how production of the alpha subunit – the one that binds IFN- γ and initiates transmembrane signaling – is regulated transcriptionally. *This contribution will be significant because it is expected to have broad translational importance in the prevention and treatment of a wide range of diseases.* For example, in diseases that are associated with hyper-responsiveness to IFN- γ , cellular responsiveness could be down-regulated by pharmacologically reducing the number of functional receptors that are available to bind the cytokine. Decreasing availability of the alpha subunit, alone, is likely to be sufficient for that purpose. Conversely, when greater responsiveness is needed – for example, to ward off pathogenic microorganisms or, in the case of immunocompromised patients, opportunistic invaders – responsiveness of host-defensive cells to IFN- γ , could be increased. Thus, important advances in the therapy of diseases and complications that are associated with cellular-immune dysfunction could be expected. It is also expected that what is learned will be equally applicable to the prevention/treatment of diseases of agriculturally relevant animals. In addition, the research will be of significance because what is learned will contribute to broader understanding of how other receptor complexes can be modulated as an approach to therapy. Furthermore, better fundamental understanding of how receptor proteins are transcribed can be anticipated.

EXAMPLE OF AN INNOVATION SUBSECTION

The status quo as it pertains to the IFN- γ receptor as a therapeutic target can be summarized as: little or no therapeutic effect. That has been the case despite numerous and quite different approaches that have been taken. The therapeutic potential of the receptor has been appreciated since 1995 (Homer et al.). This led Golum (1998) to experiment with inhibitors of the receptor's transmembrane signaling activities. That approach was only marginally effective because of alternative pathways that bypassed the inhibitors (King and Pomplun, 1999). Furthermore, many unacceptable side effects were experienced (Poulus, 2000). Blockage of the receptor with altered ligand that was incapable of initiating transmembrane signaling was also ineffective (Barnet and Cox, 2000). General inhibitors of protein synthesis were indiscriminate (Bobo and Thom, 2001) and antisense drugs (DNA – Good, 2002; RNA – Benchley and Cox, 2002; and chemical analogues – Kennedy et al., 2003) failed to inhibit receptor synthesis sufficiently to have measurable effects. *The research proposed in this application is innovative, in our opinion, because it represents a new and substantive departure from the status quo by shifting focus to the modulation of transcriptional regulation.* Our preliminary studies (see Approach subsection) strongly suggest that this approach will be effective in down-regulating the receptor's alpha subunit, which is expected to open new research horizons, particularly in drug development. Therapeutic horizons that have previously been unattainable through other means of modulating the number or functional activity of IFN- γ receptors on cell surfaces are also likely to become attainable.

OVERVIEW: PART THREE

DEVELOPMENT OF THE REST OF YOUR APPLICATION

Once you have finalized your *Specific Aims* section and the Significance and Innovation subsections of the *Research Strategy* section you will be ready to develop the remainder of your proposal. Doing so is the subject of the following chapters.

Chapter Ten, "Approach Subsection of *Research Strategy*: Research Design, Expected Outcomes and Potential Problems & Alternative Approaches," addresses development of the narrative part of your proposal. As the title implies, this will be your narrative description of how you will accomplish your proposal's goals.

Chapter Eleven, "Approach Subsection of *Research Strategy*: Review of Literature; Preliminary Studies; Progress Report; *Bibliography & References Cited* section" recommends (1) how literature should be employed throughout the application, (2) how preliminary data should be used to support feasibility of the project; (3) how an effective Progress Report should be written in support of a renewal/revision application; and (4) how to select and present references for the *Bibliography & References Cited* section.

Chapter Twelve, "*Senior/Key Person Profile(s)* Component, Biographical Sketches, and *Multiple PI Leadership Plan*" will allow you to describe your research team in such a way that the feasibility of what is proposed in the Research Plan is maximally supported.

Chapters Thirteen and Fourteen. Chapter 13, "*PHS 398 Modular Budget* Component and Justification," describes how to prepare a modular budget and budget justification for R01, R03, R15, R21 and R34 proposals that have an annual direct-cost budget of \$250,000 or less. If you will be offering a modular budget, ignore chapter 14, "*SF 424 R & R [Breakout] Budget* Component and *Subaward/Consortial Budget*." If you will be offering a breakout budget, skip chapter 13 and substitute the tips and strategies that are included in chapter 14. As its name implies, this chapter guides the preparation of a detailed budget and budget justification.

Chapter Fifteen, "Project/Performance Site Locations, *Facilities & Other Resources* and *Equipment* Sections" covers development of sections that are important in establishing the feasibility of what is proposed and which are the main source of information for evaluation of the core ENVIRONMENT review criterion.

Chapter Sixteen addresses *Human Subjects*, *Vertebrate Animals*, *Select Agent Research*, *Consortium/Contractual Arrangement*, *Resource Sharing Plan(s)*, *Environmental Impact*, *Historical Places* and *Foreign Components* should one or more of these be applicable to your proposal.

Chapter Seventeen offers tips on completing the two cover-page components that are part of an NIH application, the *SF 424 Cover Component* and the *PHS 398 Cover Page Supplement*. In addition, this chapter contains suggestions regarding how to use appendix material to your greatest advantage.

CHAPTER 10

APPROACH SUBSECTION OF RESEARCH STRATEGY: RESEARCH DESIGN, EXPECTED OUTCOMES AND POTENTIAL PROBLEMS & ALTERNATIVE APPROACHES

Application Guide's instructions for the Approach subsection of the Research Strategy section of the PHS 398 Research Plan form: Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan attachment, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, described any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should [be uploaded using field 9 of the *PHS 398 Research Plan form*].

Approach is a subsection of the *Research Strategy* section. Its format is given below:

APPROACH:

Each Aim:

- Introductory Paragraph
- Justification & Feasibility
 - Review of Relevant Literature
 - Preliminary Studies
- Research Design
- Expected Outcomes
- Potential Problems & Alternative Approaches
- Timeline
- Future Directions

In this chapter we will cover how to make reviewers *want* to read the details for each aim (*Introductory Paragraph*), the narrative description of what will be done (*Research Design*), what it will produce (*Expected Outcomes*), problems that might be encountered and, if they are, how they will be avoided/overcome (*Potential Problems & Alternative Strategies*), when the various activities will take place (*Timeline*) and what the outcomes are expected to lead to (*Future Directions*). We recommend that you write the Justification & Feasibility subsection, which is the subject of the next chapter, after you have written Research Design, Expected Outcomes and Potential Problems & Alternative Approaches. We do so because, once you know what will be done, what will be produced, and what problems could be encountered, selecting the literature

and preliminary data that will justify and establish the feasibility of the aim becomes much easier.

GENERAL COMMENTS

NIH changed how grant applications are written and reviewed, in part, to reduce the amount of descriptive detail in them. It is essential for you to understand this as you write the Approach part of your application. However, it is also essential that you don't reduce the amount of detail to the point that reviewers have would difficulty understanding what is being proposed. In other words, you need to strive for a 'Goldilocks balance' - not too much detail and not too little. From a purely practical standpoint, there isn't enough room in the 12-page length of the Research Strategy section to include excessive detail; doing so would force you to short other important emphases, such as the quality of the science and the positive impact that your results will have.

If your specific aims have been balanced appropriately, each should have approximately equal weight with respect to the number of pages that is devoted to it. The total length of the Approach subsection should be 10-11 pages. Therefore, if you have three aims, you should have 3+ pages for each – not much! Thus, you must write very succinctly and include only meaningful detail. What do we mean by that? For example, how many times will something have to be done before you reach statistical significance? How will you assess statistical significance? If you are using subjects, how many will you need – and how was that number derived? Did you just pull it out of thin air or did you use an approach like power analysis to establish the number? What are the controls? None of those examples could be written by copying a methods manual, which is the operational definition of “meaningful” detail.

Before you begin to write, consider the following general points. Development of a strong Approach subsection requires only that you answer the following five questions for each of your aims: 1) What will be done? 2) What are the means that will be used to accomplish the aim? 3) What might go wrong? 4) What alternative approaches would you turn to if something were to go wrong? And finally, 5) what are the expected outcomes and why are they important? If you are a New/Early Stage Investigator, be especially clear that the work is feasible in *your* hands.

As a final general point, we suggest again here that you write this section by scheduling time each day to do so. If you take this approach, and do so consistently, you should have no trouble completing a first-rate Approach subsection over the course of approximately three weeks while, at the same time, you manage all of your other, competing commitments. Providing you have conscientiously developed your Specific Aims section, this part of the application will be one of the easiest for you to write.

APPROACH: DEVELOPING EACH AIM

Your already-formulated specific aims should be the core of your Approach subsection. In other words, it should be subdivided along the lines of your aims. The title of each subdivision should be a verbatim repeat of an aim from your Specific Aims section. Begin by telling reviewers how you intend to accomplish aim #1. We recommend that you do so by first writing bullets, which you then convert to text.

Title of Specific Aim #1 (Verbatim Repeat from Your Specific Aims Section)

Introduction. The first paragraph under each aim should be an introductory one. This is consistent with our general strategy of gradually ratcheting up detail as the reader goes deeper into a section. The bolded, italicized title should be 'Introduction,' indented as shown at the beginning of this paragraph. Continue with text on the same line, as has been done here, with subsequent lines returning to the left margin. The paragraph should be a very brief 'overview' of what will be done and why. It should 'hook' the reviewer's interest in the aim and make him/her want to read the details that follow. Key words (e.g., *objective*, *working hypothesis*, *approach*, *expectations*, etc.) should be highlighted in non-bolded italics to allow reviewers to find these components easily. If you are using Arial or Helvetica as your typeface we recommend that you also underline those words.

Begin this paragraph with a sentence that justifies why the work under this aim needs to be performed. In doing so you should call attention to the part of the overall problem that will be addressed.

Next, write the aim's *objective*. It should be stated in such a way that its attainment will resolve the problem/question that you highlighted with your justification, above. The sentence might be something like, 'The *objective of this aim* is to _____ (solve the problem/answer the question that the aim will address) _____.'

Now, tell the reviewer how you will attain the objective that you have written. You will do so by testing the aim's *working hypothesis*. You followed the statement of this aim in the *Specific Aims* section with a working hypothesis. It should be repeated here, verbatim. It is critical that you repeat the working hypothesis in this introductory paragraph, because you want to underscore for your reviewers that the work to be done will be hypothesis-driven. We suggest that you phrase your working hypothesis something like: 'To attain the objective of this aim, we will test the *working hypothesis* that _____ etc.' [NOTE: If you are writing an aim that is driven by a statement of need, substitute that for the working hypothesis.]

Follow the working hypothesis with a sentence or two about the overall strategy or approach that will be used to test it. For example, 'We will test our working hypothesis by using the *approach of* _____ etc.'

The *rationale* for the work to be proposed under this aim – why you want to undertake this part of the research – should be presented next. The litmus test to be applied here is the same one that you used for testing the overall rationale that you wrote for the *Specific Aims* section: Does what I have written tell the reviewer what will become possible after the research proposed in this aim is completed that is not possible now? Write something like, 'The *rationale* for this aim is that successful completion of the proposed research will contribute a missing, fundamental element to our base of knowledge, without which the metabolism of compound X cannot be understood. The acquisition of such knowledge is critical to the development of improved therapeutic strategies for disease Y.'

Finally, summarize the overall outcome(s) and positive impact of this aim. Stay at a general, not detailed, level. You might write something like, 'When the proposed studies for aim #1 have been completed, it is our *expectation* that the metabolic pathway identified will entail phosphorylation of key amino acids in compound X's cytoplasmic domain. Such a finding would be of importance, because it would allow, for the first time, the development of novel and much-needed approaches to _____.'

When completed, the introductory paragraph should occupy no more than 1/4 to 1/3 of the page. The flow of logic must be clear and compelling – it must 'hook' the reviewer's interest in the details that follow. Now, skip over Justification and Feasibility and begin writing Research Design.

Research Design. Here, you will present and discuss activities or studies that will be undertaken to accomplish the objective of specific aim #1. Each paragraph should be a conceptual unit, i.e., a related group of activities/studies that address a single point. Begin by creating bullets that denote the planned activities/studies. Accompany each with an informative, interest-attracting title – a *headline* – that will be used to introduce the related paragraph in the Research Design subsection. As was the case for the aims themselves, no one of the activities/studies should be absolutely dependent on an expected outcome of an earlier one. Make certain that the range of activities/studies is sufficiently comprehensive that the outcomes will collectively attain the aim's objective. If that isn't clear, then you should revise your thinking about this subsection until it is.

Your next step should be to create bullets under each of the activities/studies that you have listed. Because there is a great range of what might be included, depending on the subject, it is not possible to provide an all-inclusive list here. We underscore again that *you need to provide meaningful* detail, not routine methodological detail. When something in the list, below, is found to be relevant, create a corresponding bullet. Embellish the list with other activities/studies that are relevant to your research.

Write an explanatory title for your first activity/study:

Approach to be used.

Overview of method(s) to be used.

Essential reagents needed.

Critical equipment required.

Numbers of subjects / animals, and how the numbers were derived.

Statistical analysis needed.

Controls (VERY important).

Replicates that will be needed.

Detailed expectations (VERY important).

How results will be interpreted.

Time required to complete the activities/studies.

Next, write the title of your second activity/study:

Consider each of the headings listed above for activity/study #2. Continue this process for other activities/studies that are needed, until you have completed a full outline of those that will be undertaken for Specific Aim #1.

Begin writing the Research Design subsection for Aim #1 by expanding the bullets you have written. As you write, remember that you *must* engender maximal enthusiasm and acceptance of your proposal. Avoid cluttering the reviewer's mind with material that is tangential to the main point that you want to make in each of your paragraphs. Write in simple declarative sentences that are free of jargon and nonstandard abbreviations and acronyms. Whenever it is credible to do so, use strong words, like 'expect,' and 'can.' Avoid weak words like 'hope' and 'try,' i.e., those that unnecessarily plant a seed of doubt in the reviewer's mind about what you are proposing (see chapter 4 for more examples of weak words). Emphasize the conceptual, because that is what is exciting and likely to attract the interest of the reviewer. Make sure, however, that you provide enough experimental detail, e.g., methodological, statistical, and appropriate controls, so that the reviewer will know not only what you plan to do but also how the resultant data will be interpreted.

If you are still unsure about how much methodological detail to include, ask yourself the following three questions: (1) Has anyone on the research team published using this methodology? If so, reference the relevant paper; don't describe the methodology in your application. (2) Does my training make it obvious that I can do this? For example, would a reviewer require a formally trained molecular biologist to detail how RNA is extracted? We think not. (3) Do I have preliminary data that make clear I can use the methodology? This is a very important question, especially if you are a New/Early Stage Investigator. If no one on the team has published with the methodology and it isn't obvious from the team's biographical sketches that one or more should be able to do it, then you need to consider inclusion of preliminary data that will validate that the methodology is feasible in your hands. Those data would be presented under the Justification and Feasibility subsection, which would obviate the need to describe the method under Research Design.

If anything is common to two or more of your aims, whether it is methods, subjects or whatever, refer reviewers in the later aims to where it is first described in the proposal. There isn't enough room under Approach to include a Methods & Procedures section, which was a viable strategy in the past. To do so would also undoubtedly be seen as counter to the level of methodologic detail that is currently being sought by NIH. And never include a Methods and Procedures appendix. Doing so would be a direct violation of instructions regarding appendix material in the *Application Guide* and would likely result in your application being returned without review.

Expected Outcomes. *It is critically important that this subsection be included for each aim.* It is your opportunity to highlight the 'return on investment' that reviewers will be seeking from the aim. Each activity described in the Research Design subsection had an outcome associated with it. This is where you pull all those outcomes together and show the reviewers that they collectively attain the aim's objective. This overview should be more extensive than the summary sentence (or two) that you wrote about expected outcomes in the introductory paragraph for the aim. What you write here can usually be presented in a single, short paragraph – 1/3-to-1/2 page, at most.

To create this paragraph, first collect all of the expected outcomes from the preceding Research Design subsection. While doing so you will see how they relate to each other and how the overall outcome and importance of these findings can be summarized. As an approach, we suggest that you copy / paste all of your detailed expected results into a new file. After making your analysis of this material, write the paragraph to: (1) summarize the expected outcomes, and (2) convey how they collectively achieve the aim's objective. The Expected Outcomes paragraph is another opportunity that you have to create excitement, so make every effort to underscore why the expected results are important. There are at least two reasons why

they are. First, they collectively attain the aim's objective, thereby advancing the field, and, second, they contribute to attainment of the application's overall objective. Be enthusiastic but, at the same time, realistic. Provide appropriate caveats, if they are needed. You must not overstate your expectations to the extent that they (and you) lose credibility.

Potential Problems & Alternative Approaches. Your goal here is to anticipate (and then eliminate) justified concerns of your reviewers. You do so by presenting alternative strategies that will be used to overcome potential problems, should they arise. You know – and the reviewers will know – that there is no such thing as problem-free research. No matter how hard you plan and prepare, problems can and will develop. *Failure to address this fact of life by not including this subsection can seriously undercut the fundability of your proposal.*

If you are doing hypothesis-driven research, first and foremost among potential problems that reviewers will expect you to address is the possibility that the working hypothesis for the aim will prove to be invalid when it is tested objectively. In that unlikely event, what would you do? To what alternative would you turn? As examples of other potential problems, reviewers will also be concerned about critical reagents: Will they be available and will they perform as expected? Will sufficient patients be available, if a clinical research project is being proposed? And will assays be as discriminating as you say they will be?

The problems presented here should *not* be major ones. Major problems should be addressed under the Research Design subsection, not here. Rather, the problems included here should be ones that could arise but probably won't. For example, were you to get into your new car on a warm, sunny morning and find that it won't start, that would be a totally unexpected problem – but it *could* happen. Alternative approaches that would allow you to reach your destination might include calling a taxi, renting a car, calling a friend, bicycling, etc. In other words, you would have no problem whatsoever convincing even the most critical reviewer of the fact that, should such an *unlikely* possibility actually occur, you would overcome the problem and get to your destination. You need to list equivalent kinds of problems and alternative approaches here for your first specific aim. Reviewers need to be assured that, regardless of what might happen, you would still reach your scientific 'destination.' Begin with what you would do, should your working hypothesis for the aim prove to be invalid. Then list other potential problems.

Summarize these potential problems in a paragraph, making certain that you have chosen only the most important and probable problems that might occur. Also make certain that the solutions you have offered are feasible and credible. You should not belabor the problems that you identify. Rather, treat them with the brevity that they deserve. For each problem identified, address 1) the nature of the perceived problem; 2) the reason(s) why you don't think that the problem is likely to arise; and 3) what alternative approach(es) you would employ, should the problem be encountered. Note that all of the alternative strategies should be proposed using conditional verb forms (an action [undertaking the alternative approach] that is dependent on a condition [problems with the original approach]), because they all represent things that would be done only if they were to become necessary. In other words, it wouldn't be 'If this happens, we will' Rather, it should be 'If this happens we would' For example: 'Our working hypothesis for this aim is _____. Although our preliminary data (see *Justification and Feasibility* subsection) solidly support the hypothesis for this aim, and are complemented by recent work published by Strong's group (Strong *et al.*, 2009), there is a remote possibility that it could be invalidated when objectively tested. In that unlikely event, we would turn to _____ as the next most likely explanation. As noted in the presentation of our preliminary data for this aim, some of our data point to this alternative, but the vast majority argues against it. Another potential problem is the way in which we have proposed to determine whether _____ will result in

_____. We expect this approach to work because _____. We acknowledge, however, that this new, rapid and inexpensive technology might not prove sufficiently sensitive to quantify X in up to 5% of the samples. Were this problem to arise, we would employ the labor-intensive, expensive 'gold standard' approach (Dickerson & Boyle, 1999) that is known to have the necessary level of sensitivity. We have used this alternative method successfully in the past (Goldman *et al.*, 2005). Another possible problem that could arise is _____, etc."

This subsection should be no more than 1/3-to-1/2 page long. We cannot emphasize enough the importance of including this topic in your Research Design subsection. Remember, *NIH requires that you address potential problems and alternative strategies* (see text box on page 84). Therefore, reviewers will expect you to do so. If you think that reviewers will be reading your Research Design subsection looking for ways to fund you, you are dead wrong. In these days of fierce competition they will be looking for disqualifying flaws in your proposal - like not acknowledging potential problems/offering alternative(s) that would overcome them, should they occur. Such an omission is often sufficient to knock an otherwise excellent application out of the funding range. By contrast, if you have thought of the same potential problems that reviewers have, and then offer solutions to them, it will leave a very positive impression.

APPROACH: CREATING A TIMELINE

This important section of the Approach subsection is not included by most applicants, in spite of the fact that they are explicitly directed to include it (see text box at the beginning of this chapter). Its inclusion can be extremely helpful to reviewers, and to the NIH. It is important to include

TIMETABLE					
AIMS/TASKS	YEAR 01	YEAR 02	YEAR 03	YEAR 04	YEAR 05
Specific Aim #1	←			→	
Title, Study #1.1	←	→			
Title, Study #1.2		←	→		
Title, Study #1.3			←	→	
Specific Aim #2		←		→	
Title, Study #2.1		←	→		
Title, Etc.			←	→	
Specific Aim #3			←		→
Title, Study #3.1			←	→	
Title, Etc.			←		→

one like that which is depicted here. Note that it applies to the entire Approach subsection. Therefore, its title should have the same 'value' as the titles for the aims (see outline of the format for the Approach subsection at the beginning of this chapter).

A well-conceived timetable can give your reviewers perspective about your project that would otherwise be lacking. It should not be perceived as an afterthought and at the opposite extreme it shouldn't be overly detailed. *This is where you provide the "benchmarks" that reviewers will be looking for* (see text box on page 84). What you want is enough detail to convince reviewers that you have thoroughly thought through how long you expect it will take to complete each component of your project. Enter each year for which you have requested support as column headings and your specific aims/studies as labels for the rows. The duration of each aim (bolded double-headed arrows), and the expected duration of the major studies that will be conducted under each aim (non-bolded double-headed arrows), should be indicated in the timetable. The titles of studies in the left column should be sufficiently explanatory that the reviewer will understand the specific tasks that will be required to accomplish the aim. If it would help make the timetable more understandable, enter the titles of specific tasks over the related arrows in the table.

If you are having problems staying within the page limitation for the Research Strategy section, you may be able to save space by providing a narrative timeline, rather than a timetable. If you decide to take a narrative approach, make certain that it is comprehensible. It is very difficult to provide a narrative summary that doesn't come across as just a stream of 'stuff.' It has to provide the same kind of temporal context that a timetable would provide.

APPROACH: PROJECTING FUTURE DIRECTIONS

This should be the final paragraph of your Approach subsection. It is the paragraph in which you tell your reviewers what they can expect in the future, should they decide to fund your proposal. You should begin by *briefly* summing up where you expect to be at the conclusion of this project. In doing so, you want to leave no doubt that the results of this period of funding will complete the next step along the continuum of research that you projected in the *Specific Aims* section with your long-term goal statement. You should conclude this paragraph by telling the reviewers what your next steps are expected to be, and why they will be important. Thus, this paragraph provides yet another opportunity to get across to reviewers that you are pursuing a continuum of research that is compatible with the overall mission of the NIH. This paragraph is especially important if you are a New/Early Stage Investigator, because reviewers will undoubtedly want to know what your vision of the future is. The 'Future Directions' paragraph gives you an outstanding opportunity to assure the reviewers, without being obvious about it, that you have such vision. You want them to know that, if they invest in this project, they can expect it to continue to grow and evolve in important directions that will relate to prevention, diagnosis or treatment of disease.

DEVELOPMENTAL STEPS FOR CHAPTER TEN:

1. Make this part of your application as easy to write as possible. Schedule a little time every day and stick to that schedule until it has been completed.
2. Understand the format for the Approach subsection of the *Research Strategy* section.
3. Understand the APPROACH review criterion and how it relates to this section.
4. Do not write the Justification & Feasibility part of each aim until all other parts of the Approach subsection have been written.
5. Emphasize what is important about your research design, which isn't descriptive, methodologic detail. Appreciate that many of the changes made by NIH in how applications are written and reviewed were made to eliminate such detail.
6. Copy and paste your first specific aim from your *Specific Aims* section into a new document file.

7. Prepare a first draft of the "Introduction" paragraph for this first specific aim. Be certain that it provides a conceptual 'overview' of everything that is exciting and important for this subsection. Make the reviewers *want* to read the details that follow.
8. Ensure that the Introduction paragraph is not longer than 1/4 to 1/3 of the page when it is completed.
9. Write the Research Design subsection for this aim. Be certain that meaningful, but not excessive or mindless, detail is provided.
10. Summarize results that you expect to obtain for aim #1 in the Expected Outcomes subsection; integrate these to show that they collectively attain the aim's objective.
11. Review your research plan and identify problems that could develop – probably won't – but could. List these, together with your solutions, in the Potential Problems and Alternative Strategies subsection for aim #1.
12. Repeat steps 6 through 11, above, for each of the remaining specific aims in your *Specific Aims* section.
13. Prepare a timetable (or narrative timeline) that summarizes when the major activities proposed in your Research Design subsections will occur, i.e., what your benchmarks are.
14. Write a brief paragraph entitled Future Directions. It should briefly summarize where you expect the projected continuum of research will lead in the future.

1. The first part of the paper is devoted to the study of the properties of the function $f(x)$ defined by the equation

$$f(x) = \int_0^x \frac{1}{1+t^2} dt.$$

2. In the second part, we consider the function $F(x)$ defined by the equation

$$F(x) = \int_0^x \frac{1}{1+t^2} dt.$$

3. The third part of the paper is devoted to the study of the properties of the function $G(x)$ defined by the equation

$$G(x) = \int_0^x \frac{1}{1+t^2} dt.$$

4. In the fourth part, we consider the function $H(x)$ defined by the equation

$$H(x) = \int_0^x \frac{1}{1+t^2} dt.$$

5. The fifth part of the paper is devoted to the study of the properties of the function $I(x)$ defined by the equation

$$I(x) = \int_0^x \frac{1}{1+t^2} dt.$$

6. In the sixth part, we consider the function $J(x)$ defined by the equation

$$J(x) = \int_0^x \frac{1}{1+t^2} dt.$$

7. The seventh part of the paper is devoted to the study of the properties of the function $K(x)$ defined by the equation

$$K(x) = \int_0^x \frac{1}{1+t^2} dt.$$

8. In the eighth part, we consider the function $L(x)$ defined by the equation

$$L(x) = \int_0^x \frac{1}{1+t^2} dt.$$

9. The ninth part of the paper is devoted to the study of the properties of the function $M(x)$ defined by the equation

$$M(x) = \int_0^x \frac{1}{1+t^2} dt.$$

10. In the tenth part, we consider the function $N(x)$ defined by the equation

$$N(x) = \int_0^x \frac{1}{1+t^2} dt.$$

11. The eleventh part of the paper is devoted to the study of the properties of the function $O(x)$ defined by the equation

$$O(x) = \int_0^x \frac{1}{1+t^2} dt.$$

12. In the twelfth part, we consider the function $P(x)$ defined by the equation

$$P(x) = \int_0^x \frac{1}{1+t^2} dt.$$

13. The thirteenth part of the paper is devoted to the study of the properties of the function $Q(x)$ defined by the equation

$$Q(x) = \int_0^x \frac{1}{1+t^2} dt.$$

14. In the fourteenth part, we consider the function $R(x)$ defined by the equation

$$R(x) = \int_0^x \frac{1}{1+t^2} dt.$$

15. The fifteenth part of the paper is devoted to the study of the properties of the function $S(x)$ defined by the equation

$$S(x) = \int_0^x \frac{1}{1+t^2} dt.$$

16. In the sixteenth part, we consider the function $T(x)$ defined by the equation

$$T(x) = \int_0^x \frac{1}{1+t^2} dt.$$

17. The seventeenth part of the paper is devoted to the study of the properties of the function $U(x)$ defined by the equation

$$U(x) = \int_0^x \frac{1}{1+t^2} dt.$$

18. In the eighteenth part, we consider the function $V(x)$ defined by the equation

$$V(x) = \int_0^x \frac{1}{1+t^2} dt.$$

19. The nineteenth part of the paper is devoted to the study of the properties of the function $W(x)$ defined by the equation

$$W(x) = \int_0^x \frac{1}{1+t^2} dt.$$

20. In the twentieth part, we consider the function $X(x)$ defined by the equation

$$X(x) = \int_0^x \frac{1}{1+t^2} dt.$$

21. The twenty-first part of the paper is devoted to the study of the properties of the function $Y(x)$ defined by the equation

$$Y(x) = \int_0^x \frac{1}{1+t^2} dt.$$

22. In the twenty-second part, we consider the function $Z(x)$ defined by the equation

$$Z(x) = \int_0^x \frac{1}{1+t^2} dt.$$

23. The twenty-third part of the paper is devoted to the study of the properties of the function $A(x)$ defined by the equation

$$A(x) = \int_0^x \frac{1}{1+t^2} dt.$$

24. In the twenty-fourth part, we consider the function $B(x)$ defined by the equation

$$B(x) = \int_0^x \frac{1}{1+t^2} dt.$$

25. The twenty-fifth part of the paper is devoted to the study of the properties of the function $C(x)$ defined by the equation

$$C(x) = \int_0^x \frac{1}{1+t^2} dt.$$

26. In the twenty-sixth part, we consider the function $D(x)$ defined by the equation

$$D(x) = \int_0^x \frac{1}{1+t^2} dt.$$

27. The twenty-seventh part of the paper is devoted to the study of the properties of the function $E(x)$ defined by the equation

$$E(x) = \int_0^x \frac{1}{1+t^2} dt.$$

CHAPTER 11

APPROACH SUBSECTION OF RESEARCH STRATEGY: REVIEW OF LITERATURE; PRELIMINARY STUDIES; PROGRESS REPORT; BIBLIOGRAPHY & REFERENCES CITED SECTION

GENERAL COMMENTS REGARDING LITERATURE AND PRELIMINARY STUDIES

As noted earlier, the changes in how research-grant applications are submitted to NIH represent a true and dramatic paradigm shift. Nowhere is this more evident than in how review of the literature and preliminary data are now handled. Instead of having their own separate sections of the Research Plan, as they did in the past, they now are integrated into other sections of the proposal. As a result, it is now easier for applicants to grasp how review of literature and preliminary data should be used to support an application. In addition, it has become more evident which data and citations are extraneous. The result is a leaner, more pertinent proposal.

REVIEW OF RELEVANT LITERATURE (PRIMARILY JUSTIFICATION & FEASIBILITY)

For years, we have been writing and speaking about the Background subsection of the *Background and Significance* section of the previous format as the least well understood part of the application. Almost to a person applicants viewed it as an opportunity to impress reviewers with the scope and breadth of their knowledge of the area. The literature review was almost always an attempt to summarize the relevant field comprehensively, which is precisely what it should not have been. Very few applicants used it for the purpose it was intended to have, which was *to help justify the need* for the proposed research.

To help solve this problem, NIH has eliminated review of the literature as a separate section in the current format. Relevant citations in support of the proposal are now scattered throughout the components of the Research Plan, the format of which is outlined, below. An asterisk denotes where selective review of existing relevant literature may be needed.

SPECIFIC AIMS *

RESEARCH STRATEGY

Significance *

Innovation *

Approach

Each Aim:

Introduction

Justification & Feasibility

*Review of Relevant Literature **

Preliminary Studies

*Research Design **

Expected Outcomes

*Potential Problems & Alternative Approaches **

Timetable

*Future Directions**

Integration of Relevant Literature Throughout the Research Plan

As noted in chapter 9, there should be few citations in the *Specific Aims* section. That section has the purpose of 'introducing' - providing an overview or executive summary of - the rest of the Research Plan. It should be primarily conceptual and there isn't a lot of room for detail - the entire section can be no longer than one page. In addition, you don't want to 'bury' reviewers in a lot of initial detail. Thus, we recommend that you cite only the most important, 'linchpin' references which justify that there is a need for what is proposed.

The first part of the *Significance* subsection of the Research Strategy section (chapter 9) should contain highly selected citations of literature that increase detail regarding existence of the gap in the knowledge base / urgent need that will drive your grant proposal. In addition, you may need additional citations in the third part of the subsection to support your assertion that benefits will accrue to the proposed research. All of these should be 'spun' to justify your proposal.

In the *Innovation* subsection of the Research Strategy section (chapter 9) existing literature should be cited in the first part of the subsection to frame the *status quo*. This provides the 'platform' on which you will make your claim for innovation. Again, the slant should be that such innovation is needed to advance the field.

The need for the research proposed under each aim must also be justified. You should do so under each aim in the first part of *Justification and Feasibility* subsection. This is where the bulk of your citations will be located. Each of these sub-subsections should be focused only on justification of the need for that part of the research. As is shown on the preceding page, each of these sub-subsections should be titled "Review of Relevant Literature."

Citations under *Research Design* for each aim (chapter 10) depart in some cases from justification of need. Such citations supplant the need for descriptive methodologic detail. Citation of your own papers is an important means of establishing methodologic feasibility in your hands.

References in the *Potential Problems & Alternative Strategies* subsection (chapter 10) will usually be to the alternative approaches that are offered to avoid/overcome potential problems. While you need enough citations to be credible, don't over-cite the literature because, by doing so, you inadvertently overemphasize the problem.

Finally, a few citations will add credibility to the *Future Directions* part of your Approach subsection (chapter 10). This can't come across as 'pie-in-the-sky' generalities. Supporting your vision of the future with well-selected citations is smart business.

Approach to Citing and Reviewing the Literature

We recommend that you cite the literature using author/year (one author = last name, year; two authors = both last names, year; more than two authors = last name of first author *et al.*, year). This is much more reviewer friendly, in our opinion, than using numerals. Your assigned reviewers, if not experts on the subject you are presenting, will be pretty close. If you give them author/year they will be able to recognize most of your citations without having to flip to the *Bibliography & References Cited* section. If you give them numerals, no matter how familiar they are with the literature of your field, they will have to go to the Bibliography and References Cited section every time to determine what you are citing. Not only does that cause them extra work, you want them to remain focused on content. That is very difficult if the reviewer is forced to flip back and forth in the proposal while s/he is trying to read it.

We recommend that you write the literature review after each aim out of the order in which it will appear in the final application. For example, selection of references to support each aim will be facilitated by writing the Research Design part before you write the related part of the aim's *Justification and Feasibility* subsection. If you think of Research Design as the 'plug' that will fill the gap related to that part of the project, once you know what the 'plug' looks like, it becomes much easier to select the literature that will justify the need for it.

Citations should be almost exclusively of primary literature. Don't make the mistake of trying to be comprehensive by citing a lot of review articles. Reviewers will not be impressed if you come across as a 'five-minute expert' based on your knowledge of review articles. What they will want to know is whether or not you have command of the primary literature of your field. Do you have the capacity to select the primary references that will best support what you are proposing? There is an exception to this 'rule:' If one of the members of the review panel you are targeting has written a pertinent review, we of course recommend that you cite it, providing that it won't appear contrived to do so.

Your treatment of the literature should be a *critical analysis* of what has been published, not a passive one (i.e., not just who did what when). Without being overly critical of other workers, use the literature to point out relevant gaps in what has previously been published. You shouldn't be comprehensive in your coverage of a specific point. For example, one of us cloned a receptor in competition with seven other laboratories. All eight laboratories were ultimately successful and, within a very short span of time, members of those groups published eight versions of essentially the same paper. Were you going to cite the cloning of that receptor you would not reference all eight of those publications. Rather, you would cite the first one and/or the one that best makes the point that you need to make. Taking this approach prevents long strings of author/year citations that would otherwise interfere with the readability of your proposal.

PRELIMINARY STUDIES (UNDER JUSTIFICATION & FEASIBILITY)

The second part of the *Justification & Feasibility* subsection under each aim should be titled Preliminary Studies. NIH's current view of preliminary data can be summed up as: it's quality, not quantity, that counts. The purpose of including preliminary data is to help *establish that the work proposed is feasible in your hands*, i.e., that you and your research team have the competence and experience needed to do what is proposed. Only highly selected data that are relevant to that purpose should be included. In other words, presentation of preliminary data should not be seen as an opportunity to impress reviewers with all that you have done in the recent past. Such indiscriminate use of the *Preliminary Studies* section in the previous format is one of the reasons that NIH eliminated it as a section, in our opinion.

Application Guide's instructions on Preliminary Studies: "For new applications, include information on Preliminary Studies [as part of the Approach subsection]. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. ... Preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data (however, for R01 applications, reviewers will be instructed to place less emphasis on preliminary data [than would be the case for] more established investigators).

Unfortunately, in the instructions above, NIH makes it appear that only data produced by the PD/PI can be included. That is not correct; data produced by any member of the research team is eligible for inclusion. Note also that the instructions suggest "experience pertinent to this application" can be included. That could be a viable approach, especially for Early Stage Investigators. However, as you will note below, real data should be included whenever possible.

You should segue seamlessly from justification of the need (Review of Relevant Literature sub-subsection) into presentation of evidence that you can do what is necessary to solve the problem(s) you have just framed (Preliminary Studies sub-subsection). Thus, you need a transition piece that will bridge between the two parts of the Justification & Feasibility subsection. For example, having just reviewed the relevant literature that justifies the need for the aim, you might write something like:

'The preceding citations and related discussion illustrate that is critically important to developing better understanding of, which is the focus of this aim. Our approach requires that we will be able to The following preliminary data support the feasibility of that approach in our hands.' You will need such a transition piece under each aim. Don't use exactly the same words each time or the transition piece will come across as 'canned' and repetitive. Clever paraphrasing is essential.

What to Include

TIP: It is essential that you present actual data, not summaries of data. Lead your reviewers through what you present, assuring that they make the connections that you want them to make.

As with selection of primary literature to cite, choice of which preliminary data to use will be facilitated by writing the Research Design part of each aim before you write the aim's Justification & Feasibility subsection.

Most of the data selected should be unpublished. Begin the selection process by collecting all of your team's unpublished work that might be relevant. Under the aim's hypothesis or statement of need, list which of the data support either its formulation or existence, respectively. In the case of a statement of need, the data should be from your own assessment of need, not the published work of other investigators who have independently called attention to its existence. Such citations belong in the preceding part of the Justification & Feasibility subsection, not here. Do the same under each of your aims – which data support the feasibility of which aim? After each group of data, write a statement regarding what that set shows and why the data are important. After you have completed this organizational step, begin to 'prune' the list, keeping only those sets of data that are complete and that persuasively contribute to the 'story' that you want to tell. Now, arrange the data sets under each aim in a logical and compelling order. Remember that your objective here is to lead your reviewers to the conclusion that you are highly capable of accomplishing what will be proposed in the next, Research Design subsection.

If your published work is needed to help support feasibility, e.g., the use of a method that you have employed successfully in the past, the relevant paper should be referenced with an accompanying discussion of why the method will be used in the current approach. In other words, use the recommended approach to avoid inclusion of descriptive methodologic detail.

Never use data from investigators outside of your own research team. The purpose of preliminary data is to support feasibility in your team's hands, not in the hands of someone else. If you want to include the unpublished work of other investigators in your application you should do so in the first part of the Justification & Feasibility subsection. Cite it as "unpublished" and accompany the proposal with a letter of support from the investigator that corroborates your claim. If you don't include such a letter, it is risky to present such data because reviewers would have nothing with which to confirm your assertion.

If you are proposing hypothesis-driven research at the R01 level, you should have preliminary data in support of the proposal's central hypothesis and each aim's working hypothesis. For either hypothesis- or need-driven proposals, the feasibility of each aim must also be supported. New/Early Stage Investigators are not required to have the same quantity of preliminary data that would be expected of an established investigator. That is one reason why New/Early Stage Investigators' applications are now 'clustered' for evaluation at the beginning of review-panel meetings. It helps reviewers remember that fact.

At the R01, R15 and R34 application levels you are allowed 12 pages for the *Research Strategy* section. At the R03 and R21 levels you are allowed only 6 pages. Thus, the approach to presentation of preliminary data for the latter kinds of applications must differ. The difference is in the quantity, not quality, of the data presented. For example, you can actually undercut the fundability of your application if you include a lot of preliminary data in support of an R03. Why? Because the purpose of most R03s is to sponsor pilot studies/produce preliminary data. If you already have preliminary data you shouldn't be using that grant mechanism. That said, in spite of what the instructions say, in our experience reviewers expect a small amount of preliminary data in support of an R03. The R21 has a different purpose, which is usually to support high-impact research that has high risk of failure associated with it. Again here, the instructions stipulate that preliminary data are not required. However, we have found that reviewers require preliminary data at the R21 level if you expect to be successful. Again, it doesn't have to be much (there can't be – you only have a total of 6 pages for the entire *Research Strategy* section), but it has to be of high quality and convince reviewers that, although there is high risk of failure associated with the project, the risk isn't so high that there is virtually no chance for success. In other words, some semblance of feasibility has to be established with a little bit of highly selected preliminary data.

Organizing and Presenting Your Preliminary Data

Technical Considerations

Each set of data / figure should be designed to make a single point / be the basis for a single conclusion. As noted earlier (chapter 4), each paragraph that you write should make one point and one point only. Thus, each data set / figure presented here should be accompanied by a paragraph that discusses it and makes a point / leads to a conclusion. Strive for simplicity. Juxtapose the text and the related data as closely as possible. Ideally, the reviewer will only have to glance back and forth between the two.

Scan or copy/paste figures / tables and embed them into the text. Wrap text around them to save space. If you are using full justification, auto-hyphenate the document to minimize wide word-spacing problems that can develop with full justification when text is wrapped around embedded figures and tables.

Vary the means of presenting your data. Even if you could present everything in a single format, table after table or histogram after histogram becomes boring. Instead, change the format to make the data as appealing to reviewers as possible. But take into account two things when choosing the formats you will use. First, how much space will be taken up by one, compared to another. You are constrained by the small amount of space that is available to you; make the most of it by choosing formats that require the least amount of space. If necessary, recreate existing presentations of data in a more space-efficient way. Second, photo-reduce figures to the greatest extent possible. A common mistake is to do so without paying attention to associated print: the figure fits the small space nicely, but print associated with it is illegible. To avoid this problem it may be necessary to redraw the figure using larger print.

A data set/figure should not be presented until after it is first referred to in the text. Thus, if there is no room at the bottom of a page after a table is first mentioned, it should not be moved to the top of that same page. Were you to do so, the reviewer would encounter it before s/he would know why it has been included. Rather, it should be moved to the top of the next page with a note on the preceding page that specifies its location, e.g., '(see Table 3, top of next page).'

Even though the electronic version of your application may contain faithful reproductions of figures that include color, you must anticipate that one or more of your reviewers will want to read and evaluate your application after first downloading and printing it using a black-and-white printer. Therefore, you should choose colors used in figures to have distinct grayscale differences when reproduced in black and white. This potential problem cannot be overcome by submitting color copies of the figure as appendix material; that use of the Appendix is no longer allowed (see section 5.5.15 of the *Application Guide*).

Editorial Considerations

With respect to calling attention to what is important, we recommend that you include a fully italicized sentence in each paragraph that helps reviewers connect with how / why the related data support feasibility. For example, the sentence might read something like, '*These data are important in establishing the feasibility of Specific Aim #2, because they validate its underlying concept.*' or '*Collectively, these data support feasibility because they unequivocally confirm that XYZ occurs, which was the essential observation needed to propose specific aim #3.*'

In our opinion, *the most common error made in this part of the application is failure to lead the reviewers through the data that are presented.* The usual approach is to provide a conclusion and then refer the reviewer to a data set or figure so that s/he can determine how that conclusion was reached. That makes the reviewer do all of the work, which is not reviewer friendly. More important, it risks that s/he either won't make the effort or will misinterpret the data. A better approach, in our opinion, is to give the reviewers the conclusion, refer them to the data/figure, and then lead them through it. For example, 'We conclude from the data in Figure 1 that _____. Note that there is a band in column one that is missing in column two. This indicates that _____.' By using this approach, you can be guaranteed that the reviewer will come down in the same place that you came down. Once there, s/he may disagree with your conclusion, but at least you will know that s/he got to the same point that you did.

Figures should be accompanied by a legend. It should begin with a descriptive and informative title. Figure legends should have two parts. The first part should include whatever description is relevant to making the figure intelligible. The meanings of all symbols should be included. Don't forget to include information about statistical notations (e.g., error bars). The second part of the legend should briefly summarize the method(s) used to generate the data. This second part

should be preceded by the title, 'METHODS.' The legend should be referred to in the text if a methodological point needs to be made there. There are two reasons for including methodologic summaries in figure legends and footnotes to tables. First, while there are strict guidelines on font size for text (at least 11 point and 15 or fewer characters and spaces per linear inch), these restrictions are relaxed for legends and footnotes. The only requirement for figure legends and footnotes to tables is that "it must be ... readily legible" and in one of the four approved typefaces. Second, 'burying methodologic summaries in figure legends and footnotes to tables makes such information accessible to reviewers but they don't have to read it unless they want to do so. We recommend that you use either 9- or even 8-point type, with the first part of the legend or footnote bolded, as is illustrated in the text box at the top of the next page. To allow you to compare them, the first part of the legend in the text box is in 9-point Arial and the second, "Methods" part is in 8-point. We prefer the 9 point.

Figure 3. Enhanced expression of TLR4 on macrophages from *B. anthracis* infected mice. The data show the level of surface expression of TLR4 in alveolar macrophages at 24 and 48 hours post infection of C57/Bl6J mice with a virulent strain of *B. anthracis* spores (open bars) is markedly elevated relative to the avirulent strain (shaded bars) or *B. subtilis* (filled bars), indicating that virulence is associated with rapid induction of innate host immunity. Methods. Mice were infected via inhalation with 10 million spores as indicated. At 24 and 48 hours post-infection, five mice from each group were euthanized and pulmonary lavage fluids were obtained. Macrophages were isolated by magnetic bead adherence using anti CD11b monoclonal antibodies, stained with fluoresce in conjugated polyclonal rabbit anti-mouse TLR4 antibody and analyzed by flow cytometry. Data are averages of triplicate determinations $\pm$ S E M.

PROGRESS REPORT FOR RENEWALS / REVISIONS

Application Guide's instructions for Progress Reports: "For renewal/revision applications, provide a Progress Report [as part of the Approach subsection]. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions."

The format of the Research Plan changes slightly if you are submitting a renewal or revision of a previously submitted proposal: a Progress Report subsection is required under the "Approach" subsection – without any increase in the number of pages that are allowed for the *Research Strategy* section. This, of course, compounds the problem of staying within the 12-page limitation for the Research Strategy section.

SPECIFIC AIMS

RESEARCH STRATEGY

Significance

Innovation

Approach

Progress Report

Each Aim:

Introduction

Justification & Feasibility

Review of Relevant Literature

Preliminary Studies

Research Design

Expected Outcomes
Potential Problems & Alternative Approaches
 Timeline
 Future Directions

Many of the principles pertinent to the presentation of preliminary data apply here, as well. However, there are some important differences. First, the section should begin with the duration of time that the *Progress Report* covers. That is not the duration of the grant. It is the period from the date of the award to the date of submission. Second, you need to present the specific aims that directed the research that will be summarized in the *Progress Report*. They may not be the ones that were submitted in the previous application. For example, if you changed the scope of the project because of budget cuts that were forced on you, that fact should be made clear. Hopefully, you would have backed up such changes by getting approval of your Program Officer and/or through the way that your annual *Non-Competing Continuation Progress Reports* (PHS 2590; see <http://grants.nih.gov/grants/funding/2590/2590.htm>) were written. You should detail these changes at the beginning of your *Progress Report*. As another example, you might have found that, in spite of your best projections, one or more of the original aims had to be changed for scientific reasons during the course of the research. You should have noted the need to make that change in one or more of your annual, *Non-Competing Continuation Progress Reports*. If there was no objection to the proposed change (and there almost never is), the revised set of aims would become what you would present at the beginning of the *Progress Report* in your renewal proposal. You should organize and present your *Progress Report* in the renewal application using the former and/or revised aims as subsection headings. Third, each paragraph in the *Progress Report* should be devoted to one discovery that you made. As is the case for presentation of preliminary data, you should include an italicized sentence in each paragraph. The difference here is that you should use such sentences to highlight for reviewers why each discovery was important and how it contributed to attainment of the grant's overall objective.

After you have completed the *Progress Report* you need to create a list of every product that came from the prior funding. The space occupied by this list will not be counted against the 12-page limit for the *Research Strategy* section. Rather, it will be uploaded as a separate PDF document into field 4 of the *PHS 398 Research Plan* form (see arrow, below).

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment



Human Subjects Sections

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It is important to realize in constructing this list that, in addition to evaluating quality, reviewers count. Therefore, we recommend that you use the instructions in the text box, below, to create the list. First, identify everything that could be construed as a product of your current funding. Prioritize these products from most-to-least important. Publications and manuscripts accepted in peer-reviewed journals will be your most important product. Therefore, begin your list with a subheading, 'Publications in Peer-Reviewed Journals.' Exclude submitted and 'in-preparation' entries from the list. Let's say that these become numbers 1 through 12. The next most important product might be three invited monographs. To include them, you would insert the subheading, 'Invited Monographs.' However, instead of numbering them 1 through 3

SF 424 Application Guide Instructions - Progress Report Publication List:

List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. When citing articles that fall under the Public Access Policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMICD is not yet available ..., indicate "PMC Journal – In Process. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMID numbers along with the full reference (note that copies of these publications are not accepted as appendix material)."

you would continue the sequence of numbers from above, i.e., they would be 13 through 15. You might continue with patents, if any, as well as any "other printed materials" (e.g., reviews, book chapters, published conference proceedings and the least important, published abstracts, which would be last).

TIP: If you decide to present published abstracts, make sure that most of the earlier ones are reflected as later, full-length publications in peer-reviewed journals. If you present numerous abstracts that do not give rise to subsequent peer-reviewed publications, it will give reviewers the impression that your discoveries either cannot pass the test of rigorous peer review or that you are satisfied to primarily publish abstracts.

When you have completed this exercise, the total number at the end of the list will be larger and much more impressive than a series of smaller totals for the various subsections.

Finally, it is important for you to appreciate that progress made with current funding is a major criterion that is used by reviewers to determine whether or not a renewal application will be funded. If you (and colleagues who you consult) recognize that insufficient progress has been made to merit a fundable priority score, the shortest route to funding is probably not through the submission of a renewal application; you would most likely be preordained to fail. *In such a case, you should consider changing the proposal enough to convert it into a new application.* By doing so, you would not have to submit a *Progress Report*. If this tactic proves to be necessary you hopefully became aware of it at the time that your last PHS 2590 *Non-Competing Continuation Progress Report* was prepared.

BIBLIOGRAPHY & REFERENCES CITED SECTION

The choice and number of citations included in support of your proposal are important. In fact, the references that accompany your application say a lot about you as an investigator. For example, including too many speaks negatively about your ability to be selective. They should mostly be citations of the primary literature, *not* reviews. They should be up to date, especially if you are resubmitting an application that wasn't funded on an earlier attempt. Forgetting to update the *Bibliography & References Cited* section in resubmitted applications is a relatively common mistake. Reviewers often check this to assess whether or not an applicant has cared enough to update the literature that supports the proposal. Citations should be complete, i.e., all authors in their published order, title, accepted abbreviation for the journal, volume, year of publication and full pagination. Finally, it is reviewer friendly to present your references in alphabetical order, based on the name of the first (or only) author. Do not open a line after each reference because it unnecessarily increases the length of this part of the application. Rather, set off each citation either by numbering it or by presenting it un-numbered in a 'hanging indent' format.

When citing books or other large documents, make certain that you include relevant page numbers as a guide to what you are referencing. You cannot expect reviewers to read the entire book/document to find what you refer to. Similarly, don't cite references that aren't readily accessible to reviewers, such as submitted manuscripts or obscure conference proceedings. If you cite a manuscript that is "in press," you should include it in its entirety as an appendix. You are allowed up to three such manuscripts. It is permissible to include them because such manuscripts are not yet publicly available. That is one of the litmus tests used to decide whether literature can be included in the appendix. Never cite manuscripts that are "in preparation."

You must include either the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central reference number (e.g., PMCID234567) when citing articles that either fall under Public Access Policy or were authored/co-authored by you as the applicant and arose from NIH support. If the PMCID is not yet available because the journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process. You can find a list of such journals at http://publicaccess.nih.gov/submit_process_journals.htm. Although URLs are generally prohibited in NIH grant proposals, citations that are not covered by the Public Access Policy, but are publicly available in a free, online format, may include them, along with the full reference.

The *Bibliography & References Cited* section should be created as a separate PDF file and uploaded into field 9 of the SF 424 Other Project Information form (see arrow at top of next page).

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001

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6 b. Optional Explanation:				
7. * Project Summary/Abstract		Add Attachment	Delete Attachment	View Attachment
8. * Project Narrative		Add Attachment	Delete Attachment	View Attachment
9. Bibliography & References Cited		Add Attachment	Delete Attachment	View Attachment
10. Facilities & Other Resources		Add Attachment	Delete Attachment	View Attachment
11. Equipment		Add Attachment	Delete Attachment	View Attachment
12. Other Attachments	Add Attachments	Delete Attachments	View Attachments	☐

DEVELOPMENTAL STEPS FOR CHAPTER ELEVEN:

Review of Relevant Literature

1. Appreciate that review of literature must be integrated throughout the application as a means of justifying the need for what is proposed.
2. Citations should also be used in the Research Design subsection, under Approach, to reference methodology, thereby minimizing descriptive methodologic detail.
3. Cite primary literature, not reviews.
4. Assemble a file of the key literature citations that you will plan to use in support of your application.
5. Be certain that you have thoroughly familiarized yourself with the information in each of these publications. This means reading more than the abstract.
6. Cite references using author/year, not numerals.
7. In general, selection of primary literature in support of an aim is facilitated by writing its Research Design subsection before its Justification & Feasibility subsection.

Preliminary Studies

8. Appreciate that preliminary data are included in your proposal for one reason, only: support of the project's feasibility in your hands. That purpose should guide your choice of preliminary data.
9. Understand that different grant mechanisms (e.g., R01 vs. R03) require different amounts of preliminary data.
10. In spite of NIH instructions stipulating that preliminary data are not required for R03 and R21 applications, we recommend that a small amount be included to meet reviewer expectations.
11. Also appreciate that New/Early Stage Investigators need less preliminary data in support of their applications, but what is presented must be of high quality.
12. As is the case for selection of supporting references, selection of preliminary data will be facilitated by writing the Research Design subsection for each aim before you attempt to write the second half of Justification & Feasibility.

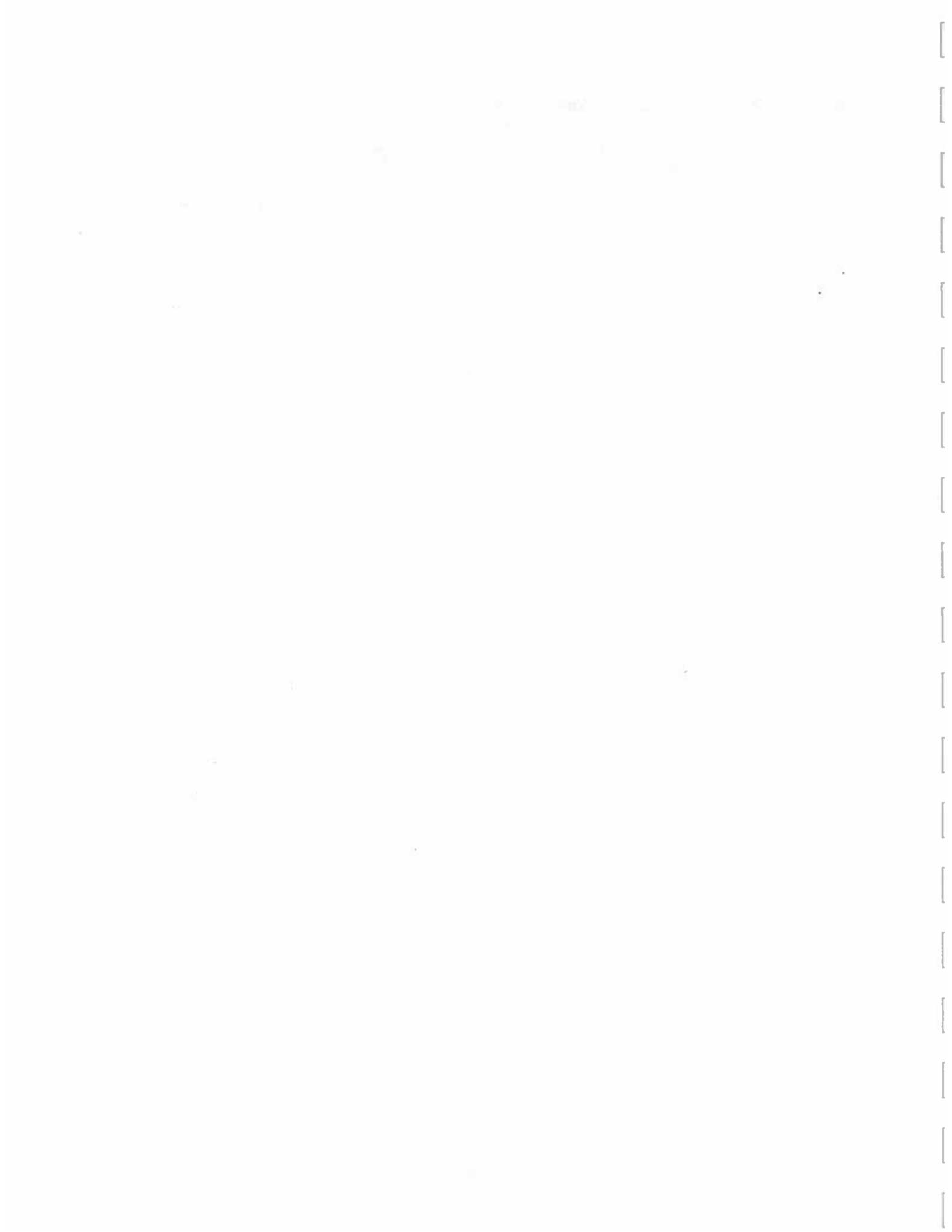
13. Most of your preliminary data will be presented under Approach in the second part of the Justification & Feasibility subsection for each aim.
14. Assure that your review of relevant literature in the first part of the Justification & Feasibility subsection segues seamlessly into your presentation of preliminary data in the second part.
15. The great majority of your preliminary data should be unpublished.
16. Use your published work to support feasibility of methods in your hands, thereby avoiding inclusion of methodologic detail.
17. Do not include unpublished work of others in support of feasibility. It must be feasibility in your hands, not theirs.
18. Presentations of preliminary data should be organized to make one point and one point only. Data presentations should be accompanied by a text paragraph that does the same.
19. Write accompanying text in such a way that it leads reviewers through the data; don't make reviewers interpret what you present.
20. At the end of each paragraph, include a fully italicized sentence that tells reviewers why what has just been presented supports feasibility in your hands.
21. Wrap text around figures and tables to save space.
22. Vary the format used to present data, making them maximally appealing to reviewers.
23. Make certain that none of your preliminary data appear in the application before they are first referred to in the text.
24. Assure that no figures or tables have been photo-reduced to the extent that print associated with them has become illegible.
25. Select colors in figures to have distinct grayscale differences, thereby assuring that the figure will be interpretable when printed in black and white.
26. Figures should be accompanied by a two-part legend. The first part should facilitate interpretation of the figure and the second should summarize how related the work was done.
27. Reduce the size of font to 9 points in figure legends and footnotes to tables.

Progress Report for Renewal Applications

28. Make a decision, based on relative productivity with the current funds, whether or not to submit a renewal. The shortest path to funding may be a new application if you have not made reasonable progress during the current period of grant support.
29. Begin by offering the beginning and ending dates since the last competitive review. The ending date will be the date of submission of the renewal.
30. Summarize the specific aims for the current period of support, including any changes in them that were caused by budget cuts or change in scientific direction.
31. Use the titles of the specific aims to organize the Progress Report into subsections.
32. Use a separate paragraph to present each of your discoveries.
33. Write a fully italicized sentence at the end of each such paragraph that highlights the importance of the discovery and how it contributed to attainment of the grant's overall objective.
34. Convert the Progress Report into a PDF file and upload it into field 2.4 of the *PHS 398 Research Plan* form.
35. Create a list of the products – most will be publications – from the current period of support, ranked in order of greatest to least importance. Be sure to include PMCID numbers, when possible.
36. Convert the list to a PDF file and upload it into field 2.7 of the *PHS 398 Research Plan* component, Progress Report Publication List. Do not include manuscripts in the list that are either submitted or 'in-preparation.'

Bibliography and References Cited Section

37. Assure that most references are primary literature, not reviews.
38. Present them in alphabetical order based on the last name of the first author.
39. Either number them or use hanging-indent format, without a separating open line between entries.
40. Ensure that the bibliography is up to date, especially if you are resubmitting a proposal.
41. Use a standard, consistent format for each entry that is complete, e.g., has full pagination.
42. Ensure that cited books and other large documents have specific page numbers associated with them, thereby telling reviewers exactly where to look to find the reference.
43. Do not reference anything that would be difficult or impossible for a reviewer to find, e.g., a submitted manuscript or a conference proceeding that was not published in a readily accessible source.
44. Include PMCID numbers, if available.
45. Convert the document to a PDF file and upload into field 8 of the R&R *Other Project Information* form.



CHAPTER 12

SENIOR/KEY PERSON PROFILE(S), BIOGRAPHICAL SKETCHES, AND MULTIPLE PI LEADERSHIP PLAN

GENERAL CONSIDERATIONS

The profiles and biographical sketches of essential members of your research team are prepared and included in the application using the *RESEARCH & RELATED Senior/Key Person Profile (Expanded)* component (section 4.5 of Part I of the *SF424 [R&R] Application Guide for NIH and Other PHS Agencies*).

Each member of the Senior/Key Personnel set and all Other Significant Contributors must provide both a profile and a Biographical Sketch. Generically, these individuals are defined as ones without whom completion of some part of the project would become problematic. The distinction between these two personnel categories relates to time committed to the project: Senior/Key Personnel "contribute in a substantive, [measurable] way to the scientific development or execution of the project, whether or not salaries are requested." Other Significant Contributors "have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project." Thus, the distinction between the two is measurable effort.

Senior/Key Personnel include the Principal Investigator (all Principal Investigators if there are multiple PDs/PIs), Co-Investigator(s), and can include Collaborators and Consultants if their effort is measurable. Even though post-doctoral research fellows, graduate students and technicians may have measurable effort on a project, they rarely qualify as Senior/Key Personnel because their level of expertise can usually be replaced relatively easily. Thus, they usually will not be represented in the application by a profile and a Biographical Sketch. The credentials of such members of the research team, along with their roles in the project, should only be described in the Personnel Justification of a Modular Budget (see chapter 13) or, if the *SF 424 R&R [breakout] Budget* form is used (chapter 14), in its Budget Justification.

Other Significant Contributors are usually either collaborators (e.g., someone who provides a critical reagent, technology or access to subjects without measurable effort) or consultants who have such a limited role in the project that their effort is not quantifiable.

PERSONNEL PROFILES

Each Senior/Key Person and Other Significant Contributor must have a profile prepared for him/her. Such profiles are created using the series of blocks on the *SF424 Senior/Key Person Profile(s) Component* (see next page). There is a separate profile at the beginning of the form for the Principal Investigator ("PROFILE - Project Director/Principal Investigator"), which is followed by another part that is used to create the profiles of other Senior / Key Personnel and any

Other Significant Contributors ("PROFILE – Senior/Key Person 1"). If there are multiple PD/PIs, the contact PD/PI should be listed first, followed by the remaining PD/PIs in alphabetical order.

OMB Number 4040-0001

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator			
Prefix:	* First Name:	Middle Name:	
* Last Name:			Suffix:
Position/Title:	Department:		
Organization Name:			Division:
* Street1:			
Street2:			
* City:	County/ Parish:		
* State:	Province:		
* Country:	* Zip / Postal Code:		
* Phone Number:	Fax Number:		
* E-Mail:			
Credential, e.g., agency login:			
* Project Role:	PD/PI	Other Project Role Category:	
Degree Type:			
Degree Year:			
* Attach Biographical Sketch		Add Attachment	Delete Attachment View Attachment
Attach Current & Pending Support		Add Attachment	Delete Attachment View Attachment

PROFILE - Senior/Key Person 1			
Prefix:	* First Name:	Middle Name:	
* Last Name:			Suffix:
Position/Title:	Department:		
Organization Name:			Division:
* Street1:			
Street2:			
* City:	County/ Parish:		
* State:	Province:		
* Country:	USA: UNITED STATES		* Zip / Postal Code:
* Phone Number:	Fax Number:		
* E-Mail:			
Credential, e.g., agency login:			
* Project Role:	Other Project Role Category:		
Degree Type:			
Degree Year:			
* Attach Biographical Sketch		Add Attachment	Delete Attachment View Attachment
Attach Current & Pending Support		Add Attachment	Delete Attachment View Attachment

Delete Entry
Next Person

To ensure proper performance of this form, after adding 20 additional Senior/ Key Persons, please save your application, close the Adobe Reader, and reopen it.

Senior/Key Personnel should be presented next, in alphabetical order. Other Significant Contributors should then be presented, again in alphabetical order. Profiles after the first Senior/Key Person's are created by clicking the "Next Person" button beneath the lower right corner of the "PROFILE - Senior/Key Person 1" fields. If there are more than 20 profiles be sure to save the application, close the Adobe Reader and then reopen it. Not doing so risks a malfunction of the system. Up to 99 Senior/Key Person profiles, in addition to that of the PD/PI, can be created, for a total of 100.

For applications with multiple PD/PIs, each must be registered in the eRA Commons. A very common mistake made by multiple-PI applicants is failure to enter the eRA Commons ID (User Name) for the PD/PI(s) in the "Credential, e.g., agency login:" field. This is not a requirement for other members of the Senior/Key Personnel set.

The "Project Role" field of the Senior/Key Person Profile (Expanded) component is another place where mistakes are frequently made. The role selected for each PD/PI (if there are multiple PD/PIs) must be "PD/PI." NIH and other PHS agencies do not recognize the "Co-PI" choice that is included on the drop-down menu. Unlike previous iterations of this form, the Adobe C version has "Co-Investigator" and "Post-Doctoral Scholar" as choices on the drop-down menu. For Other Significant Contributors, select "Other" from the drop-down list for "Project Role" and then type "Other Significant Contributor" in the "Other Project Role Category" field.

The field in the Senior/Key Person profile that is titled "Attach Current & Pending Support" should not be used for applications to NIH and other PHS agencies unless a funding opportunity announcement specifically requires it. This information will be submitted later, "just in time" to fund the proposal.

If you decide part way through a Senior/Key Person profile that it is not needed, there is no easy way to 'empty' it. You must complete it. Then, click the "Next Person" button at the bottom right of the page, which will activate the "Delete Entry" button at the lower left of the page. Clicking the latter button will then delete the unwanted profile.

BIOGRAPHICAL SKETCH

The biographical sketches are the primary means used by reviewers to score the INVESTIGATOR(S) core review criterion for your application. In addition, they are one of the most important contributors to reviewers' assessment of feasibility of the project in your research team's hands. Extensive thought should be given to the preparation of this part of the application, therefore.

Application Guide instructions for the INVESTIGATOR(S) core criterion:

"Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?"

Given the importance of this part of your application, *never simply copy biographical sketches from other applications as a means of saving time*. To do so is a serious strategic error, in our opinion. Such biographical sketches were prepared to support other applications, not yours. In that regard, the Personal Statement may not be as pertinent to your proposal as it should be. In addition, each will look different with respect to formatting and, in some cases, typeface. They should all look alike to emphasize that yours is a fully integrated research team, not a bunch of disparate parts that have been cobbled together at the last minute. Finally, the biographical sketches will almost surely be out of date if the 'copy-paste' approach is used. The approach that we recommend to assure that each Biographical Sketch maximally supports your proposal while, at the same time, it contributes to the image of integration, is described later in this chapter, under the 'Preparation' subsection.

Each Biographical Sketch must be uploaded as a PDF file using the "Add Attachment" button that is adjacent to the "Attach Biographical Sketch" field near the bottom of each Senior/Key Person's and Other Significant Contributor's profile.

Format of the Biographical Sketch

The NIH/PHS-specific instructions near the end of section 4.5 of Part I of the SF 424 *Application Guide* should be substituted for the generic SF424 (R&R) instructions regarding how to prepare the biographical sketches. The relevant instructions are offered under the title, "Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch." They are provided in the text box, below.

General Instructions for NIH and Other PHS Agency Applications: "Use the sample *format* on the **Biographical Sketch Format Page** to prepare this section for **all** (modular and other) grant applications. Include biographical sketches of **all Senior/Key Personnel and Other Significant Contributors**. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page."

A Version C copy of the Biographical Sketch Format Page is supplied for all NIH and other PHS agency applications at <http://grants.nih.gov/grants/funding/424/index.htm>, along with an example of a completed form. It must be used to prepare the biographical sketches for your proposal. You must adhere to typeface and font-size requirements. After completing each Biographical Sketch, convert it to a PDF file to preserve its formatting before uploading it into your application using the "Add Attachment" button to the right of the "Attach Biographical Sketch" subheading. Two examples of biographical sketches, which are adapted from the sample that is provided by NIH, are included at the end of this chapter. There is one for established researchers and another for New/Early Stage Investigators. Despite these instructions and examples, our experience is that most applicants still make numerous small mistakes in the preparation of their research team's biographical sketches. They are completely avoidable mistakes. All you have to do is read and follow the instructions carefully. It is important to do so because, if your proposal is replete with many small mistakes that are clearly attributable to not reading and following instructions, it says something very negative to reviewers about your attention to detail – and what is research about other than attention to detail?

Education/Training Table. This part of the Biographical Sketch should begin with the baccalaureate and conclude with post-doctoral training, i.e., the entries should be in chronological order. A common mistake is to put post-doctoral training under Positions and Honors, rather than

in this table. Include enough information that it is clear which institutions were involved in your education/training and when. Make sure that both the month and year of completion, not just the year, are included in the table's MM/YY column. If fewer/additional rows/columns are needed in this Word table, use the "Table" dropdown from the toolbar to manipulate the layout, as needed. Vertical and horizontal lines can be moved left and right or up and down, respectively, by clicking on the relevant line and then dragging it to the desired new location.

Personal Statement. The purpose of the Biographical Sketch is to support feasibility of the project in the hands of the assembled research team. The Personal Statement is the most important contributor to reviewers' appreciation for that. In other words, you have the opportunity to tell reviewers why each member of the research team has been included. Accordingly, it is the most important contributor to evaluation of the INVESTIGATOR(S) core review criterion. It doesn't have to be long, but it does have to be comprehensive and relevant in describing each Senior/Key Person and Other Significant Contributor. *The Personal Statement for each Senior / Key person should be written in first person singular.* Begin with the person's role in the project. Follow with how the subject person's formal education, training and experience qualify and prepare him/her for that role. Early Stage Investigators who have recently completed a period of relevant post-doctoral training should briefly describe the research, what it produced that is relevant to this application, and who the post-doctoral mentor was. Call attention to mastery of relevant technical skills and the role the person had, if any, in generating preliminary data that accompany the proposal. Stipulate how participation of the individual assures access to relevant resources, equipment and/or subjects, if that is pertinent. If the person has worked and published in the past with other members of the research team, call attention to that. Management and administrative experience should be summarized for anyone who has the role of PD/PI. Previous extramural funding that is relevant to the current project should be summarized. New and Early Stage Investigators should call attention to that status in their Personal Statement. Mentors (e.g., for K-Award or Fellowship applications) should call attention to training experience and outcomes. An example of how this critically important paragraph should be written is provided at the end of this chapter.

Each non-PD/PI member of the research team should write his/her Personal Statement to reflect how s/he will complement what the PD/PI contributes. In other words, each such Personal Statement should not be about the attributes of that investigator, *per se*. Rather, it should be about how those attributes complement the PD/PI and the rest of the research team, thereby increasing the likelihood that the project will be successful.

Positions and Honors. Make these entries chronologically, concluding with your present position. Refer to the sample biographical sketches at the end of this chapter for examples of how this subsection should be configured. As will be seen, it is permissible to subdivide this part of the Biographical Sketch into subsections that are pertinent to its title.

Selected Peer-Reviewed Publications. These also should be presented chronologically. Only peer-reviewed publications that are published or in press should be included. That means no reviews, book chapters or published abstracts. Submitted and 'in-preparation' manuscripts are not allowed. Divide the section into the following two subsections: (i) Most relevant to the current application, and (ii) Additional recent publications of importance to the field. Include no more than 15 publications distributed between the two subsections.

Research Support. This section should be divided into two subsections: (1) Ongoing Research Support, and (2) Research Support Completed During the Last Three Years. Use the format for this section that is shown in the sample Biographical Sketch at the end of this chapter / on the

NIH website. The cutoff date for deciding whether completed support is too old to be included is three years from the date for submission of the proposal.

Research support should be presented from most to least relevant to the subject of the current proposal. In other words, it is not meant to be chronological, reverse chronological, or in order of the most to least important role (e.g., PI, Co-I, Consultant).

The purpose of the Research Support section of each Biographical Sketch is to contribute additional information about each participant's expertise and scientific accomplishments. If it is possible to do so, the scientific focus of each source of support and the investigator's role in it should be related to your project. In other words, existing and prior research support should be used to help reviewers better understand why the investigator in question has been asked to fill the specific role that is proposed for him/her in the current project.

A common error made in this section is failure to include all kinds of funding. All federal AND non-federal support should be included. For example, we are often asked if New Investigators should include their start-up funds. The answer is YES – absolutely YES – because such departmental or institutional funding is a tangible mark of institutional support and commitment. Remember that reviewers are told to look for evidence of institutional commitment when reviewing the applications of New Investigators. Another common error is to confuse this section with Current & Pending Support (“Other Support” – see section 1.8 of Part III of the *Application Guide*), where amounts and percentage effort associated with each source of support must be given. The purpose of the Other Support information is to check for overlap with other projects, which is very different from the purpose of Research Support section of the Biographical Sketch. Other Support – Current & Pending Support – information is submitted only after an applicant has been notified that his/her application is being considered for funding. In other words, it is submitted ‘just in time’ for an award to be made.

Tips on Preparation of the Biographical Sketch

To ensure that all of the biographical sketches are identical in format and typeface to the Principal Investigator's, we recommend the following approach. The PI should ask each member of the Senior/Key Personnel group, as well as Other Significant Contributors, to provide an electronic copy of the Biographical Sketch from his/her most recent grant application, along with an updated copy of his/her *curriculum vitae*, to include current and pending research support, and a Personal Statement written to support the proposal that is under development. The PI should review the Biographical Sketch and remove anything from it that is not relevant to the project being proposed. Next, edit the Personal Statement to maximize its relevance to the new project. Then, go through the c.v. and add to the Biographical Sketch any relevant information that was missing from the original, e.g., honors, relevant experience, and/or recent publications. After revisions have been completed, the biographical sketches should be retyped in the same format as the Principal Investigator's. Examples of the format we recommend, which are adapted from the sample Biographical Sketch that is available from the NIH website, http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx, appear at the end of this chapter. Finally, have each Senior/Key Person / Other Significant Contributor review and either approve or modify his/her Biographical Sketch.

Principal Investigator, Co-Investigators and Collaborators. The Principal Investigator is, of course, a member of the Senior/Key Person set. The same applies to the others if there are multiple PD/PIs (see discussion of when this is appropriate at the end of this chapter). Each

PD/PI must have a written Principal Investigator Assurance on file with his/her institution before an application is submitted (see section 2.14 of Part III of the *Application Guide*).

Co-investigators are also members of the Senior/Key Person set because they will have measurable person months invested in the project. Collaborators, on the other hand, will seldom have measurable effort associated with their participation. Therefore, they should almost always be included as Other Significant Contributors – those who have a key role but no measurable effort. Any individual without measurable effort must provide a letter of support with the application, which will be included by uploading it into sub-subsection 16 of subsection 2 of the *PHS 398 Research Plan* form (see Chapter 20 for details). *The PI should draft all letters of support him/herself*, because s/he knows better than anyone else why individuals have been asked to participate in the research project. The 'example' letter of support should be given to each Other Significant Contributor with the understanding that a letter 'like' the one you have prepared is needed. This usually will result in the Other Significant Contributor embellishing what you have written and, therefore, a final letter of support that is even stronger than the draft that you provided. At the worst, you will get your 'example' back verbatim on the Other Significant Contributor's letterhead. It will say exactly what you want it to say and the 'writer' will appreciate that you provided the example, because it will have saved the Other Significant Contributor time.

No one should be included as a member of the Senior/Key Person or Other-Significant-Contributor group unless s/he is proposed for a readily identifiable scientific purpose. Thus, including someone senior as a mark of respect or including an established investigator who duplicates the credentials of a junior member of the team is usually inappropriate. In the latter case, inclusion of the senior person could undermine the perception that the junior person is truly an independent investigator, especially if s/he is the Principal Investigator. Whether or not a person should be included will usually become crystal clear when the Personal Statement for that individual is written. If it is difficult to write credibly about how someone will contribute to the project's feasibility s/he probably shouldn't be included.

In preparing the publication lists of research-team members, remember that *three things are relevant*: (1) has the person been productive in the recent past; (2) what is the quality of his/her publications; and (3) are they relevant to what that person has been recruited to do in the proposed research program? A member of your research team who has few or no publications relevant to your proposal or who has not been publishing in the recent past probably will be considered as a 'weak link' by reviewers. You may, therefore, want to replace such an individual.

A New/Early Stage Investigator should be particularly diligent in preparing his/her Biographical Sketch, because the INVESTIGATOR(S) review criterion is a particularly high bar for him/her to clear. In particular, the extent and quality of the New/Early Stage Investigator's background and training should be highlighted in the Personal Statement, because there may not yet be much of a record of productivity to use as a gauge of past performance. Thus, if relevant, a New/Early Stage Investigator should consider including his/her dissertation as a peer-reviewed publication. If the dissertation abstract is publicly available via the Internet, the relevant URL should be included after the citation. If the dissertation abstract is not publicly available it can and should be included as an Appendix item. Either of these gestures will be seen as considerate of reviewers because of the time and effort that would otherwise have to be invested to access the dissertation abstract. An additional strategy is to accompany particularly strong or relevant entries in the list of publications of a New/Early Stage Investigator with a sentence or two that highlights for the reviewer why that(those) publication(s) is(are) relevant to the current proposal and, especially, how the work that produced those papers has helped to prepare the applicant to under-

take the work being proposed. Note that reprints of publicly available papers cannot be included in the application as Appendix material.

Include in the Biographical Sketch only information that is specifically relevant to the project being proposed. Never 'pad' a Biographical Sketch with extraneous entries, such as being included in 'Who's Who in American Biological Science in New England, 2009', or trivial ones, such as hobbies. This is an especially important point for New/Early Stage Investigators, who may try to increase the length of, i.e., 'pad,' their biographical sketches with such non-relevant entries. Instead, as mentioned above, find legitimate ways to highlight the quality of training, productivity during training, and the quality of material that has been produced to date. These are highly relevant ways for a New/Early Stage Investigator to 'flesh out' his/her Biographical Sketch.

If a member of the research team has had a gap in productivity, as reflected by absence of grant support, employment, and/or publications, we strongly recommend that the cause be addressed in the Personal Statement of his/her Biographical Sketch. For example, if the person had an extended illness or was mobilized for a term of military duty, the vast majority of reviewers will understand and be sympathetic. Simply explain the cause without being defensive about it. If this is not done, reviewers will wonder about the gap and, as a result, could potentially discount the person's value to the research team.

Consultants. These are individuals who have exceptional credentials in support of the proposed research program but will have only a limited commitment (usually intellectual). They can either be members of the Senior/Key Person set, if the extent of their effort is measurable or be included as an "Other Significant Contributor" if their involvement cannot be quantified. Regardless of their role in the project, a consultant's Biographical Sketch should be written to emphasize specific qualifications that are relevant to what s/he will do — for example, to act as an external advisor to a Program Project or as the provider of a specific kind of critical expertise for such a short time that it would be impractical and cost-ineffective for the Principal Investigator to develop it in his/her own laboratory. An example of the latter kind of consultant would be an outside evaluator. If the consultant is included as an Other Significant Contributor, you will need to draft a letter of commitment for him/her, as described above.

MULTIPLE PI LEADERSHIP PLAN

If you are offering multiple Principal Investigators for your project you must provide a Multiple PI Leadership Plan. It will be uploaded into line 10 of the *PHS 398 Research Plan* form. The location of this part of the application is shown at the top of the next page. Sample leadership plans are provided at http://grants.nih.gov/grants/multi_pi/sample_leadership_plans.pdf.

In our experience there is great misunderstanding among applicants regarding when it is appropriate to offer multiple PDs/Pis on a project. The problem is confusion between other agency's 'Co-PI' category, which does not exist at NIH and other Public Health Service agencies, and the 'multiple PI' concept. The policies and procedures related to multiple PDs/Pis are described in detail at http://grants.nih.gov/grants/multi_pi. A very helpful additional site is the one that provides answers to Frequently Asked Questions about the multiple PI/PD approach. It can be found at http://grants.nih.gov/grants/multi_pi/faq.htm#b10. The bottom line is that the project must be one that involves team science and the applicants must be able to offer strong scientific justification for electing to take the multiple-PD/PI approach. In other words, it would not be appropriate to simply assign PD/PI status to all co-investigators as a means of enhancing their status or attracting them onto the research team. Nor would it be justifiable to assign that title to a

senior member of the research team as a mark of respect. NIH makes clear in its instructions that multiple PD/PI applications will be the minority of those funded. If you are going to take this approach there must be a defensible scientific reason for doing so. For example, two disciplinarily different parts of the project or geographical separation of parts of the project. Otherwise, offering multiple PDs/PIs will seriously detract from your application during its review.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
////////////////////////////////////				
Other Research Plan Sections				
8. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
9. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
10. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
11. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
12. Letters of Support		Add Attachment	Delete Attachment	View Attachment
13. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
Appendix (if applicable)				
14. Appendix		Add Attachments	Remove Attachments	View Attachments

DEVELOPMENTAL STEPS FOR CHAPTER TWELVE:

1. Understand the instructions that guide preparation of biographical sketches.
2. Make a decision as to whether or not the multiple PD/PI approach is appropriate for your project – is it scientifically defensible? If so, develop a Multiple PI Leadership Plan.
3. Prepare your own Biographical Sketch exactly as instructed using the format suggested by the example at the end of this chapter.
4. Obtain an electronic copy of the most recent Biographical Sketch and updated *curriculum vitae* from each member of the Senior/Key Personnel and Other Significant Contributors set.
5. Ask each Senior/Key Person and Other Significant Contributor to send you a Personal Statement that is relevant to the application that you are developing.
6. Revise/update each Biographical Sketch, to include the individual Personal Statements. Ensure that each such Personal Statement is written in the first person and projects how the person's qualifications and expertise complement what the PD/PI contributes.
7. Have all of the biographical sketches retyped so that they appear alike, i.e., like yours.
8. Have members of the research team approve/modify their revised biographical sketches.
9. For each member of the Other Significant Contributor group (i.e., participants without measurable effort on the project), draft a letter of specific commitment for him/her (see creating Letters of Support, Chapter 20).

BIOGRAPHICAL SKETCH FORMAT PAGE

(Downloadable from http://grants.nih.gov/grants/funding/424/SF424R-R_biosketch_VerC.docx)

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

NOTE: This form is not 'protected' when it is downloaded as a 'Word' table. The number of rows can be expanded or contracted using the approach to modifying tables that is appropriate for your version of Word. Column width can be optimized by dragging vertical lines to the left or right.

If for some reason the form arrives 'protected,' you can 'unprotect' it by using the "Unprotect Document" function.

See the pages that follow for two examples of a Biographical Sketch, which have been adapted from the sample that is provided by NIH at http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx.

SAMPLE BIOGRAPHICAL SKETCH

Established Investigator

(Adapted from http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME Hunt, Virginia Lively		POSITION TITLE	
eRA COMMONS USER NAME (credential, e.g., agency login) huntvl		Associate Professor of Psychology	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

A. Personal Statement

My role in the proposed project is that of PD/PI. The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have a demonstrated record of accomplished and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

B. Positions and Honors

Positions and Employment

- 1998-2000 Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
- 2000-2002 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
- 2001-Present Consultant, Coastal Psychological Services, San Francisco, CA
- 2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
- 2005-Present Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

- 1995-Present Member, American Psychological Association
- 1998-Present Member, Gerontological Society of America
- 1998-Present Member, American Geriatrics Society
- 2000-Present Associate Editor, Psychology and Aging
- 2003-Present Board of Advisors, Senior Services of Eastern Missouri
- 2003-04 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
- 2005-09 NIH Risk, Adult Addictions Study Section, member

Honors

- 2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO
- 2005 Excellence in Teaching, Washington University, St. Louis, MO
- 2008 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Selected Peer-reviewed Publications#Selected from 42 peer-reviewed publications)#

Most relevant to the current application

1. Merrylye, R.J. & Hunt, V.L. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
2. Hunt, V.L., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. *International J. Geriatric Psychiatry*, 24(9), 1124-1135.
3. Hunt, V.L., Wiechelt, S.A. & Merrylye, R. (2008). Predicting the substance-abuse treatment needs of an aging population. *Amer. J. Pub. Hlth*, 45(2), 236-245. PMID: PMC9162292
4. Hunt, V.L., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. *Gerontology*, 46(3), 122-145.
5. Hunt, V.L. & Sher, K.A. (2009). Successful intervention models for older drug-abusers: Research across the life-span. *American Psychologist*, in press. NIHMSID: NIHMS99135

Additional recent publications of importance to the field

6. Gryczynski, J., Shaft, B.M., Merrylye, R., & Hunt, V.L. (2002). Community based participatory research with late-life addicts. *Amer. J. Alcohol and Drug Abuse*, 15(3), 222-238.
7. Shaft, B.M., Hunt, V.L., Merrylye, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. *Interntl J. Drug Policy*, 30(5), 46-58.
8. Hunt, V. L., Marks, A.E., Shaft, B.M., Merrylye, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. *J. Applied Gerontol.*, 28(2), 26-37.
9. Hunt, V.L., Merrylye, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. *J. Amer. Geriatrics Soc.*, 57(4), 15-23.

10. Hunt, V.L., Pour, B., Marks, A.E., Merryly, R. & Jensen, J.L. (2005). Aging out of methadone treatment. *Amer. J. Alcohol and Drug Abuse*, 15(6), 134-149.
11. Hunt, V.L., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2006). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMID: PMC9000292
12. Merryly, R. & Hunt, V.L. (2006). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: PMC9002364
13. Hunt, V.L., Jensen, J.L. & Merryly, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. *J. Amer. Geriatrics Soc.*, 60(6), 214-237.
14. Hunt, V.L. (2009). Intervening successfully with the older methadone patient. *Journal of Applied Gerontology*, 13(4), 67-79.
15. Hunt, V.L. (2009). Contrasting ethnicity with race in the older alcoholic. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, in press. (Manuscript included as Appendix #1) PMID: PMC Journal – In Press.

D. Research Support

Ongoing Research Support

R01 DA942367-03 Hunt (PI) 09/01/11-08/31/16
 Health trajectories and behavioral interventions among older substance abusers
 The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
 Role: PI

R01 MH922731-05 Merryly (PI) 07/15/10-06/30/15
 Physical disability, depression and substance abuse in the elderly
 The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.
 Role: Co-Investigator

Faculty Resources Grant, Washington University Hunt (PI) 08/15/13-08/14/15
 Opiate Addiction Database
 The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.
 Role: PI

Research Support Completed During the Last Three Years

K02 AG442898 Hunt (PI) 09/01/07-08/31/12
 Drug Abuse in the Elderly
 Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.
 Role: PI

R21 AA998075 Hunt (PI) 01/01/11-12/31/13
 Community-based intervention for alcohol abuse
 The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.
 Role: PI

SAMPLE BIOGRAPHICAL SKETCH

New/Early Stage Investigator

(Adapted from http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.doc)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME Hunt, Virginia Lively	POSITION TITLE Assistant Professor of Psychology
eRA COMMONS USER NAME (credential, e.g., agency login) huntvl	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/00	Psychology
University of Vermont	M.D.	05/06	Medicine
University of California, San Francisco	Residency	08/09	Psychiatry
University of California, San Francisco	Chief Resident	08/10	Psychiatry

A. Personal Statement

My role in this project is that of PD/PI. I am an Early Stage Investigator making my first R01 application. The objective of the proposed research is to understand how the interplay between drug abuse and the normal aging process can impact human health. The subjects will be a group of older drug users and matched controls. Specifically, I and my co-investigators plan to measure changes in cognitive ability and mental and physical health across a five-year period. I am highly motivated to pursue an academic research career. The base of expertise needed to carry out the proposed studies began to develop while I was under the mentorship of Dr. James Cantwell at the University of Vermont pursuing an honors-research elective. My training in research continued under the guidance of Dr. Cameron Carlucci at UC San Francisco during the third, research year of my residency. During that same time I conducted ethnographic and survey research and performed secondary data analysis on the psychological aspects of drug addiction. I also opted to take courses in research design, statistics, and attended a seminar program that was focused on the pathophysiology of the aging brain. Drs. Cantwell and Carlucci are both leading experts in disciplinary and technical areas that are directly related to the subject of this application. I continued to attend Dr. Carlucci's laboratory meetings and taught medical students and junior residents during the fourth year of my residency. I also attended two national research meetings during that year (National Society for Cognitive Research and the American Society for Experimental Psychiatry) and presented the results of my research at each. The ASEP poster presentation was selected as the best at the meeting. Both presentations matured into peer-reviewed research publications. My first fully independent publication is in press (see section C, below). Because of this background and experience I feel well prepared to carry out the research proposed in this application, which builds on the work that I initiated during the third year of my residency. In addition to having the necessary expertise to be successful with the proposed research, I offer leadership and administrative skills that were developed during my tenure as chief resident. These will enhance my effectiveness as a PD/PI, in my opinion. Finally, I have assembled a research team that includes two co-investigators (Drs. Gryczynski and Newlin) who provide essential expertise in cognition, gerontology and geriatrics that is complementary to my own (please refer to their biographical sketches). In summary, I have had a long-standing interest in research during my training, with demonstrated research

productivity during that time. I am qualified and prepared to conduct this research and look forward to having the opportunity to do so.

B. Positions and Honors

Positions and Employment

2010-2012 Lecturer, Department of Psychiatry, University of California, San Francisco

2012-Present Assistant Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

2001-Present Member, American Psychological Association

2006-Present Member, Gerontological Society of America

2009-Present Member, American Society for Experimental Psychiatry

Honors

2008 Award for best poster, American Society for Experimental Psychiatry

C. Selected Peer-Reviewed Publications:

Most relevant to the current application

1. Hunt, V.L., Jensen, J.L. & Carlucci, C. (2010). Substance abuse and mental health among community-dwelling elderly. *International Journal of Geriatric Psychiatry*, 24(9), 1124-1135.
2. Hunt, V.L., Wiechelt, S.A. & Carlucci, C. (2011). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMID: PMC9162292
3. Hunt, V.L. (2012). Successful intervention models for older drug-abusers: Research across the life-span. *American Psychologist*, in press. (Manuscript attached as Appendix #1)
NIHMSID: NIHMS99135

Additional recent publications of importance to the field

1. Merrylye, R., Marks, A.E., Venturi, R., Crenshaw, W., Hunt, V.L., Ratonian, A., Jensen, J.L., Shaft, B.M., and Carlucci, C. (2008) Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: PMC9002364
2. Carpenter, A.V., Gordon, P.X., Campbell, G.H., Hunt, V.L., Cramer, D.C., Fortner, P.C., and Carlucci, C. (2009). Intervening successfully with the older methadone patient. *Journal of Applied Gerontology*, 13(4), 67-79.

D. Research Support

Ongoing Research Support

Departmental Start-Up Grant, Washington University Hunt (PI) 10/01/12-09/30/14
Research Initiation Funds

The purpose of this grant is to set up the PI's laboratory and fund preliminary studies needed to be competitive for extramural research support..

Role: PI

Research Support Completed During the Last Three Years

None

SUPPLEMENT TO CHAPTER 12

Modification of the NIH Biographical Sketch: Potential Implications for Applicants

PURPOSE OF THIS SUPPLEMENT

BIG changes are being considered with respect to how the NIH Biographical Sketch is prepared and reviewed. These changes will impact, either positively or negatively, how the INVESTIGATOR core-review criterion is evaluated. Our purpose in writing this supplement is to inform NIH investigators of what can be expected. Such foreknowledge will potentially allow them to capitalize on the changes when they are made, thereby maximizing the positive/minimizing the negative impact that the modifications will have on their future applications.

BACKGROUND

On June 1, 2012 NIH released NOT-OD-12-115 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-115.html>), which alerted its readers to the fact that changes in the Biographical Sketch were being considered. It also sought input from members of the extramural community.

The Notice went on to state that the approaches being considered were ones that were already being used by the Howard Hughes Medical Institute. The link to HHMI included in the Notice is no longer active, but the requirement that applicants include descriptions of their most important research achievements and their most important scientific contributions/publications can be found in the Program Announcement for HHMI's 2015 Investigator Competition. It can be downloaded from <http://www.hhmi.org/programs/biomedical-research/investigator-program>.

Because NIH appears to be patterning the projected change in the Biographical Sketch, in part, on the kinds of information that HHMI seeks about applicants, we consider it highly instructive to read the entire referenced Program Announcement to understand fully what HHMI considers important in selecting investigators. Accordingly, we recommend that you do so.

On May 22, 2014 NIH updated their deliberative process with the publication of NOT-OD-14-091 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-091.html>). The Notice announces that a first round of piloting of the proposed changes has resulted in a new, preliminary format and instructions for the Biographical Sketch that have been posted online at <http://grants.nih.gov/grants/funding/424/index.htm> (and reproduced at the end of this Supplement). These will be the subject of a new round of pilot studies, which are expected to yield a final product that NIH believes "will offer reviewers a better picture of a researcher's accomplishments and capabilities, and will help illuminate the downstream effects of scientific discovery." Publication of the new Notice was accompanied by an issue of *Extramural Nexus – Rock Talk* (<http://nexus.od.nih.gov/all/2014/05/22/changes-to-the-biosketch/#>) in which Dr. Sally Rockey, NIH's Deputy Director for Extramural Research, projects that the changes will be finalized and required "for all grant applications received for FY 2016 funding and beyond (which generally refers to applications submitted in early 2015)."

NOT-OD-14-091 also projects that applicants will be able to include a link in the modified Biographical Sketch to their complete publication record, which can be set up in either the SciENcv (http://rbm.nih.gov/profile_project.htm) or My Bibliography (<http://www.ncbi.nlm.nih.gov/books/NBK53595>) public databases.

One additional piece of background information that we consider relevant is a position paper recently published in PNAS by Bruce Alberts, Marc W. Kirschner, Shirley Tilghman and Harold Varmus (Rescuing US biomedical research from its systemic flaws; <http://www.pnas.org/content/early/2014/04/09/1404402111.full.pdf>). The authors, one of whom (Varmus) is a former Director of the National Institutes of Health and the current Director of the National Cancer Institute, convincingly make the case that our system of training and funding academicians to do biological/biomedical research is broken and unsustainable. The ever-increasing number of investigators has outstripped the amount of funding that is available for research. This circumstance has led to what the authors refer to as "hypercompetition" for grant funds. One of their many potential solutions to this problem is: "The tools used [by reviewers] to judge past performance should be sharpened to identify the *strongest candidates for support* [Our emphasis]. The qualitative aspect of each candidate's major scientific achievements should receive more emphasis than the numbers and venues of publications."

OUR RECOMMENDATIONS

In our opinion, the proposed changes in NIH's Biographical Sketch should be seen through the prisms of Alberts et al.'s exceedingly important and thoughtful publication and the criteria used by the Howard Hughes Medical Institute to select their investigators. In other words, NIH has put applicants on notice that it is seeking to support only the strongest possible candidates with the relatively limited grant funds it now has available. While that has always been implied, current (and probably future) fiscal realities require a more explicit approach.

Substitution of "Contributions to Science" for "Selected Peer-Reviewed Publications" is the major change that is currently projected for the Biographical Sketch. As of now, the planned new section will consist of: (i) brief narratives of the applicant's scientific contributions; (ii) citation of up to four of the applicant's publications in support of each listed contribution; and (iii) a link to a complete list of the applicant's publications. We expect that the proposed Contributions to Science section, together with the related Personal Statement, will be the primary sources of information that future reviewers use to score the INVESTIGATOR core-review criterion.

Short-Term Strategy: Between Now and Adoption of the New Biographical Sketch

Whether you are an established or early stage investigator, now is the time to begin crafting how you will present yourself as a strong candidate for support. You have approximately one year from the date of this writing (June 2014) to do so. We recommend that you begin by creating a full listing of your publications in either "My Bibliography" (<http://www.ncbi.nlm.nih.gov/books/NBK53595>) or "SciENcv" (http://rbm.nih.gov/profile_project.htm). The latter is currently available in a 'beta' version (<https://nexus.od.nih.gov/all/2013/11/20/test-drive-sciencv>). Future iterations will allow applicants to create biographical sketches for other federal agencies.

Next steps will differ, depending on whether you are an early stage or established investigator.

Established Investigators

Inventory what you have contributed to your field, i.e., make a list of the vertical advances that your work has enabled. Create a title for each that reads like a newspaper headline: The fewest,

most informative words that will immediately attract interest. We recommend that you include a title, even though it is not a part of NIH's example (included at the end of this Supplement), because it will make the contribution's first impression on reviewers. To maximize its positive impact, the title should highlight the contribution and its importance (see Chapter 18 of this *Workbook*). Follow with a brief description of how the contribution was made and the role that you played in making it. Continue with a description of why the contribution was innovative, especially how your departure from the *status quo* opened new research and/or clinical horizons that otherwise would likely have remained unattainable (see Chapter 9). Next, describe why the contribution was significant, i.e., why it had positive impact on something that is important to NIH and its mission (also Chapter 9). Select up to four of your papers in support of each contribution.

Next, using a service like CiteTrack Alerts (<http://highwire.stanford.edu/help/citetrack>), determine who has referenced the publications that you have listed. If those investigators have built/are building on what you contributed, call attention to that fact, naming names and citing publications to increase the credibility of your assertion. Such citations (e.g., Smith et al., 2012 J. Exciting Results 358: 1422-1434) should be within the narrative paragraph, i.e., they should not be included among the list of your citations that supports your claim of a contribution.

Early Stage Investigators

If you are an ESI, you should do as much of what is listed in the paragraph, above, as you can. NIH takes the position that the new format will work to your advantage. For example, in her May 22, 2014 *Rock Talk* posting (see URL, above), Dr. Rockey states: "... this new format will give early career investigators a platform for describing and framing the significance of their contributions, which should help reviewers better understand their accomplishments without having to rely simply on a list of publications." We sincerely hope that she is right. But we are concerned that she may not be entirely correct. Early Stage Investigators (http://grants.nih.gov/grants/new_investigators/index.htm), especially those in the earliest stages of their career development, are unlikely to have as many contributions to highlight as established investigators will. In addition, ESIs may not have fully developed the skills needed to optimally present themselves as strong candidates for research support. If you find yourself in that position, now is the time to begin strengthening your marketability. First, if you have written a Ph.D. (or some other) dissertation but have not fully published its results in peer-reviewed journals, now is the time for you to do so. It should become one of your highest priorities! The same holds true for data that you have acquired, but not yet published, since entering your postdoctoral or first academic position. One of our other workbooks, *Writing for Biomedical Publication. A Publication Guide for Biomedical Scientists* (http://www.grantcentral.com/workbook_biomedical_publication.html), could be of assistance in helping you to do so. Second, you need to maximize your rate of publication. One way to do so is by trying to write your next manuscript well before you can actually submit it for publication. There is no better means, in our experience, to identify what is lacking, i.e., what is preventing you from submitting the manuscript for publication. Such an approach will help to sharpen your focus and reduce – even eliminate – tangential, unproductive research directions that you might otherwise pursue. Third, if you are concerned about your ability to 'sell' your contributions to reviewers, don't be shy: Seek help in developing those skills from more experienced colleagues/mentors. As a complement, we recommend that you use the approach to describing your contributions that we have described, above, in the last paragraph under Experienced Investigators.

Long-Term Strategies

Whether you are established or an Early Stage Investigator, if you haven't done so already, we

recommend that you identify a long-term goal that will vertically advance your field when it is attained. In other words, one that will yield a research continuum which is productive of the kind of scientific contribution(s) that NIH wants to see in the new Biographical Sketch.

If you are an Early Stage Investigator who is a postdoctoral fellow, by definition, you are in a mentoring relationship with an established investigator. Our recommendation is that both you and your mentor work to ensure that your research project has the potential to lead to a scientific contribution that will strengthen your Biographical Sketch, thereby helping to project you thereafter as a strong candidate for independent grant support. We also recommend that your postdoctoral project be the initial step in a continuum of research that you can take with you into your first academic position. The time to pursue other avenues of research is either after you have attained your initial long-term goal or when you have become sufficiently well established that you want to develop a second line of research and grant funding. The best time to do that, in our opinion, is approximately half-way through your first period of R01 support. Having two grants offset in that way helps to dampen the negative impact of a delayed or failed grant renewal.

PILOT BIOGRAPHICAL SKETCH AND INSTRUCTIONS

(Downloaded from <http://grants.nih.gov/grants/funding/424/index.htm>)

OMB No. 0925-0046 (Approved Through 5/31/2016)

BIOGRAPHICAL SKETCH—Pilot Format (To Be Used for Specific FOAs only)

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME		POSITION TITLE	
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contributions to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications that are relevant to that contribution. The description of each contribution should be no longer than one half page including figures and citations. Please also provide a URL to a full list of your published work as found in a publicly available digital database such as PubMed or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

NIH's EXAMPLE OF A COMPLETED PILOT BIOGRAPHICAL SKETCH

(Downloaded from <http://grants.nih.gov/grants/funding/424/index.htm>)

OMB No. 0925-0046 (Approved Through 5/31/2016)

BIOGRAPHICAL SKETCH—Pilot Format (To Be Used for Specific FOAs only)

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES**

NAME Hunt, Morgan Casey	POSITION TITLE		
eRA COMMONS USER NAME (credential, e.g., agency login) huntmc	Associate Professor of Psychology		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise

in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g., staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

1. Merrylye, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. *International Journal of Geriatric Psychiatry*, 24(9), 1124-1135.
3. Hunt, M.C., Wiechelt, S.A. & Merrylye, R. (2008). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMID: PMC9162292
4. Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. *Gerontology*, 46(3), 122-145.

B. Positions and Honors

Positions and Employment

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2007-	Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995-	Member, American Psychological Association
1998-	Member, Gerontological Society of America
1998-	Member, American Geriatrics Society
2000-	Associate Editor, <i>Psychology and Aging</i>
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-05	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11	NIH Risk, Adult Addictions Study Section, member

Honors

2003	Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004	Excellence in Teaching, Washington University, St. Louis, MO
2009	Award for Best Paper in Interdisciplinary Ethnography, International Ethnographic Society

C. Contributions to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers

to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.

- a. Gryczynski, J., Shaft, B.M., Merryly, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
 - b. Shaft, B.M., Hunt, M.C., Merryly, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. *International Journal of Drug Policy*, 30(5), 46-58.
 - c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryly, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. *Journal of Applied Gerontology*, 28(2), 26-37.
 - d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMID: PMC9000292
2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.
- a. Hunt, M.C., Merryly, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. *Journal of the American Geriatrics Society*, 57(4), 15-23.
 - b. Hunt, M.C., Pour, B., Marks, A.E., Merryly, R. & Jensen, J.L. (2005). Aging out of methadone treatment. *American Journal of Alcohol and Drug Abuse*, 15(6), 134-149.
 - c. Merryly, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: PMC9002364
3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy & commercial implications associated with these findings.
- a. Hunt, M.C. & Jensen, J.L. (2003). Morbidity among elderly substance abusers. *Journal of the Geriatrics*, 60(4), 45-61.
 - b. Hunt, M.C. & Pour, B. (2004). Methadone treatment and personal assessment. *Journal Drug Abuse*, 45(5), 15-26.
 - c. Merryly, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. *Journal of Ageing*, 54(1), 24-41. PMID: PMC9112304
 - d. Hunt, M.C., Jensen, J.L. & Merryly, R. (2008). *The aging addict: ethnographic profiles of the elderly drug user*. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:

<http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRDdWFmjWAO/?sort=date&direction=ascending>

Ongoing Research Support

R01 MH922731-05	Merryle (PI)	12/15/07-11/30/12
Physical disability, depression and substance abuse in the elderly		
The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.		
Role: Co-Investigator		

Faculty Resources Grant, Washington University	08/15/09-08/14/11
Opiate Addiction Database	
The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.	

Completed Research Support

K02 AG442898	Hunt (PI)	02/01/02-01/31/05
Drug Abuse in the Elderly		
Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.		
Role: PI		

R21 AA998075	Hunt (PI)	01/01/02-12/31/04
Community-based intervention for alcohol abuse		
The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.		
Role: PI		

CHAPTER 13

PHS 398 MODULAR BUDGET FORM and BUDGET JUSTIFICATIONS

GENERAL CONSIDERATIONS

NOTE: If your direct-cost budget exceeds \$250,000 per year (excluding F&A related to a contract or consortium), skip to the next chapter, because you must present a detailed, breakout budget using the SF424 R&R Budget form. Similarly, if you are submitting an application to the Agency for Healthcare Research and Quality, skip to the next chapter, because *AHRQ does not accept modular budgets*.

There is a difference – a BIG difference – between the budget for a modular grant application and one that is prepared using the traditional, breakout format. Because the difference is so great, we will treat each type of budget separately, with the modular approach described in this chapter and the breakout budget approach in the next. The former of these two is the budget format that should be used for most NIH research grants.

The modular approach to budgeting was introduced for two reasons: (1) reviewers were spending too much of the applicant's 15-to-20-minute window of opportunity at review-panel meetings haggling about 'nickle-and-dime' details of breakout budgets, and (2) even with applicants' best-faith efforts, detailed budgets were, at best, only rough approximations that often required extensive re-budgeting after grants were awarded. To overcome these problems, NIH adopted a modular budgeting format. The modular approach is used for all R03, R15, R21 and R34 applications, as well as R01s that have an annual direct cost budget $\leq$ \$250,000. The direct-cost budget for each year is presented as the sum of \$25,000 'modules,' which is what gives the approach its name. Salaries that are included as part of the module calculation must conform to NIH guidelines. FY 2013 salary maximums for faculty members and other non-students can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>. For FY 2013 stipends for graduate students and post-doctoral fellows, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-033.html>. A new set of guidelines is published each fiscal year; please refer to the one that is relevant to your application, e.g., NOT-OD-13-064 - for FY 2013.

The *PHS 398 Modular Budget* form is used to present a modular budget (see section 5.4 of the *Application Guide*). If you create a modular budget you must not complete the *R&R Budget* form that is detailed in section 4.7). In other words, one or the other of the two budget types should be prepared for an NIH application, but never both.

Although different, it is not difficult to create a modular budget. The three most important things that you can do to assure that you get it right are: (1) read the instructions; (2) Read the Instruc-

tions; and then (3) REALLY READ THE INSTRUCTIONS, both here and in the *Application Guide*.

CREATING A MODULAR BUDGET

Modular Budget Subcomponents

The form, below, is from the Grants.gov application package. It differs from the one in the SF424 *Application Guide* in that it has a "Next Period" button at the upper right corner (see arrow, below). After completing Budget Period 1, by clicking on that button you will open the form for Budget Period 2. Continue doing that until you have completed the number of budget periods for which you will be applying, up to five. If you are applying for less than five, simply leave the unused budget periods blank.

PHS 398 Modular Budget

OMB Number: 0925-0001

Budget Period: 1				
Start Date:		End Date:		Next Period
A. Direct Costs		Direct Cost less Consortium F&A 0.00 Consortium F&A Total Direct Costs 0.00		
B. Indirect Costs				
	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
1.				
2.				
3.				
4.				
Cognizant Agency (Agency Name, POC Name and Phone Number)				
Indirect Cost Rate Agreement Date		Total Indirect Costs		
C. Total Direct and Indirect Costs (A + B)		Funds Requested (\$) 0.00		

Cumulative Budget Information	
1. Total Costs, Entire Project Period	
Section A, Total Direct Cost less Consortium F&A for Entire Project Period	\$ 0.00
Section A, Total Consortium F&A for Entire Project Period	\$
Section A, Total Direct Costs for Entire Project Period	\$ 0.00
Section B, Total Indirect Costs for Entire Project Period	\$
Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period	\$ 0.00
2. Budget Justifications	
? Personnel Justification	Add Attachment Delete Attachment View Attachment
? Consortium Justification	Add Attachment Delete Attachment View Attachment
? Additional Narrative Justification	Add Attachment Delete Attachment View Attachment

Entering Your Budget Requests

Your budget for each year must be perceived by reviewers as consisting of the correct number of modules. Accordingly, we *strongly* recommend that you derive your budget figures by constructing an 'old-fashioned' breakout budget, not for submission, but for your own, internal use (Officials in your Sponsored Programs Office [or equivalent] may require that you provide them with such a breakout in support of your Modular budget; check this point with them.). If you decide to use a breakout budget as a step toward creating a modular budget, read and follow the instructions that are contained in the next chapter of this *Workbook*. When you have estimated the breakout cost for the first year, you should inflate that amount per year by 3-to-4% (the current estimate for the rate of inflation) compounded over the number of years that you are requesting. This approach will give you a figure for each of the years for which you are requesting support. By averaging those figures and selecting the module that is closest to the average you can set up the kind of modular budget that is preferred by NIH: the same number of modules across all years. With such an approach, because it is an average, you will have more money than you need in the first years and less than you need in the last years of the grant's life. Thus, you need to manage your money carefully with this approach: initially, you should spend only up to the amount of the breakout figure, carrying forward the 'extra' money from the early years, if you are allowed to do so, to make sure that you have what you need during the final years.

Even though NIH prefers that the number of modules requested be constant across all years, it is permissible for you to vary the number if there is a need to do so. If you elect to use this approach, you must justify such variation in the Budget Justifications subsection (see below).

There are three lettered subsections in each budget period (year) that must be completed:

Subsection A - Direct Costs. The first field under this subsection is labeled "Direct Cost less Consortium F&A." It should contain the sum of the direct costs for all performance sites *excluding* consortium F&A if your project includes such a relationship. The next field below requests "Consortium F&A." If you do not have a subaward or consortial relationship with another institution, leave this field blank. If you do have such an arrangement, the total of the Facilities and Administrative (indirect) costs of the other institution(s) must be entered in this field. The figures in these first two fields should then be added to produce the figure you will enter in the third field, "Total Direct Costs." Note that the F&A costs for subaward/consortial partners become part of your total direct costs. This is why you must carefully evaluate the cost/benefit of a large subaward or consortium: high direct costs at another institution will generate high F&A, which can dramatically increase your total direct-cost budget.

NOTE: It is important to appreciate that the F&A costs of other institutions are not considered when deciding whether to submit a modular or breakout budget. "Direct Cost less Consortium F&A", not "Total Direct Costs", are used to decide whether the annual budget of the proposed research exceeds \$250K.

Subsection B - Indirect Costs. This subsection pertains to your indirect costs, i.e., the figures entered here are independent of the indirect costs of other institutions (which are included in subsection A). These fields are labeled "Indirect Cost Type," "Indirect Cost Rate (%)," "Indirect Cost Base (\$)" and "Funds Requested (\$)." If you do not know which type or types of indirect costs should be entered in these fields (e.g., "Salary & Wages" or "Modified Total Direct

Costs”), and/or you are unsure of the indirect cost rate/base for each, consult either your unit’s financial administrator or your Sponsored Programs Office (or equivalent) for help in completing these fields.

Subsection C - Total Direct and Indirect Costs (A + B). As the title suggests, this subsection is simply the sum of the totals for subsections A and B.

Cumulative Budget Information

There are two numbered subsections at the bottom of the *PHS 398 Modular Budget form*.

Subsection 1 - Total Costs, Entire Budget Period. No input from you is required in this first subsection because it auto-populates as you complete the budget fields for each year in which you are requesting support. As a matter of fact, you cannot enter anything in this part of the form even if you would want to do so. If any of the five subtotals look out of line, check the accuracy of the related amounts in the individual budget years.

Subsection 2 - Budget Justifications. The narrative justification for each year of a modular budget is simplified, compared to what is required for a traditional, breakout, R&R budget (chapter 14). The format requires that you create a separate PDF file for each of the three categories of justification, “Personnel Justification,” “Consortium Justification,” and “Additional Narrative Justification.” Each justification needed (see following criteria) is then uploaded into the application using its related “Add Attachment” button.

NOTE: For detailed descriptions of how to justify budget categories, please refer to chapter 14, where examples of justifications are provided.

Personnel Justification. The current iteration of the *SF424 Application Guide* contains confusing instructions regarding how effort on a grant proposal should be projected. On page I-78, under section 4.7, which covers the R&R Budget Form, the instructions offer the following general statement: “NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort.” The specific instructions that follow then direct applicants to use person months to express effort in the R&R Budget Form. By contrast, the instructions for completing the Modular Budget Form, specifically those in section 5.4.2, under “Personnel Justification”, appear to mandate a very different approach: “List all personnel, including names, percent of effort and roles on the project.” In other words, there is no mention of person months in the instructions for completing the Personnel Justification (and also the Consortium Justification - see below). We were confused by this apparent discrepancy, to the extent that we contacted the Office of Policy for Extramural Research Administration, Division of Grants Policy, which you can do in similar circumstances by using the GrantsInfo@nih.gov e-mail address that is provided in section 2.16.3 of the *Guide*, “Finding Help For Application Preparation”. Within 24 hours, we received an e-mail message that assured us that effort in modular budgets should be expressed in person months, which is consistent with the general statement that appears on page I-78. Not only that, we were thanked for pointing out the apparent discrepancy and told that this apparent source of confusion would be eliminated from the next iteration of the *Guide*. If you ever encounter something similar in the *Guide*’s instructions, we urge you to take the same approach that we took here. Not only would it help to assure that your own proposal is written correctly, it would likely assist other members of the academic community in making their future applications.

The name, role (title in the project, e.g., Principal Investigator or Research Assistant), person months that will be invested in the project, and responsibilities of each person who will participate in the proposed research must be included, *whether s/he is salaried or not*. (The exception is anyone who is appointed at a consortial institution. Such personnel must be described separately, in the Consortium Justification – see below). *Neither salaries nor fringe benefits should be included*. However, the NIH-allowed salary maximums for faculty members, postdoctoral scholars and graduate students (see page 121 for the related URLs) should be factored into your choice of module - but without mentioning either individual salaries or fringe benefits in the Personnel Justification.

The person months committed by each individual is something that reviewers examine very carefully. Credibility can be lost by proposing either too little or too much. For example, New/Early Stage Investigators should offer more hands-on effort as Principal Investigator than an established investigator should. Reviewers appreciate that New/Early Stage Investigators often have many competing responsibilities when starting their academic career. Accordingly, they want tangible evidence of hands-on commitment to making the proposed research successful. We recommend, therefore, that New/Early Stage Investigators commit *at least* 3.6 person months (30% of overall effort) as PD/PI. Established investigators can get into trouble by proposing too little effort as PI. Even if there is a 'Number-2' person in the group who will handle the routine demands of the research program, we recommend that established investigators offer at least 1.2 person months (10% of effort), with 1.8 (15%) or 2.4 person months (20%) being much more credible. All other members of the research team should offer person months of effort that are commensurate with their research roles.

If someone is included who will invest effort, but who will not be paid from the grant for that effort, your justification for him/her should include that fact. *Without giving specific figures*, indicate what alternative source(s) will provide the salary support. It is important to include such information about cost-free effort because, without it, reviewers could erroneously conclude that too much of the annual direct-cost request is committed to personnel, i.e., that not enough is committed to support the research that is proposed.

It is usually very bad strategy to include To-Be-Recruited (a.k.a. To-Be-Announced, To-Be-Hired, To-Be-Identified) personnel of any kind on requests for periods of support less than three years. Reviewers know that, if the proposal is funded, it will take time to find and train the individual, which means that a substantial part of the first year will be lost in terms of the proposed research. That perception is deadly on a two-year proposal, e.g., for an R03 or R21.

The Personnel Justification should be formatted to have three subsections:

Senior/Key Personnel. As Principal Investigator, your name, effort and role in the project should be listed first. Thereafter, all other Senior/Key personnel (including other PDs/Pis, if any) should be listed, paid or not, in alphabetical order. Persons who are 'To Be Recruited' should be listed last. While it is possible to include TBR positions in this category, we strongly recommend against it. Reviewers will not be able to assess that person's qualifications, which is usually a major negative when the INVESTIGATOR core-review criterion is scored. Each person's position must be credible, both in terms of the relevance of his/her expertise and the person months devoted to the project. *Anyone whose participation cannot be credibly justified should be dropped from the project.*

Senior/Key Personnel include members of the research team who meet the generic definition of Senior/Key (remove the person and something becomes problematic) and who have person months invested in the project. The *Principal Investigator* is, of course, essential. S/he must be described under this subheading, therefore. Other PDs/PIs, if any, would be included here, as well. Justification for taking the multiple PD/PI approach, if you have done so, does not go here. Rather, such justification should be provided as part of the Multiple PI Leadership Plan, which is discussed at the end of chapter 12. *Co-Investigators* will almost always be included here, as well. They should be individuals who have intellectual involvement in the project, will routinely provide essential expertise, and will have person months (and often salary), on the application. To be listed as a Senior/Key Person, a *Collaborator* or *Consultant* would have to have time invested in the project that is quantifiable. This is usually not the case, so they are rarely listed under the Senior/Key Personnel category.

Other Significant Contributors should be individuals who will provide an essential service or technology, but who will have no person months invested in the project. For example, an OSC might be someone who will provide technical backup if trouble with a demanding method develops or will provide a critically needed reagent, but nothing more. This is the category under which most *Collaborators* and *Consultants* will usually be justified. Collaborators will rarely have measurable time invested, so they are almost always classified as Other Significant Contributors. An individual who will provide critical, but limited, intellectual input for only a short period of time (not measurable in person months) we recommend be listed as a Consultant. In most cases, Consultants should be justified on the basis that it is neither cost- nor time-effective to create the needed expertise within the research team.

Other Personnel. Students (undergraduate and graduate), post-doctoral research fellows and technical staff should be justified under this heading. Even though these individuals will almost always have measurable time invested in the project it is not appropriate to include them under the Senior/Key Personnel category, because loss of such an individual will rarely cause a part of the project to become problematic; they can be replaced relatively easily.

With respect to budgeting for undergraduate and graduate students, they should be included in most research grants only if they will make a credible research contribution to the project. Training of students in research is supported at NIH by individual and training-grant fellowships, not through research grants. Therefore, unlike what is appropriate for proposals to the National Science Foundation, students should not be included on most NIH research grants purely as a means of training them: 'R' (research) grant mechanisms support research, not training. Given that fact, if you include a graduate student in the budget for an R01 (and most other R-series activity codes), you should emphasize in your justification of him/her that you have requested support only for time devoted to research, i.e., that classroom work and similar training will not be supported by the grant. The exception is the R15, which has as one of its purposes exposing undergraduate and professional students to biomedical research. You are eligible to submit an R15 if your institution is not listed as ineligible; see http://grants.nih.gov/grants/funding/area_ineligible_list_2013.pdf. If you are eligible, it would be particularly important to include students, especially undergraduates, in your project. However, as noted earlier, the R15 must be seen as an exception. Students included in the budget of any research project should be named, if at all possible, and their effort described in the Personnel Justification, together with specifics regarding what each will contribute to the research effort.

Post-doctoral research scholars will almost always be justified under this category. If a post-doc is senior enough to have developed expertise that is critical to the project, you can elect to include him/her as a member of the Senior/Key Personnel set, primarily so that his/

her *Biographical Sketch* will accompany the application. But remember that senior post-docs will likely be moving on soon, which means that you will have to address, as part of the justification, how a member of the Senior/Key Personnel set will be replaced when that time comes. A better strategy is to include the post-doc here, in the Personnel Justification, together with a summary of the person's credentials in his/her justification.

For technical personnel, their participation clearly must be relevant. The specifics that make them relevant, e.g., training, job skills, experience, should be detailed in your justification. Even though they will have effort (and in most cases salary) on the application, technicians are almost never included in the Senior/Key Person category. The reason is the same as for students and post-doctoral research fellows: they can be replaced in most cases relatively easily. However, if a technician has a skill that would be exceptionally difficult to replace, then you may be justified in making him/her a member of the Senior/Key Person set, in which case a Biographical Sketch that justifies such inclusion must be included.

General-purpose personnel, e.g., administrative assistants, secretaries and clerical personnel, are usually not justifiable, even if they will be typing manuscripts, purchase orders, and other things that are related to the project. Such general-purpose personnel will almost always be considered the responsibility of the applicant's institution, i.e., part of institutional commitment that is supported by F&A costs that your grant will earn after it is funded. If you need to include a person who will be doing clerical or secretarial work, we recommend that you give him/her a less vulnerable title than 'clerk' or 'secretary,' e.g., 'program coordinator', and de-emphasize duties in your justification that would likely cause him/her to be classified as 'general purpose.'

All applications will have a Personnel Justification. Create it as a separate file. To upload it into your application, convert and save it as a PDF file. Click the "Add Attachment" button to the right of the "Personnel Justification" field under the "Budget Justifications" subsection of the "Cumulative Budget Information" subcomponent. Browse to where the "Personnel Justification" file is saved, click on the file name to select it, and then hit "Open" to upload it into the application.

Consortium Justification. If you have no subcontractual or consortial relationships, leave this field blank. If you do have such relationships, this is where you must justify them. The organization(s) with which you have a relationship that is relevant to the proposed research project should be named, along with the specific investigator(s) there who will be involved. The person months of effort and role for each person at the other institution(s) should be described, but neither the salary nor the fringe benefits should be included. The institution(s) should be designated as either foreign or domestic. Such designation is required, because F&A costs payable to a foreign institution are legislatively different than what can be paid to a domestic institution. The estimated total cost (direct costs + F&A) of the relationship, *rounded off to the closest \$1,000*, should be provided as part of the justification.

Create "Consortium Justification" as a separate file if you have such a relationship to justify. Upload it by following the instructions at the end of the preceding subsection, with the exception that you should use the "Add Attachment" button to the right of the "Consortium Justification" field under the "Budget Justifications" subsection of the Cumulative Budget Information" subcomponent.

Additional Narrative Justification. If you increase (or decrease) the Budget for any year by one or more modules, that change must be explained and justified in the third, "Additional

Narrative Justification," field of the Budget Justifications subsection. For example, the shift in modules requested might be due to adding or eliminating a salaried participant, entering into or exiting from a subaward/consortial agreement, or proposing the purchase of equipment (acquisition cost $\geq$ \$5K). Without giving figures, the relevant change should be denoted and justified as the cause of the variation in the number of modules requested. In the case of adding or subtracting personnel, you would also include that information in the "Personnel Justification," i.e., the name, person months of effort devoted to the project, and role of each person added or subtracted. The same approach would be used if entry into or exit from a consortium were responsible for the variation: the consortium would be described in the "Consortium Justification" subsection and the need to enter into/exit from it justified here as the cause of the related change in modules requested. Purchase of equipment is usually a one-time only event and occurs most often in the first year. The need to purchase the equipment would be offered as the basis for the change in modules requested. Full, objective description of the equipment should be provided, but without the cost of purchase.

The justification must be a scientifically based. In other words, for an R21 in which you can request up to \$275K distributed over two years, you could not offer that the reason for the year-one request for \$150K and the \$125K budgeted for year two is because it is impossible to divide \$275K equally in \$25K modules between years one and two. You would either have to request a total of \$250K, which can be divided equally, or provide a scientific justification for the higher number of modules requested in year one of the \$275K total direct-cost budget.

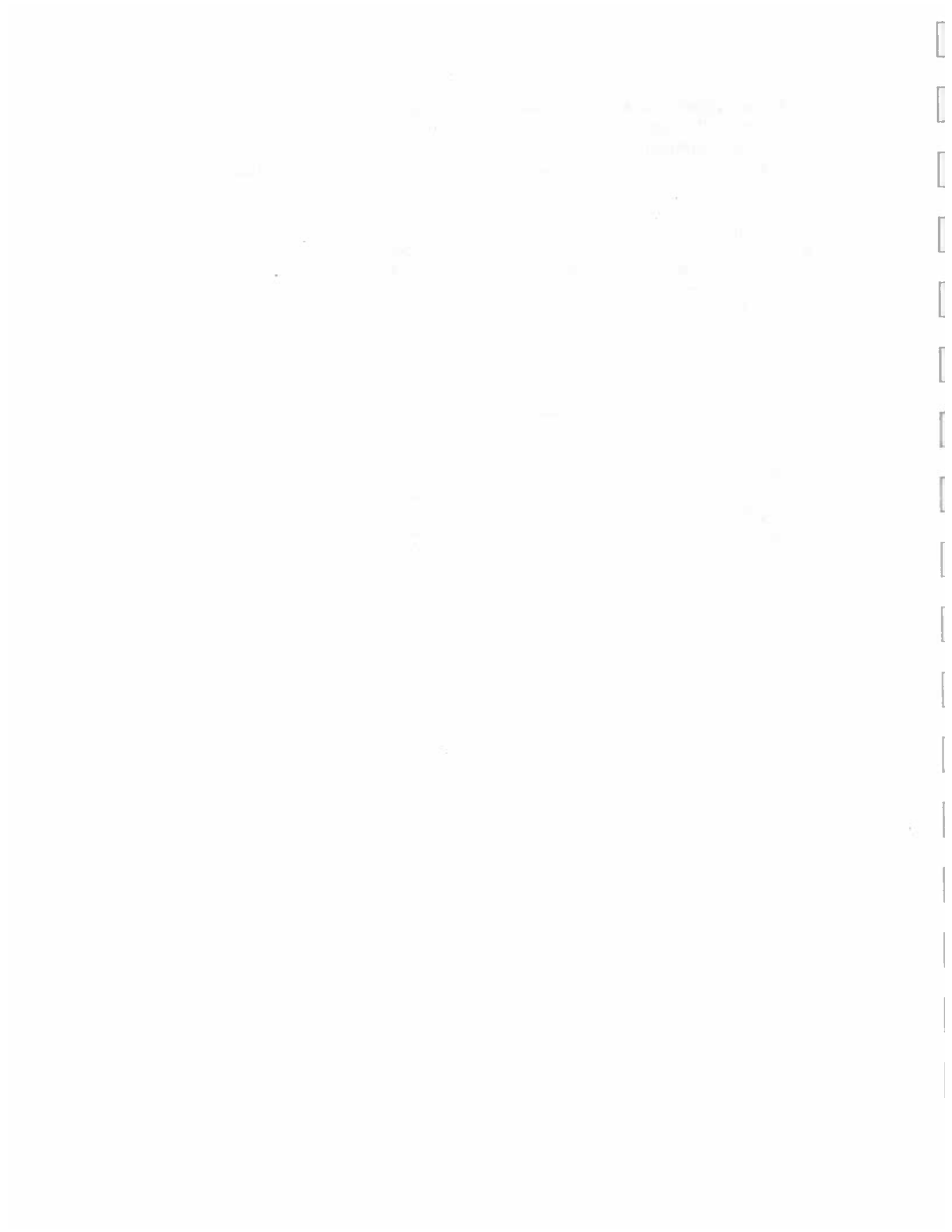
If there are year-to-year changes in indirect costs created, for example, by purchasing equipment when using the Modified Total Direct Costs approach to calculating indirect costs, such differences need to be justified in the "Additional Narrative Justification." In the example used here you would simply state that the difference is attributable to the purchase of equipment in whichever year.

Create the "Additional Narrative Justification" subsection as a separate file and upload it using the "Add Attachment" button to the right of the "Additional Narrative Justification" field.

DEVELOPMENTAL STEPS FOR CHAPTER THIRTEEN:

1. Decide whether you need to use the Modular Budget form or the detailed *R&R Budget* form for your application. AHRQ applications use only the latter form.
2. Know what the allowable salary maximums are for the fiscal year in which you are applying.
3. Create a first-year, detailed direct-costs breakout budget for your own, internal use, even though you will be submitting a Modular budget.
4. Currently, applicants are not allowed to increase salaries (and most costs) each year by the cost of inflation (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-064.html>). Special needs, such as for equipment and/or additional personnel, will continue to be considered.
5. Do not request 'To-Be-Recruited' personnel for grants with a duration of less than three years.

6. Either: (1) average across all years and pick the next-highest \$25,000 module that is closest to the average figure, or (2) choose the approach of varying the number of modules requested each year.
7. Enter the annual direct costs, indirect costs, and total direct and indirect costs for each year of support being requested.
8. Check to ensure that all categories of the auto-populated Total Costs - Entire Budget Period subsection are accurate in the "Cumulative Budget Information" subcomponent.
9. Prepare the Personnel Justification. Include all personnel, whether salaried from the grant or not, except for those who are at other, consortial institutions. Include name, project title, person months of effort, and role in the project. Do not include salaries or fringe benefits. Convert the file to PDF and upload it into the Budget Justifications subsection using the "Add Attachment" button opposite the "Personnel Justification" field.
10. Ensure that justification of undergraduate and graduate students is related to their research contribution, not training. Do not request support on a research grant for the didactic phases of graduate-student training.
11. Justify any consortial or contractual relationships in the "Consortium Justification".
12. Describe consortial personnel in this justification, not in the Personnel Justification. Upload the related PDF file using the "Add Attachment" button opposite the "Consortium Justification" field.
13. Scientifically justify any other items (e.g., changes in number of modules or indirect costs requested) by uploading an appropriate PDF file using the "Add Attachment" button opposite the "Additional Narrative Justification" field.



CHAPTER 14

SF 424 R & R [BREAKOUT] BUDGET COMPONENT and SUBAWARD/CONSORTIAL BUDGET

NOTE: This chapter complements sections 4.7 and 4.8 of the *PHS SF 424 (R&R) Application Guide*.

As noted in chapter 13, the modular approach to budgeting is required for R03, R15, R21 and R34 applications, as well as for R01s that have an annual direct-cost budget $\leq$ \$250,000. Those in excess of \$250,000 and all AHRQ grant applications, require that the *R&R Budget* component of the PHS SF424 application forms package be used to present a detailed, breakout budget.

With respect to credibility, remember that you can lose it by proposing *either* too much or too little, and that once *any* figure becomes suspect, *all* will be scrutinized more closely. What you must strive for is a budget that is so well justified that it will be readily accepted as credible by your reviewers without discussion.

Annual budgets in excess of \$500,000 must be pre-approved by relevant NIH program staff before the application is submitted.

The *R&R Budget* form consists of three data-entry screens (Sections A and B – personnel; Sections C through E – equipment, travel and participant/trainee support; and Sections F through K – other direct costs, total direct costs, fees, and budget justification) and a Cumulative Budget page. Each of the first three data-entry screens begins with organizational information that requires no comment here, with one exception: “Budget Type.” If there are no subawards or consortia, check “Project.” If subawardees or consortial partners are included in the proposal, and they will perform a “substantive portion” of the work that is proposed, then the “Subaward / Consortium” block should be checked and the *R&R Subaward Budget Attachment(s)* form should be completed (see instructions for doing so at the end of this chapter).

A detailed budget for each year of requested support must be prepared. This is accomplished by completing all of the required information (marked with an asterisk) on the three data-entry screens for the first budget period. Doing so will activate the “Next Period” button at the upper right of data-entry-screen three, after which entries for the next budget period can be made. If you are not requesting funds in a required category, enter “0” or the “Next Period” button will not activate. With one exception, you will repeat this process until a budget has been created for each of the years for which support is being requested. The exception is the Budget Justification (section K) for budget-period 1, which must be for all years of support that are requested (see details, below).

SECTIONS A and B – Personnel (data-entry screen below)

Personnel is usually the most costly part of a detailed budget — often 65-to-80% of the total funds requested. It is, therefore, the part of the budget to which reviewers will turn first if they feel that the overall budget is excessive. That is why justification of each position must be extensive and credible (see section K, Budget Justification).

This part of the application consists of two subsections, "Senior / Key Person" and "Other Personnel." The form shown below is from the Grants.gov application package, not the *Application Guide*. Note the "Delete Period" button at the upper right of the form and the "Add" buttons near the end of sections A and B. They are not seen in the form that is shown in the *Guide*.

General Comments

The Senior/Key Person category should include all members of the research team without whom some part of the proposed research would become problematic. In other

RESEARCH & RELATED BUDGET - Budget Period 1
OMB Number 4040-0001
Expiration Date: 6/30/2016

ORGANIZATIONAL DUNS: Enter name of Organization:

Budget Type: ☐ Project ☐ Subaward/Consortium Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			

Project Role:

Additional Senior Key Persons:

Total Funds requested for all Senior Key Persons in the attached file:

Total Senior/Key Person:

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

Total Other Personnel:

Total Salary, Wages and Fringe Benefits (A+B):

words, they contribute to the development or execution of the research in a substantive, measurable way, whether salary support is requested or not. All of the individuals who are included in the earlier "Senior/Key Person Profile(s)" component, i.e., those who have a Biographical Sketch accompanying the proposal, should be listed in section A. Other Significant Contributors, who by definition have no measurable effort but who contribute substantively to the research effort in some other measurable way (e.g., providing access to an essential technology), should also be included here. Consultants – even those who otherwise meet the definition of a Senior/

Key Person should not be included here because such individuals will be listed in the third data-entry screen, under subsection F.3, "Consultant Services." The second, "Other Personnel" section (B) should include everyone else (e.g., most post-doctoral scholars, students and technicians).

The most vulnerable part of a personnel budget is the TBR (To-Be-Recruited; also called TBA, To-Be-Announced, or TBI, To-Be-Identified) participant. Such positions are especially concerning to reviewers if they are associated with expertise without which some part of the Research Plan would become problematic. For this reason, it is our recommendation that you not consider submitting a proposal until you have the full complement of Senior/Key Personnel in place. If the duration of support requested is relatively short, e.g., two years, even TBRs included under section B, "Other Personnel," would be viewed with particular skepticism; there just isn't enough time to recruit and train someone. In addition to these reasons, TBR positions are vulnerable because reviewers have a tendency to think that, if there is no one already identified for the position, there is no 'guilt' associated with cutting it, i.e., no one will be put out of a job. For all of these reasons, if you include a 'TBR' request it would have to be justified in section K even more compellingly than if there were a name on the line. A more certain strategy is to figure out some way to include the name of a real person. For example, you may have a post-doctoral research associate who is included in the "Other Personnel" section, but you know that s/he will be leaving in four months, i.e., before the proposed research will be funded. Even so, you should use his/her name for that position. That allows you to present the credentials of the post-doc who will be leaving as part of the justification of the position. You will, of course, explain in the Budget Justification that s/he will be leaving. However, you would be able to say that you will replace him/her with someone who has equivalent qualifications. Such an approach is much more likely to succeed, in our opinion, than simply listing the position as "TBR." Another approach would be to use start-up funds to hire such a person, with the intention of switching him/her to the grant after it is awarded. Still another strategy would be to have your department/institution 'invest' in your research project by providing the salary of a needed person until you can assume responsibility for it using grant funds. Either of the two preceding approaches should be highlighted by New/Early Stage Investigators as tangible evidence of institutional commitment.

Senior / Key Personnel (section A)

Room is provided in section A for the PD/PI. Up to seven additional persons can be uploaded using the "Add Additional Key Person" button. Begin with those who have measurable effort. Upload them in alphabetical order. Other Significant Contributors – individuals without measurable effort – should be listed in alphabetical order after those with measurable effort are listed. If there are more than eight persons who qualify to be listed under section A use the "Additional Senior Key Persons" field that is provided at the end of the section. To do so, create a single PDF attachment that includes the same information for additional senior/key persons that is required for the first eight and upload it using the "Add Attachment" button. Total the funds requested on the attachment, and enter that figure in the field to the right of where the "Additional Senior Key Persons" attachment is uploaded, in the field labeled, "Total Funds requested for all Senior Key Persons in the attached file". Complete this part of the proposal by entering the total of funds requested for Senior/Key Persons, up to 8, plus what is requested for additional Senior/Key Persons listed in the attachment, if any, in the "Total Senior/Key Person" field.

Including a well-known Co-Investigator or an additional Principal Investigator, the latter as part of a multiple-PI approach, who has expertise similar to that of a less well-known Principal Investigator is usually a strategic mistake. Doing so can undercut the perception that

the PI is fully independent and capable of undertaking/overseeing the proposed research. Similarly, a PI who is a New/Early Stage Investigator can undermine the perception of his/her independence by proposing a former mentor in a substantive intellectual role, e.g., Co-Investigator. Including a former mentor in a minor way (e.g., a collaborator who would provide access to a reagent or patient population), especially if s/he is at a different institution than the PI, is usually not a problem, but including such a person in an intellectual capacity can be, and often is, disastrous.

Other Personnel (section B).

This section has four pre-set categories, one of which is devoted to post-doctoral associates and two others that pertain to different kinds of students. The fourth covers secretarial/clerical personnel. The blank fields arranged horizontally under the "Secretarial/Clerical" fields, coupled with the "Add Additional Other Personnel" button allow you to create your own 'special-purpose' Other Personnel categories, as needed.

The left column under Other Personnel allows you to enter the number of individuals in each of the categories.

Post-doctoral associates will usually be listed under section B. If you have included a post-doctoral researcher under section A, Senior/Key Person (which would require a Biographical Sketch for him/her), do not include that person in the number of post-doctoral scholars listed in section B.

Administrative assistants, secretaries, and other kinds of clerical personnel are generally considered to be 'general-purpose.' As such, their support is usually seen by reviewers and program staff as the responsibility of your institution, because their salaries are almost always covered as part of the indirect costs that your grant will earn for the institution, in addition to what you merit for research. Thus, even if such persons are doing things that are specifically related to the proposed project, such as preparing purchase orders and/or manuscripts, they should not be included in the budget. Administrative/clerical persons can only be included if they are dedicated to some facet of the research, such as patient accrual. Even then, it is safest to give such persons a title that is other than a general-purpose one, e.g., 'Patient Coordinator'. Taking that approach would allow you to include him/her under a special-purpose category that you would create under subsection B.

Note that the names of Other Personnel are not included on the data-entry screen. Rather, entries should reflect only the "Project Role." Thus, you might have one 'Patient Coordinator' and three 'Collaborators.' The names and specific contributions of these individuals would be included in the third data-entry screen, under section K, "Budget Justification."

Fields Common to Sections A & B.

There are fields on the right side of sections A & B that are common to each. They pertain to the person months invested and the associated salaries/fringe benefits that are associated with each individual.

Base Salary. It is not necessary that a person's annual base salary be included; this field can be left blank if you choose to do so. However, if you do not include someone's base salary in the application, you will be required to provide that information to PHS staff at a later time before an award can be made.

Person Months. These are either calendar months or months that are distributed on the basis of the academic year and summer months. If a person's / category's commitment of effort is constant month-to-month, use the "Cal. Months" field to enter the number of person months that will be invested. If effort committed will increase during the summer, compared to months of the academic year, enter nothing in the "Cal. Months" field and distribute effort as person months proportionately between the "Acad. Months" and "Sum. Months" fields. Additional help in understanding and calculating person months can be found at: http://grants2.nih.gov/grants/policy/person_months_faqs.htm and http://grants2.nih.gov/grants/policy/person_months_conversion_chart.xls, respectively.

Requested Salary must take into account the maximums that are allowable by NIH (FY 2013 salary maximums for faculty members and other non-students can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>. For FY 2013 stipends for graduate students and post-doctoral fellows, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-033.html>). A new set of guidelines is published each fiscal year, e.g., NOT-13-064 for FY 2013.

We recommend that you request salary that is proportional to effort even if you have a 'hard-money' source of support available – providing that there is an appropriate 'safety net' to replace your hard-money-salary support should your grant not be renewed at some later time. First, this guarantees that research time supported by the grant is protected; if you are paying for it, it's yours. Second, you may be able to negotiate with your administration that the salary money that is freed up be shared with you (e.g., part to you and part to your department or college). The funds made available by this approach could be sufficient for you to hire an additional technician or post-doctoral research fellow, for example.

It is possible to request less salary for an individual than would be expected from a strict percent-of-effort apportionment. If you do make such a request, an explanation for that approach should be provided in your justification (see section K, below).

Fringe Benefits. Be certain that you calculate fringe benefits for each personnel category appropriately. If you don't, your credibility with reviewers will suffer. For example, reviewers will know that graduate students do not have fringe benefits that are comparable to those of faculty members. Assure reviewers by stipulating what formulas were used when you justify the requests for fringe benefits in section K.

Funds Requested. These are straightforward summations of the salaries and fringe benefits requested for Senior/Key Persons and Other Personnel. The final field on the first data-entry page is the grand total of all personnel funds requested.

Joint University and Department of Veterans Affairs Appointments. Special instructions are provided in the *PHS SF 424 (R&R) Application Guide* (page I-81 & -82) for personnel who have joint university/V.A. appointments. Those instructions are complemented by the information and example at: http://grants2.nih.gov/grants/policy/person_months_faqs.htm#q16, FAQ #8.

SECTIONS C (Equipment), D (Travel) and E (Participant/Trainee Support) [relevant form is at the top of the next page]

The data-entry screen reproduced, below, from the Grants.gov application kit is used to upload information on equipment and travel. It is also used to upload information about participant/trainee support costs; however, the latter are not relevant for most kinds of PHS applications.

Equipment (section C)

Tip: R&R Budget form definition of what constitutes equipment: "an item of property that has an acquisition cost of \$5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year."

The "Equipment" category is vulnerable to budget cuts. Nothing should be included in section C, therefore, that does not qualify as 'equipment.' In other words, the definition given in the text box, above, should be applied. Notice that the definition is echoed at the top of the data-entry sheet, but not correctly. It should read \$5,000 or more. If you try to enter an amount less than \$5,000 it will be disallowed. Small items of equipment (cost <\$5,000), should be requested and justified under "Materials and Supplies". The latter category, which is included under section F, "Other Direct Costs," is much less subject to being cut. Accordingly, if you find that buying a full set of items equals or exceeds \$5,000, don't buy the set. Instead, purchase each item separately, which allows the request to be made under Materials and Supplies.

C. Equipment Description

List items and dollar amount for each item exceeding \$5,000

Equipment Item	Funds Requested (\$)
☒	
Add Additional Equipment	
Additional Equipment: Add Attachment Delete Attachment View Attachment	
Total funds requested for all equipment listed in the attached file	
Total Equipment	

D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested (\$)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees	
Total Participant/Trainee Support Costs	

If you want to request more than one piece of equipment, click on the "Add Additional Equipment" button (arrow) and a new line will open. If you need to exceed the form's capacity of ten lines, you can make additional requests on a separate PDF file, which would be uploaded into the "Additional Equipment" field. The total cost of items above ten is then entered in the field above the "Total Equipment" field, into which you would enter your entire equipment request.

In estimating the cost of each item, make certain that the costs of shipping and any service or maintenance agreements are included in your request for funds. Such costs should be made here, not under "Other Direct Costs" in section F.

Equipment requested should be complementary to what has already been provided by your institution. In other words, if you are just getting started, you should not expect NIH to provide all of the equipment needed to set up your research program. That is your institution's responsibility. Whether you have been provided a basic equipment package will be used as one means of assessing institutional commitment – or lack thereof – to you and your research program. This is an especially important fact if you are a New/Early Stage Investigator.

Just as there are 'general-purpose' categories of personnel (e.g., secretarial and clerical positions), there are categories of equipment that are considered 'general purpose' and, therefore, the responsibility of the institution. Items such as a personal laptop computer, even if used in the project, will almost surely be cut. The exception is a computer that is dedicated to some aspect of the research, e.g., one that is dedicated to running a piece of equipment.

Travel (section D).

This is one of the very few sections for which reviewers will often have a predetermined figure in mind. Unfortunately, this amount is usually significantly less than the real cost of the proposed travel. Therefore, unless you either have supplementary source of travel funds or are willing to re-budget from another category, you need to provide the kind of objective justification in Section K (see below) that will encourage reviewers to recommend approval of your full request. Foreign travel is particularly in need of compelling justification.

Participant/Trainee Support Costs (section E).

This section should be left blank in almost all cases. If you are responding to a Funding Opportunity Announcement that requires that this section be completed then, of course, do so. Even though line E.1 would appear to be where things like tuition remission for graduate students should be included, those costs should not be entered here. They will be included under the next, "Other Direct Costs", section (see below).

SECTIONS F (Other Direct Costs), G (Direct Costs), H (Indirect Costs), I (Total Direct and Indirect Costs), J (Fee), and K (Budget Justification) [relevant form is at the top of the next page]

The data-entry form on the next page is reproduced from the Grants.gov application kit. The "Add Period" button at the lower right is not shown in the *Application Guide*. It is for the purpose of adding an additional budget period.

Other Direct Costs (section F).

All that is required on each line (1 through 7) of section F is the total amount requested for each of those supply categories. Lines 8 through 10 allow you to create additional categories, which also require only the total funds requested. Thus, as with "Equipment", thorough justification (in section K) of how these amounts were reached is essential if cuts are to be avoided. We recommend that you enter a '0' in the field at the right of any line that is not associated with a budget request.

Materials and Supplies. Each supply category must have at least \$1,000 in it to justify making it a separate itemization in your Budget Justification. Make certain that *all* costs are included. An example of a cost that is often overlooked is shipping charges. If you are using

F. Other Direct Costs				Funds Requested (\$)
1.	Materials and Supplies			
2.	Publication Costs			
3.	Consultant Services			
4.	ADP/Computer Services			
5.	Subawards/Consortium/Contractual Costs			
6.	Equipment or Facility Rental/User Fees			
7.	Alterations and Renovations			
8.				
9.				
10.				
Total Other Direct Costs				

G. Direct Costs		Funds Requested (\$)
Total Direct Costs (A thru F)		

H. Indirect Costs			
Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
☐ ☐			
Add Additional Indirect Cost			
Total Indirect Costs			

I. Total Direct and Indirect Costs		Funds Requested (\$)
Total Direct and Indirect Institutional Costs (G + H)		

J. Fee		Funds Requested (\$)

K. Budget Justification			
(Only attach one file)		Add Attachment	Delete Attachment
			View Attachment
Add Period			

animals in your project, this is where the cost of their purchase is included. The cost of their maintenance should be included later, on one of lines 8-10.

Publication Costs. The costs associated with publication, which can be a *significant* expense, need to be included here, complemented by detailed justification in section K. Make sure that you include a substantial, but reasonable, amount in this category, because dissemination of results through publication will be expected by reviewers. Requesting little of no

funds here can have the unintended consequence of suggesting to reviewers that you don't intend to publish. When funds are requested here, a mistake commonly made by applicants is to not provide adequate justification in section K (see example, below, of adequate justification).

Consultant Services. The total of Consultants' fees, travel, per diem allowances, and any other costs must be included here — not under Personnel (sections A & B) or Travel (section D). This is also where confirmed members of advisory committees and monitoring boards should be included. Consultants involved at subcontracted institutions should not be included here; they should be included in the budget for the subcontract (see discussion at the end of this chapter). Costs associated with paid Consultants are often consequential, especially when travel and per diem expenses are included. It is very important, therefore, that you use the strategies described under section K to justify their inclusion in the project. Unpaid consultants must be included in the justification, as well, listing their names, organizational affiliations and roles in the project. If only unpaid consultants are included in the proposal, enter '0' in the field at the right of line F.3 and then provide justification for each unpaid consultant in section K (see below).

ADP/Computer Services. If you will be paying for computer support, e.g., to search databases or retrieve scientific / technical information, such costs should be totaled here and thoroughly justified in section K.

Subawards/Consortium/Contractual Costs. Both direct and indirect costs of all subawards, consortial relationships and contracted (fee-for-service) work should be totaled and entered here, with appropriate justification under section K. With respect to subawards and consortial arrangements, if they are substantive, i.e., are required to accomplish a significant amount of the work that is proposed, you will need to complete a separate budget for each using the R&R Subaward Budget Attachment(s) Form (described at the end of this chapter). Because the indirect costs of subcontracted institutions are included here, remember that they become part of your direct costs when the amounts in sections A-F are totaled under section G ("Direct Costs"). Also remember that reviewers will often be concerned that investigators at other, particularly distant, institutions won't really be involved in the research, i.e., that they are included as 'window dressing'. You should anticipate this and present compelling and credible reasons in your section-K justification for including such investigators in the project.

Equipment or Facility Rental / User Fees. In some cases, it is more cost effective/efficient to rent equipment or temporarily occupy space than to purchase it/occupy it permanently. The total costs related to such strategies should be entered here, accompanied by appropriate justification in section K. Enter "0" here if you will not have such costs associated with your project.

Alterations and Renovations. It is unusual for the costs of alterations/renovations to be allowable under a research grant. Most of the time, such costs are considered to be the institution's responsibility. If the costs of alterations/renovations are not prohibited by the Funding Opportunity Announcement to which you are responding, we recommend that you not include these costs in your Budget without the prior approval of your Program Officer.

Lines 8 through 10. Direct costs that are not covered under the previous seven subsections should be included here. Three blank lines are provided. If three lines are not enough, use lines 8 and 9 for named categories, e.g., 'Inpatient-Care Costs' and 'Outpatient-Care Costs.' Then, on line 10, enter the category title, 'Additional Direct Costs' and to the right

of that enter the sum of all those costs. You must then provide a breakout of what is included in that sum in section K, Budget Justification.

Tuition Remission This is where tuition remission for graduate students is included. Create a category with that title and enter it here.

Animal-Care Costs As already discussed above, the cost of purchasing animals should be included as a request under "Materials and Supplies" (line F.1). Funds for the care and maintenance of animals should be included as a category here. Make certain that you query the head of your animal-care office to ensure that there are no increases in maintenance fees projected for future years. If there are projected increases, obtain a letter from the appropriate institutional official documenting that fact, and include the projected increases in your budgets for future years.

Patient-Care Costs If you will have both inpatient and outpatient costs, they must be entered as separate categories under Section F. The expense of patient accrual should also be included here. Cost account and justify patient travel in the same way that you do your own (see Travel, section K).

Direct Costs (section G), Indirect Costs (section H), and Total Direct and Indirect Costs (section I)

The total for direct costs that is entered in section G is reached by summing the totals for sections A through F.

In section H you need to enter all indirect (facilities and administrative) costs that are associated with research at your institution. The indirect costs associated with researchers at other institutions who will perform a substantive portion of the project should not be entered here; they will be entered when you prepare the "R&R Subaward Budget Attachment(s) Form" for each such institution.

Section H allows you to create four separate lines under it, should you need to do so in order to offer different types of indirect costs. After completing the first line you would use the "Add Additional Indirect Cost" button shown in the preceding figure. For example, there would be a difference between on-site and off-site indirect costs. Or there would likely be a difference between the negotiated rate for Salary and Wages, compared to Modified Total Direct Costs. If you are confused by these differences – and most applicants are – we recommend that you seek the help of personnel in your Contracts and Grants/Sponsored Programs Office to ensure that this part of the application is completed correctly.

The field for section I, Total Direct and Indirect Costs, is calculated by adding the totals for sections G and H.

Fee (section J)

Fees are not allowed in the budgets of most research grants, as opposed to the SBIR/STTR grant mechanisms, which do allow fees. If you are preparing a research grant, leave this field blank unless a fee is specifically authorized under the Funding Opportunity Announcement to which you are responding.

Budget Justification (section K).

Justification is the key to convincing reviewers that your budget request is appropriate and reasonable. With respect to the amount of support requested, unless there is either a formal cap that limits the amount of funding that can be requested or you are aware from discussions with your Program Officer that there is an unofficial but operational cap (e.g., "Realistically, we just can't support a budget that exceeds \$300,000 per year."), let the research dictate the budget, not the other way around. In other words, request what you need — NOT what you or someone else has arbitrarily decided is the maximum that reviewers will approve. Don't make the mistake of low-balling your budget in the hope that it will help you get funded, because the one thing that you most assuredly don't want is an approved budget that leaves you unable to do all that you have proposed. Sections A through F have allowed you to enter amounts for each budget category. Here, in section K, you must justify the need for, and the appropriateness of, what you have requested. Unfortunately, many applicants provide insufficient justification, which is why most budgets are cut. Thus, in our opinion, cuts in the budget are usually the fault of the applicant, not the reviewers nor NIH. There is no limit on the number of pages allowed in section K. You should take full advantage of that fact; rarely is there such a thing as too much justification.

Note that section K must contain the justification for all years for which support is requested. To make the section more reviewer friendly we recommend that you separate it into two subsections, 'Justification of Direct Costs for First Year' and 'Justification of Direct Costs for Subsequent Years'.

Justification of Direct Costs for First Year Each section/subsection of the budget in which specific direct-cost requests are made (sections A through F) should be justified. It is very reviewer friendly to identify each line item in your justification by its letter and numeral, as well as its title. For example, F.2 Publication Costs, which would be followed by justification of how that cost estimate was derived.

Personnel (sections A & B) Each person listed in section A, whether paid or not, must be justified with respect to both expertise and effort. List his/her name, the project role that s/he will have (e.g., Co-Investigator), the person months s/he will commit to the project, and the responsibilities s/he will have in the project. Make sure that the responsibilities described here are concordant with those described in the Personal Statement of the Biographical Sketch. There must be a clear, scientifically defensible reason for including each person. Suffi-

EXAMPLES

Sheldon, Connie J., Co-Investigator, 2 academic + 1 summer person months. Dr. Sheldon has been included in the investigative team to head the molecular biological approaches associated with the proposed research (see her Biographical Sketch), especially the activities that are associated with Specific Aim #2. She will work closely with the PI to design and execute experiments in this area, interpret resultant data and contribute to publication/dissemination of results. In this capacity she will supervise a full-time molecular biology technician (Sandoval – see Other Personnel) and one graduate student (James – see Other Personnel).

Jennings, Alfred F., Collaborator, no measurable effort. Dr. Jennings has agreed to provide us with access to a specimen collection that is critical to completion of Specific Aim 3. His letter of support accompanying this application confirms his willingness to provide us with access to this material.

cient and credible detail is needed for each request. No one should be included as 'window dressing,' i.e., because of their prominence, especially if that person's expertise overlaps someone else's on the team who is less well known. No one should be included out of respect, e.g., a former mentor who the applicant would like to honor.

Section B of the R&R Budget Component, "Other Personnel," grouped each category of individual and listed them numerically by "Project Role". Detail that was missing in section B of the data-entry form must be provided here. Exactly the same approach that was described in the preceding paragraph should be applied here for each individual. Remember to use titles for their positions that will not raise a general-purpose 'red flag', which 'secretary' or 'clerk' would almost be guaranteed to do.

Members of the "Other Personnel" set should not have biographical sketches accompanying the application. If someone has particularly attractive credentials that you want to highlight, e.g., a technician with an extraordinary and difficult-to-find skill or a post-doctoral scholar with background and training that are especially relevant to the project that is being proposed, use the justifications of such individuals to highlight those features. Do not do this for members of the research team who have a Biographical Sketch in the proposal.

EXAMPLE

Post-Doctoral Associate #1: Mallaby, Curtis R., 12 person months. Dr. Mallaby will be working closely with the PI to conduct and interpret the results of all interviews that are designed to identify sources of health-care disparities. These are expected to total 250-300 interviews per year, some at other institutions that have agreed to participate (see accompanying letters of commitment). He is superbly qualified for this role, having done his post-graduate training with one of the leading figures in the field of health-disparities research, Dr. Seymour Cantrell. One of Dr. Mallaby's publications with Cantrell (*Journal of Health Disparities Research*, 2005: 74, 296-312) is considered a landmark in the field. Dr. Mallaby has had both formal training and practical experience in conducting the kinds of investigative interviews that are proposed in this application. In addition, he is culturally sensitive to the subjects with whom he will be dealing, being a member of the same minority group that many of them are.

Graduate and undergraduate students must be justified on the basis of the research that they will do, not on the basis of giving them training – unless you are using the R15 grant mechanism. In the latter kind of application exposing students, especially undergraduates, to biomedical research in ways that will introduce them to new career directions is an important review criterion. Thus, for most research grants, if you have a graduate student who will be involved 50% in class work and 50% in research, you should only request support

EXAMPLE

Graduate Student #2: James, Carol Lee, 8 person months. Ms. James' dissertation research focuses on the hypothesis that is the centerpiece of Specific Aim 2. She has reached the stage where 75% of her time is spent in active research, which is the level of support requested in Budget Period 1. The remainder of her support during the first year will come from departmental funds. She already has two first-author peer-reviewed publications (see Dr. Sheldon's Biographical Sketch). She will work directly with Dr. Sheldon in the design and execution of molecular biological experiments, including those requiring gel-shift and nuclear run-on assays, as well as cloning of relevant genes.

for the 50% that is devoted to research and you should make clear in your justification that only that part of the graduate student's effort will be supported. Where the non-research support will come from should also be described.

If you request less support for an individual than would be expected on the basis of his/her effort and base salary, you should justify that discrepancy. In such cases, provide a description of the other source of support and its duration (e.g., Dr. Gonzales will be supported throughout the first two years by his own individual post-doctoral research fellowship from the National Cancer Institute [F32CA012345]). Providing objective detail, like grant numbers, increases credibility. You should also justify differences in effort (if any) during academic and summer months. Why is the increase necessary and appropriate during the summer months? You don't want to leave reviewers with the impression that you are simply providing a source of summer income for the individual, with no justifiable basis for doing so.

If a member of the research team has a higher base salary than the maximum that is allowed by NIH, make certain that you indicate in your justification of his/her requested salary and fringe benefits that they are based on the NIH maximum (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html> modified by [NOT-OD-13-064 \[http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-064.html\]](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-064.html) for FY 2013), not on his/her actual salary.

The final part of your personnel justification should be detail regarding how fringe benefits are calculated. If there are differences between personnel categories (e.g., faculty members and graduate students) make certain you indicate that the appropriate formula has been used for each category.

Equipment (section C). As noted earlier, the equipment section is one of the most vulnerable in your budget. Success in having your equipment request approved is often attributable to anticipating reviewers' concerns and then prospectively providing justification that will overcome such apprehensions. Some of the commonest concerns that reviewers have about equipment requests follow. Knowing of them will help you understand how to better justify your request.

(1) False Claim of Dedicated Need for Expensive Equipment. To overcome this suspicion, you must make clear either that equivalent equipment is not available to you, either in core laboratories or by borrowing from other investigators, or that your use has become so great that it is no longer feasible to share the equipment with others. If the latter argument is the basis for your request, i.e., that you have been monopolizing the equipment, there is an objective means of demonstrating your dedicated need. Create a table that summarizes your use versus others'. Obtain your data from the usage log book for the equipment you have been using. Use the table in the justification to show objectively that you have been monopolizing the equipment, which compromises it as either a core or shared item.

(2) The Amount Requested is Not Correct. To shore up your request, provide a valid bid as part of your justification, especially for an expensive item. Describe the bidding process and how it resulted in the lowest possible cost. Don't use catalog price as a 'bid,' because it will damage your credibility: reviewers know that almost all institutions receive substantial discounts. If you have to use the catalog price, reduce it by an amount that is commensurate with the discount that your institution usually receives from the relevant vendor. For this latter approach, get a validating letter from either a purchasing agent or vendor, if possible.

(3) Purchase and Maintenance are not Prorated. If a piece of equipment has a life expectancy of 10 years, why should a three-year grant pay the full cost of

purchase? If you are lucky enough to have an alternative source of support for acquisition of equipment (e.g., another grant, start-up funds, endowment), proposing to cost share the purchase and maintenance of a piece of equipment is a very powerful and persuasive means of increasing your budgetary credibility. In the example given, you would request 30% of the purchase price. If you use this approach, you must assure the reviewers that you have the 70% from other sources (e.g., the number of an existing grant that will share the cost of purchase or a letter of commitment from some other source). If your institution will provide a letter of support for the remainder, you have outstanding, objective evidence of institutional commitment, a fact that you should highlight, especially if you are a New/Early Stage Investigator. Service contracts and other costs of equipment maintenance/repair should also be included here. Prorate them among all projects that benefit from the use of the equipment. Make clear in your justification that you are doing so.

(4) The Requested Equipment is More Sophisticated than Needed for the Proposed Research. When applicants request unneeded 'bells and whistles', they are often caught out by reviewers. They will be peers who will know what is needed and what is not. If they suspect you of making an excessive request, one of two things will usually happen. Either the reviewers will become sufficiently annoyed to recommend cutting the entire piece of equipment from your budget or, at the least, they will cut you back to the lesser model that is justified. Even if the second scenario is the outcome, you lose, because your credibility will be damaged and other parts of your budget request will become suspect. To allay such concerns you need to include in your justification why the characteristics of the requested model are necessary to accomplish the proposed research.

EXAMPLE

Centrifuge (Hettich Rotanta [Advanced Model]), Refrigerated, Large Capacity, with Angle Rotor: \$9,877 + \$563 shipping + \$386 annual service contract; \$5,413 is requested. This centrifuge is required to conduct experiments described under each of the three aims, all of which require a bulk-processing step. Estimated use over the course of the project will be 3-4 hrs daily. This level of use would monopolize the only comparable centrifuge, which is used extensively by investigators in two other departments and is located in another, unconnected building. The price for the requested centrifuge has been established on the basis of competitive bids, which accompany this proposal and include the University's 30% discount. Half of the cost is requested because the instrument will be used, in part, for other projects in the PI's laboratory. The other half of the cost will come from the PI's endowment funds (see accompanying letter of support from the University's Endowment Association).

(5) Existing Equipment Isn't Really Worn Out. Reviewers' concerns about requests for replacement equipment are often exacerbated by the perfunctory justifications provided by applicants ("Replacement of worn-out centrifuge: \$????"). Use the same strategies to create your justification here that are listed above (e.g., prorate with other projects), but with an added wrinkle. Get a letter from the company that made the equipment certifying why it is worn out (e.g., lack of replacement parts, inability to provide a service contract, no longer provide repair service, etc.). Vendors will often provide such a letter, especially if you plan to purchase the replacement equipment from them.

Travel (section D).

Reviewers' concerns about travel can usually be overcome with strong, detailed justification. Your justification needs to include two different but equally critical kinds of information.

(1) Who Will Travel and Why? Your first obligation is to make certain that the reviewers know who will travel and why such travel will *tangibly* benefit the project. "Travel for PI and one postdoc to one national meeting each." is clearly not sufficient. Rather, detailed justification is absolutely essential, because there is no "God-given" right to travel under the auspices of an NIH research grant. Justifying that travel will tangibly contribute to the project is usually easy, because most of the time you would be proposing to attend meetings where you and your co-investigators would have the opportunity to present data, discuss your field with investigators who are at other institutions, keep up with latest developments, etc. Your justification should clearly and persuasively state these (or similar) points. Remember that training of students, *per se*, is NOT appropriate justification for travel in a research-grant application.

(2) Cost Account Your Proposed Travel. Most societies have their annual meetings scheduled years in advance. Call the Society that will sponsor the meeting you have decided to attend. Determine where the next meetings will be held. Ask what the convention hotel will be and what room rate has been negotiated. Ask what the registration fee and any incidental costs associated with the meeting will be. Also ask whether or not the organizers have arranged for transportation to and from the airport and, if so, what those costs will be. If they cannot provide that information for you, make a reasonable estimate, based either on calls to cab companies in the convention cities or on your own past experience. From a travel website or your travel agent, determine what a full-fare coach ticket to each of the convention

EXAMPLE

Travel to the annual meeting of the American Nephrology Society (\$3,068) is requested for the PI and one Co-I; the two co-investigators will alternately attend future meetings. This meeting is the principal scientific venue related to the subject of this proposal. Results of the proposed research will be presented there, constructive feedback will be obtained from colleagues and new ideas and collaborations will be developed. The cost of attending has been cost accounted on the basis of actual quotes: coach-fare ticket = \$540; convention hotel rate \$90/night X 4 nights = \$360; transportation to & from airport = \$86; university per diem = \$87/day X 4 days = \$348; meeting registration = \$200. Total per individual = \$1534 X 2 individuals = \$3,068

cities will cost. You know what your institution allows per day for meals. Increase the travel estimates for future years by the appropriate percentage (if any) that is allowed for inflation. And so on. By taking this approach, you can come up with an *unassailable* estimate of what the cost of attending each meeting will be. Therefore, *providing that you have made a strong enough case for who should travel and why*, you should be awarded most, if not all, of the funds required to attend the proposed meeting.

Participant/Trainee Support Costs (section E). This section is rarely included in PHS research-grant applications. If you encounter a Funding Opportunity that does make use of this component, modify and apply the approaches discussed above to meet the need for justification.

Other Direct Costs (section F).

As noted earlier, each of the line items that is included in your budget must be accompanied by substantive justification. Application of the following strategies will decrease the likelihood that any of your requests in this section will be cut.

(1) F.1 Materials and Supplies. The most common mistake made in this subsection, in our opinion, is the use of 'made-up' numbers, i.e., ones that have no basis in fact. This problem is compounded when applicants telegraph that the numbers aren't real by using only round numbers. As an alternative and much more persuasive approach, we suggest that you make your request much more credible (and accurate — which will benefit you) by cost accounting. Assuming that the majority of items will be the same as those that you have purchased previously (both with respect to kind and quantity), consult your file of purchase orders and, for each supply category, determine *exactly* what you spent during the past year. Increase such figures 3-4% to adjust for inflation. *If you use this approach to generate your request for supplies, make clear in your justification that you have done so.* It also shows a level of commitment to accuracy that is not often seen by reviewers. If your proposed research will differ significantly from that of previous years, which would preclude your use of previous purchase orders, develop your new supply budget by a careful needs analysis. Group your supplies into logical categories, each of which must be $\geq \$1,000$. List them, rounded off to the nearest \$10, and justify each.

EXAMPLE

F.1 Materials and Supplies: \$16,860 total. The amount requested in each of the following categories has been derived by cost accounting using actual expenditures over the past year (from purchase orders) increased by 3% for inflation. Iododeoxyuridine: \$4,610 (4 mCi; sp. act. $\sim 2,000$ Ci/mmol in buffered aqueous solution). This radiochemical is required for radiolabeling RNA, as proposed in specific aim 3. Plasticware: etc.

(2) F.2 Publication Costs. First, make a realistic estimate of the number of papers that you and your colleagues expect to publish per year (based on past rates of publication, if you are an established investigator) and identify the journals in which you intend to publish. Second, estimate what the cost of publishing in those journals will be, including submission and/or review fees, page charges, reprint charges, the cost of color illustrations, and any other publication costs that are applicable. It is critically important that you do a detailed analysis of these costs, because the cost of publishing continues to escalate and, like travel, can be a cause of re-budgeting from other categories if you underestimate what will be needed.

EXAMPLE

F.2 Publication Costs: \$5,680 Our rate of publication has been 5 papers/year, each averaging 10 pages with one color and four half-tone figures. The *Journal of Biophysical Chemistry* is preferred. On average, one 10-page publication in that *Journal* is estimated to cost \$1,140 (submission fee \$60; half-tone figure charge $\$25/\text{figure} \times 4 = \100 ; color figure (1) charge = \$300; page charges $\$50 \times 10 = \500 ; etc.) $\times 5 = \$5,680$.

(3) F.3 Consultant Services. Consultants have important but limited roles in a proposed research project. Each should have an established reputation and unassailable expertise in an area for which there is limited need in the proposed project. The need is so limited that it makes little sense to create such expertise *de novo* in your own group. Thus, you should usually justify consultants on the basis that it would be more time- and cost-effective to have an already established individual meet the limited need, rather than train a

member of your own group. A consultant's Biographical Sketch should be constructed to highlight the reputation and expertise that have caused you to engage him/her. Consultants who are classified as Other Significant Contributors, i.e., who have no measurable effort invested in the project, must provide a letter of commitment that confirms their willingness to provide the consultation. In addition to organizational affiliation and role in the project you need to include in your justification of each consultant the consultation fee, if any; duration of the consultation; the cost of travel; per diem allowance; lodging; and any other justifiable costs. The per diem costs for food and lodging should be those allowed by your institution, a point that should be made in the justification. It is relatively rare for an investigator from your own institution to be approved as a paid consultant; such individuals are expected to provide their knowledge and expertise without compensation as evidence of institutional commitment. In addition to such a narrative description for each consultant, for the sake of reviewer friendliness, we recommend that you provide a summary table as part of this justification.

EXAMPLE

F.3 Consultant Services:

SUMMARY OF COSTS FOR CONSULTANT SERVICES

	<u>Sandoval</u>	<u>Oliver</u>
Affiliation	Univ. of ???	[Applicant's Institution]
Duration of consult	9 days	3 days
Consultation fee	\$8,550	-0-
Travel	524	-0-
Lodging	882	-0-
Per diem	585	-0-
Parking	108	-0-
Other costs	-0-	-0-
Total cost	\$10,649	-0-

Consultant #1 (\$10,649), Maximillion Sandoval, PhD, Regents Professor, University of ????. Dr. Sandoval is an international expert on the extremely demanding process of isolating nanosomes from fruit-fly mitochondria. We have a very limited but important need to isolate such organelles in order to accomplish a key experiment under Specific Aim #1 (see section D.4.3 of the Research Plan). Professor Sandoval has agreed to assist us in accomplishing this part of the work. He estimates that his involvement will be needed for 9 days. We will compensate him with a per diem honorarium of \$950 (consultation fee = $\$950 \times 9 = \$8,850$). He will drive the 560 miles one-way from his institution to ours and expects to be busy enough that he will make only limited use of his automobile while here (hotel to laboratory = 23 mi round trip). Mileage reimbursement will be \$0.395/mile. Travel = $(\$0.395[560 \times 2] + [23 \times 9]) = \524 . Parking at the university is \$12/day $\times 9 = \$108$. Per diem and lodging allowances allowed by the university are \$65 and \$98, respectively ($\$65 \times 9 = \585 and $\$98 \times 9 = \882). No other expenses are anticipated.

Consultant #2, (\$0.00), Ernestine Oliver, M.D., Professor, [Applicant's Institution]. Dr. Oliver has agreed to ...

(4) F.4 ADP/Computer Services. Justify these by relating them closely to the research that is proposed and why it is necessary to have others do this for you. Computer services can include, among other things, computer-based retrieval of scientific, technical and educational data. Objective detail should be provided that will allow reviewers to understand how the total figure was derived. If applicable, be sure to include the computer service rates that have been established at your institution.

(5) F.5 Subawards/Consortium/Contractual Costs. The total amount entered on line F5 should include subawards/consortial arrangements, as well as any services that you contract for. For any subawards/consortial arrangements that are substantive, you will need to provide a separate budget AND budget justification using the R&R Subaward Budget Attachment(s) Form (see below). There, your colleagues at the separate institution(s) will justify each component of their budget(s). Here, you justify the need for each subaward or contractual arrangement. The best approach is usually to make the case that such expertise is not available at your own institution. To overcome the suspicion that the relationships with investigators at other institutions will not be integrated into the research effort, it is important to include a 'management plan,' either in the Research Plan or here, in the justification for the subaward/consortial arrangement. The advantage of putting such a plan in the Budget Justification is that it does not count against the page limit for your Research Plan. An unassailable way to substantiate that the relationship is both real and practicable is essential. The most compelling is evidence in your justification that you have been working productively with the investigators from whom you are geographically separated. The best evidence of this kind that you can offer is co-authored peer-reviewed publications. If you don't have any, and there is sufficient time to write an abstract or review together, we recommend that you do so. Another important means of establishing that the relationship is real would be to include evidence that you have been meeting through teleconferences. If you include the latter approach, be sure to include the costs in your budget and describe the teleconferencing equipment, either in the Facilities and Other Resources or Equipment section.

Any services you contract to use should be justified on the basis of why it is more efficient/cost-effective/dependable to use this approach rather than do those things yourself.

(6) F.6 Equipment or Facility Rental/User Fees. Occasionally there are times when it is justified to rent rather than to purchase. Such justification usually pertains when the need for equipment or space is temporary. If you include rental/user fees in your budget, make the case here that this is the most cost-effective approach. Also provide evidence that you have sought bids to ensure that you have obtained the best deal.

(7) F.7 Alterations and Renovations. If you include alterations/renovations, you will need to provide especially compelling justification, because most reviewers and granting agencies will expect such costs to be borne by your institution, especially if the utility of the altered/renovated space will extend beyond the duration of funding that you are requesting. To justify alterations/renovations, provide evidence that you have bid every aspect of the project to accomplish it at the lowest possible cost. Break out the total cost in categories, each one of which is justified with objective detail. Such categories might include such things as demolition, framing, finish carpentry, cabinets, plumbing, electrical, heating/air conditioning, painting, etc. If appropriate, be certain to provide the cost per square foot. The latter is a very important figure, because reviewers and program staff will have a good idea of what is reasonable in this regard.

(8) F.8-10 Other Direct Costs. These are the categories that you create yourself. These, of course, must be justified to the same extent that you did the pre-set lines. If you have more than three of your own lines the total cost on line F.10 will be the sum of costs for items 10 through the total number that you have. In this circumstance you need to provide the breakout for the line F.10 total here, in the Budget Justification, item by item. If you include patient-care costs, remember that you need to provide separate line-item costs AND justifications for inpatient and outpatient care. In creating your justification for patient care you should be sure to address what is included in the "Special Instructions for Patient Care Costs," which are provided at the end of subsection F of the *PHS SF 424 (R&R) Application Guide* (page I-89). The number of subjects that will be needed should be estimated statistically, e.g., on the basis of power analysis. The justification for patient care costs should include the statistical calculations used to derive the number. Make certain that you document that your institution can supply the numbers needed. If recruitment will be problematic relying only on your own institution, include a believable and manageable contingency plan, such as recruitment from other institutions (backed by letters of support), that can be implemented if it becomes necessary to do so.

Justification of Direct Costs for Subsequent Years. This second section of the Budget Justification has several purposes. First, it is used to justify the total number of years requested. Second, describe here how recurring direct costs have been adjusted upward for inflation, if such increases are allowed (see below). And, third, use this subsection to justify any significant increase / decrease in requests that are made in years after the first.

Duration of the Project. The years requested must be justified by the content of your Research Plan. A common mistake made by applicants is to request the maximum amount of time allowed by NIH (5 years) without adequately justifying that there is a need for that length of time. To help confirm that there is a real basis for the number of years that you have chosen, reproduce the timetable here that appears at the end of your *Research Strategy* section (see chapter 10, page 90). Make sure that there is sufficient detail in the timetable to allow reviewers to see, at a glance, what will be done and when it will be done. Write a narrative description that accompanies the timetable here.

Inflationary Adjustments. Currently, inflationary adjustments are not allowed (see NOT-OD-13-064 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-064.html>). When, hopefully, such adjustments are reinstituted, choose and justify such inflationary increases objectively using the Federal Reserve Board of Governor's current estimate for the rate of inflation if your institution doesn't stipulate what the rate of increase should be. In the latter circumstance, you would be required to use that estimate. Check with your Sponsored Programs/Research Office to determine if there is such a figure at your institution. If your institution has such a figure, don't use that fact as the justification; use the objective criteria that went into deriving the figure, which you should be able to obtain from your administration.

Significant Increases/Decreases. A frequent error is to forget that decreases, as well as increases, in the out years must be justified. If there are neither extraordinary increases (more than the cost of inflation) nor decreases in the years after the first one, include this subsection in your justification with "None" under it. Otherwise, reviewers may conclude that you forgot to include the subsection. If there are such increases/decreases (e.g., created by the purchase of equipment in a given year or the addition or deletion of personnel), describe the basis for the increase/decrease and justify why that change is necessary and appropriate.

CUMULATIVE BUDGET

The Cumulative Budget form page looks daunting, but it isn't, because it auto-populates as you fill in the other sections of your budget. You can't make entries in this form, even if you want to do so.

After completing the budget for each of the periods for which funds are requested, carefully review the totals that are generated automatically on the Cumulative Budget form. If any total looks off, review the related entries in the individual budget periods and change anything that is incorrect. Making such changes will automatically correct the related totals on the Cumulative Budget form.

R & R SUBAWARD BUDGET ATTACHMENT(S) FORM

If a subaward/consortial agreement will be included to accomplish a substantive amount of the proposed research, then the *R&R Subaward Budget Attachment(s) Form*, below, must be completed. Only the upper part of the form is shown; it will accommodate up to 30 subcontracts.

OMB Number: 4040-0001

Expiration Date: 6/30/2016

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

[Click here to extract the R&R Subaward Budget Attachment](#)

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1		Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2		Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3		Add Attachment	Delete Attachment	View Attachment
4) Please attach Attachment 4		Add Attachment	Delete Attachment	View Attachment
5) Please attach Attachment 5		Add Attachment	Delete Attachment	View Attachment
6) Please attach Attachment 6		Add Attachment	Delete Attachment	View Attachment
7) Please attach Attachment 7		Add Attachment	Delete Attachment	View Attachment
8) Please attach Attachment 8		Add Attachment	Delete Attachment	View Attachment
9) Please attach Attachment 9		Add Attachment	Delete Attachment	View Attachment
10) Please attach Attachment 10		Add Attachment	Delete Attachment	View Attachment

The investigators at each subcontracted institution should click on the "Click here to extract the R&R Subaward Budget Attachment" button (arrow in the figure, above). A "Save" dialog box will appear, which will allow the *R&R Budget* form to be saved locally. On the first page of the Form, the "Budget Type" choice at the upper left should be "Subaward/Consortium". The completed Budget form, to include the Justification, should be emailed back to you at the lead, grantee institution. You should upload the subcontract/consortium grantee's completed *R&R Budget* form

into your application's *R&R Subaward Budget Attachment(s)* form. If there will be more than one such upload, each must have its own, distinct file name.

If the other institution's indirect-cost rate is less than yours, make certain that you prominently highlight that fact in your justification and underscore that the approach for that part of the research will actually be less expensive, in terms of total costs, than if all activities were performed at your own institution.

DEVELOPMENTAL STEPS FOR CHAPTER FOURTEEN:

1. Determine whether your department, Research Office, or Sponsored Programs Office provides assistance with the development of a budget.
2. Determine when you must submit your budget, budget justification, and Cover Form to your institution's Sponsored Programs Office.
3. Confirm that you need to prepare a non-modular, breakout budget.
4. Establish the Budget Type to prepare, either "Project" or "Subaward/Consortium, and check the appropriate field at the top left of the first Budget Form page (sections A & B).
5. List the Senior/Key Persons and Other Personnel who will be participants in the project, with each group in alphabetical order. Create your personnel budget for the first year.
6. Determine what the definition of non-expendable 'equipment' is at your institution and whether it differs from NIH's ($\geq \$5,000$ and a useful life of greater than 1 year). Your institution's definition supersedes NIH's if there is a difference.
7. Create your equipment budget, being sure to include shipping and maintenance costs in each item's cost.
8. Establish who will travel to what event and why. Create your travel budget by accounting for all expected costs for each person who will travel.
9. Determine the amount that will be requested on each pre-named line of section F, Other Direct Costs.
10. If substantive subawards or consortial arrangements will be included in the project, e-mail an R&R Subaward Budget Attachment Form to the investigators at the subaward institution. Include their costs in the total for line F.5 of Other Direct Costs.
11. Create a category for any Other Direct Costs that cannot be accommodated by one of the pre-named lines in section F. Enter the related amounts you are requesting.
12. Total your direct costs (sections A through F) and enter that number under section G.
13. If your annual budget will exceed \$500,000 in annual direct costs, you must contact the NIH program you are targeting and obtain their approval before submitting your proposal.
14. Enter indirect (facilities and administrative) costs in section H, taking into account different approaches to calculating them, if applicable.
15. Inflate first year figures the estimated rate of inflation, if that is allowed (NIH does not allow such increases at this writing). Extraordinary increases or decreases (greater or less than the rate of inflation) in later years should be flagged and justified in section K.
16. Copy and import the Timetable from your Research Design subsection into the justification of the number of years being requested.
17. Create your Budget Justification (section K for the first year) for all years, line by line, remembering that there is no page limit and that there is no such thing as too much objective justification.

CHAPTER 15

PROJECT/PERFORMANCE SITE LOCATIONS, FACILITIES & OTHER RESOURCES SECTION, and EQUIPMENT SECTION

GENERAL CONSIDERATIONS

Project performance site(s) is(are) included by completing the *Project/Performance Site Location(s)* form. The number of sites helps to inform how the *Facilities & Other Resources* and *Equipment* sections will be completed. The latter are attached to the application as PDF files using the "Add Attachment" buttons that are associated with lines 10 and 11, respectively, of the SF424 *Other Project Information* component.

The sections that are the topics of this chapter, together with the biographical sketches and the Preliminary Studies described under the *Research Strategy-Approach* subsection, help reviewers assess the feasibility of the proposed research in the hands of the proposed research team. They are usually some of the least thought-about sections of the proposal, to the extent that they are often given little more than superficial attention. In fact, they are very important parts of the application because they are the source of most of the information that reviewers need to score the ENVIRONMENT core-review criterion. To refresh your memory, to score the ENVIRONMENT review criterion reviewers will be asking the questions posed in the text box, below.

SF424 Application Guide, Part I, Section 6, page I-128, Environment:

"Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the proposed project? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?"

Do not use 'boiler plate' supplied by either your institution or departmental office to create these sections. Similarly, do not copy these sections from a colleague's proposal. Either approach will likely introduce extraneous information that has little or no meaning to the work that is proposed. Worse, these approaches can result in critically important resources being overlooked.

New/Early Stage Investigators, especially, have a great amount to gain from these sections if they are done well, and a lot to lose if they are done badly. Why? Because this is where New/Early Stage Investigators have the opportunity to project two things that are particularly relevant to the review of their proposals: 1) the extent to which their institution is committed to them and their research program, and 2) how well equipped they are to conduct the proposed research.

PROJECT/PERFORMANCE SITE LOCATION(S) FORM

The component into which you enter information about the performance site(s) is reproduced below. It is reproduced from the Grants.gov application package, not the SF424 *Application Guide*; the "Next Site" button at the lower right of the Grants.gov version of the form is not shown in the one offer in the *Application Guide*. Note that there is an initial subsection that is for the primary location. That is all that needs to be completed if there is but a single performance site. If there will be more than one, up to 300, the lower part of the component is completed. The part of the component that is titled

[View Burden Statement](#)

OMB Number: 4040-0010
Expiration Date: 9/30/2016

Project/Performance Site Location(s)

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization

Project/Performance Site Primary Location

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country:

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Project/Performance Site Location 1

☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization

Organization Name:

DUNS Number:

* Street1:

Street2:

* City: County:

* State:

Province:

* Country:

* ZIP / Postal Code: * Project/ Performance Site Congressional District:

[Delete Entry](#)[Next Site](#)

Additional Location(s) [Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

"Project/Performance Site Location 1" should not be a repetition of the Primary Location, which is what the title seems to suggest. It should be the location of the first *additional* performance site. For more performance sites than two, click the "Next Site" button at the lower right of the form, which will allow you to add up to 299 more.

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If you need to add more than 300 additional performance-site locations, they should be described in a separate, single file using the same format as is used on the Project/Performance Site Location(s) form. Adding sites greater than 300 has been simplified by NIH: They have provided a Word-based format page, "Additional Performance Sites - Forms C >300", which can be downloaded from <http://grants.nih.gov/grants/funding/424/index.htm>. Simply delete the instructions at the top of the supplementary form page and fill out as many of the four Word tables as are required; delete any that aren't needed. If there aren't enough tables on the supplementary form page, simply highlight one of the tables, copy, and paste it until you have created the number needed. When all Project/Performance Site locations in excess of 300 have been listed, convert the file to a PDF document and upload it into the "Additional Locations" field at the bottom of the form page using the "Add Attachment" button (see preceding page).

FACILITIES & OTHER RESOURCES SECTION (No page limit)

Generic Application Guide instructions: "This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project."

PHS-specific instructions: "Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements. For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support. If there are multiple performance sites, describe the resources available at each site. Describe any special facilities used for working with biohazards or other potentially dangerous substances."

In describing your access to facilities and other resources, be specific and objective. Present only relevant items, and do so in such a way that it will be clear why each is important and sufficient to accomplish the work that will be undertaken. Avoid subjective assessments and clichés, such as 'adequate' office space, and 'cutting-edge' or 'state-of-the-art' equipment, respectively. Such assertions provide no objective detail that reviewers need to evaluate for themselves what is available to the project. For example, if you have a 10 ft X 12 ft office that is adjacent to your laboratory or outpatient clinic and is equipped with telephone, fax and a copy machine, that is what the reviewers want to know. When you describe your computer system and peripherals, the details of the hardware, the software and your levels of access to relevant databases and the Internet should be included. Be sure to include relevant resources of your co-investigators, collaborators and consultants, especially if they are at other Project/Performance Sites.

As noted earlier, the number of Project/Performance Site locations helps to inform how this section should be organized. If you plan to conduct some of the proposed work at a location that is separate from the primary site, the relevant facilities and resources at the other location(s) should be detailed separately in a subsection that is clearly labeled with the name of the other one or more performance sites. For example, the first part of the document might be labeled: **FACILITIES & OTHER RESOURCES – NAME OF PRIMARY LOCATION**. The relevant facilities and resources at the second site should be titled something like: **FACILITIES & OTHER RESOURCES – NAME OF SECOND LOCATION**.

We strongly recommend that, if you have members of your research team who are geographically removed from the remainder of your team, you include teleconferencing facilities (or Skype or similar other capabilities) in the *Facilities & Other Resources* section. A major concern that reviewers will almost surely have about geographically separated parts of the program is that such dissociation will interfere with effective communication. That suspicion can be largely overcome if there is concrete evidence that telecommunication capabilities exist and will be used by the proposed researchers at all locations, e.g., for weekly research meetings. Describe them, your videoconferencing capabilities and your team's access to them at each institution, either in the "Other:" subsection (if they are institutional core facilities) or under the "Computer" subsection (if Skype or a similar personal program is used).

The format for the *Facilities & Other Resources* section should be:

FACILITIES AND OTHER RESOURCES

Environment – Contribution to Success

Institutional Commitment to ESI [include only if PI is an Early Stage Investigator]

Facilities:

- Laboratory
- Animal
- Clinical
- Computer
- Office
- Other Resources

Environment – Contribution to Success. This subsection should be used to describe how each performance site will contribute to the project's probability of success (see first part of PHS-specific instructions, above). It should be a narrative overview that integrates details provided later, in the Facilities subsection. Both physical and intellectual resources should be considered in the overview.

Institutional Commitment to the Early Stage Investigator. This subsection should only be included when the PD/PI qualifies as an ESI. In a multiple-PD/PI application, each would have to qualify in order for the application to be considered as coming from an ESI. The subsection addresses a long-standing problem, namely, insufficient institutional support for individuals offering themselves as PD/PI. Having to write this subsection forces both the Early Stage PD/PI and his/her institution to face that issue. Having to write this paragraph should prevent well-intentioned ESIs from investing time and effort writing grant proposals when they are handicapped by the often fatal flaw of being under-resourced. Being unable to write this paragraph credibly would, hopefully, stimulate dialogue between the ESI and his/her administration that would lead to resolution of the problem and ability to write a fully competitive proposal. *Early Stage Investigators should view this subsection as vital to their potential for success, therefore.*

Examples of institutional commitment include, but are not limited to: (i) level of academic appointment (e.g., tenure track); (ii) institutional start-up (dollar amount not required), especially if start-up funds were instrumental in developing the preliminary data needed to make the application competitive; (iii) protected, salaried time for research; (iv) space; (v) equipment; (vi) technical support and/or support for graduate students; (vii) administrative support; (viii) access to relevant shared and/or core facilities; (ix) access to subjects or patients, if applicable; and (x) availability of faculty-development programs, such as responsible/ethical conduct of research or manuscript/grant-proposal development.

During the time that an applicant qualifies as an ESI, s/he knows that s/he will have to write the subsection described above. Therefore, while interviewing for their first academic appointment, applicants who are serious about meriting NIH research funding must ensure that they negotiate what they need in order to be able to write a strong "Institutional Commitment to the ESI" subsection. Not doing so would likely create a fatal flaw with respect to meriting NIH funding.

Facilities. This is where you provide detail in support of the narrative description you have provided in the first part(s) of this section. We recommend that you use bolded, italicized subheadings for each of the facilities/resources categories that are required by the *Application Guide* instructions, i.e., those listed below. If one or more of the stipulated subsections is not applicable to your application, include the heading followed by "Not Applicable." Otherwise, reviewers could wonder whether you overlooked the missing subsection(s) when you prepared your proposal. Conclude each subsection with a fully italicized sentence that details how that part of the facilities/resources available to you contributes to the potential success of the project. *Be careful to write these sentences in such a way that they do not repeat sentences from the preceding "Contribution to Success" and, if applicable, "Institutional Commitment to the ESI" subsection(s).*

As a final general point, relevant equipment with a cost of less than \$5,000 should be included in this section; 'major' equipment that cost \$5,000 or more should be described in the *Equipment* section. A common mistake made by applicants is to include all equipment, including 'minor' equipment, in the *Equipment* section.

Laboratory: Describe its size, configuration and content of relevant 'minor' equipment. Be specific and comprehensive. If one or more Select Agents (<http://www.cdc.gov/od/sap/docs/salist.pdf>) will be used in the laboratory environment, be sure to thoroughly describe the local containment facilities, with major equipment described in the *Equipment* section.

Animal: If you will be using experimental animals, provide detailed information on the quality of your source, the relative availability of the species/strain chosen (if it is an uncommon one), and the quality of the facilities/veterinary care that will be associated with maintenance of the animals. Remember that your institution must have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (<http://grants.nih.gov/grants/olaw/olaw.htm>). If your institution's animal-care facilities have been accredited by the AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care, International), you should indicate that fact. This field should contain information that is complementary to and not repetitious of what is included in the Vertebrate Animals attachment to the Research Plan Component (section 5.5.8 of Part I of the *Application Guide*).

Clinical: If your proposal is one that will require patients or patient-derived materials, there is no such thing as too much objective detail: One of the principal causes for the failure of clinical applications is insufficient documentation of access to the quantity and quality of clinical material that will be needed to complete the study. Description of relevant physical facilities should

be included, as well. Last but not least, if there are other complementary clinical programs and/or investigators in your environment, describe them and the relevance that they have to the proposed project.

Computer: Provide detailed information about relevant hardware and software that are in your laboratory/research space and office. Also include information about your local area network. The administrator of your LAN is a very important resource. Therefore, s/he should be described here, especially if computers and your LAN are particularly important to implementation of the proposed research. Remember to include any personal telecommunications equipment here (e.g., Skype) if it is used to communicate with members of the research team who are located at other project/performance sites. Finally, if you are a member of a wider network that includes colleagues at other institutions, describe that resource here – providing, of course, that it will contribute to your project in a meaningful way.

Office: Provide relevant objective detail about your office and its proximity to the other parts of your operation. If office space for co-investigators, technical personnel and/or students is relevant, be sure to describe those facilities.

Other: Although the instructions for this section would appear to restrict your discussion to physical facilities and other physical resources (see text box, above), we recommend that you consider it to have a much broader context.

- **Intellectual Resources/Useful Collaborations.** If there are other investigators in your research environment who are funded to do research that is complementary to your own, list them here. Doing so gives reviewers an objective means of assessing the intellectual quality of your research environment – i.e., the presence in your environment of investigators with whom you will have the opportunity to interact and collaborate. Using a simple table, list them by name, their granting agencies and grant titles. These should be investigators who are not members of your research team. This is where former mentors who are at the same institution as an ESI should be included, i.e., not in an intellectual capacity such as co-investigator or as one of multiple PD/Pis. Indicate in text that follows the table exactly how each will contribute to the success of what you propose, whether it is through critical discussions of research results, the opportunity to share reagents/equipment collaboratively, or some other reason. If you have regular interactions/collaborations with colleagues at other institutions via videoconferencing, e-mail, and/or telephone, particularly if these are substantive and project-relevant relationships in which data are exchanged and evaluated, include such individuals in the table as intellectual resources. Denote them with an asterisk that refers reviewers to a brief footnote to the table describing what the means of communication is/are. *Such 'long-distance' intellectual resources are particularly important to investigators at institutions that have a relative lack of local intellectual resources which are relevant to the proposed project.*
- **Administrative Support.** If you are a New/Early Stage Investigator you should describe your administrative support in the "Institutional Commitment" subsection, as is noted above. If you are an established investigator we recommend that you offer a separate sub-subsection under "Other:" for the purpose of doing so.
- **Core/Shared Facilities** and their relevance to your project should be included here, along with descriptions of your proximity and the extent of access that you have to them. If a Select Agent (<http://www.cdc.gov/od/sap/docs/salist.pdf>) will be handled using core facilities, comprehensively describe what is relevant to biocontainment of that agent. In addition to

describing the physical attributes and minor equipment in core/shared facilities, be clear about how they will be operated. Reviewers should be given precise understanding of how the activities of such resources will facilitate the work that you are proposing, i.e., how the activities of the core will increase the likelihood for success of your project. Make certain that you include all relevant core/shared facilities. For example, don't forget things like your institution's library and relevant specialized Centers (e.g., a Cancer Center, a Center for the Study of the Family, or a CTSA [Clinical & Translational Science Award]). Major equipment in core/shared facilities should not be described here. Those items should be included under the *Equipment* section (see below).

EQUIPMENT SECTION (No page limit)

Application Guide Instructions: "List major items of equipment already available for this project and, if appropriate, identify location and pertinent capabilities."

"Major Equipment" includes not only that which is assigned to you, but also that which is shared and in institutional cores. Be certain to get a letter of support from anyone who has agreed to give you access to a piece of their major equipment. In the "Other Resources" subsection of the *Facilities & Other Resources* section you should describe core/shared facilities that will support the research you are proposing, to include relevant 'minor' equipment. Here, in the *Equipment* section, you detail relevant major equipment that is assigned for your dedicated use, as well as that which is present in cores/shared facilities.

For example, if you would propose to use a flow-cytometry core facility you would describe its physical characteristics, relevant minor equipment, relevance that the core has to your project and the kind of access and proximity that you have to it under the "Other:" subsection of *Facilities & Other Resources*. Then, under "*Equipment*," you would thoroughly describe the major equipment in it, e.g., the kind(s) of flow cytometer(s) and capabilities they have that are pertinent to your research. You would not include equipment in the facility that is irrelevant to your project – no matter how contemporary and 'sexy' it might be.

Again here, it is smart business to include a fully italicized sentence at the end of the section that tells reviewers how the major equipment described increases the likelihood that your project will succeed. Alternatively, provide such a sentence at the end of the description for each piece of major equipment.

DEVELOPMENTAL STEPS FOR CHAPTER FIFTEEN:

1. List the Project/Performance Sites for your project. Prepare a Project/Performance Site profile for each.
2. Appreciate that the *Facilities & Other Resources* and *Equipment* sections for each project/performance site will be where reviewers get most of the information that they will use to evaluate the ENVIRONMENT core review criterion as it relates to your proposal. *Accordingly, give this part of the application the time and effort it deserves.*
3. Inventory and characterize the physical resources that are assigned to you at the primary location using the subheadings for the *Facilities & Other Resources* section that are described in this chapter.
4. Repeat the preceding process for each additional project/performance site. Include at the other sites only those things that are relevant to the project.

5. Be sure to include 'minor' equipment (cost < \$5K) in your description of facilities under each of the subsections.
6. Write an italicized sentence after each subsection that conveys how what is described supports the project's prospects for success.
7. Inventory and characterize the physical resources at the primary location, including minor equipment, to which you have either shared access or that are available to you through institutional core facilities.
8. Make a separate inventory of major equipment (cost ≥\$5K) to which you have access at the primary location, either on a dedicated or shared basis.
9. Obtain a letter of support from anyone who has agreed to share their major equipment with you.
10. If the research proposed requires human subjects, thoroughly document in the "Clinical" subsection the demographics of the population and characterize the extent of your access. If clinical facilities will be needed, detail their characteristics, including relevant minor equipment.
11. If subhuman vertebrate animals will be used, describe the facilities in which they will be housed and cared for.
12. Inventory and characterize the intellectual resources/relevant collaborations that are either located in your immediate research environment, at the other project/performance sites, and that are available at other institutions through your wide-area network.
13. Characterize facilities and/or equipment that will facilitate communication between geographically separated members of the research team and/or collaborators.
14. If you will be working with what qualifies as a Select Agent (<http://www.cdc.gov/od/sap/docs/salist.pdf>), make sure that you describe the relevant biocontainment facilities that will be needed.
15. For each project/performance site, write an overview paragraph titled 'Environment - Contribution to Success.' Insert this paragraph at the beginning of the *Facilities & Other Resources* section for each project/performance site.
16. If you are a New/Early Stage Investigator, make certain that you include a second subsection that provides objective evidence of your institution's commitment to your success as a researcher. Title it, 'Institutional Commitment to the Early Stage Investigator'.
17. Create the *Facilities & Other Resources* and *Equipment* sections as separate PDF files. Upload these files into your application by clicking the relevant "Add Attachment" button, after which you browse to where you have saved the file and then click "Open".

EXAMPLE OF FACILITIES & OTHER RESOURCES SECTION

FACILITIES & OTHER RESOURCES – NAME OF PRIMARY PERFORMANCE SITE

Environment – Contribution to Success

The facilities and other resources available to the PD/PI and his research team at the primary performance site include everything needed to undertake and complete the proposed research project successfully. When he set up his office and adjacent laboratory they were equipped with this project specifically in mind. These resources are complemented by a contemporary, departmental core flow-cytometry facility to which he has access 24/7. Additional complementation includes a pathogen-free animal-care facility and laminar-flow racks that will help to assure high-quality starting material for experiments. Face-to-face videoconferencing equipment maximizes interactions between members of the research team, especially those who are at a distance (see *Consortium/Contractual Arrangements and Facilities & Other Resources – Name of Second Performance Site*). The intellectual environment is rich with other extramurally funded investigators who are doing work that is complementary to what is proposed here. These facilities, together with those described for the other project/performance sites (see following descriptions), collectively provide a scientific environment that is strongly supportive of the proposed research and, therefore, success of the project.

Institutional Commitment to the Early Stage Investigator

The PI qualifies as an Early Stage Investigator for two more years. There is extensive evidence of institutional commitment to his development as an academic researcher. His salaried 12-month, tenure-track academic appointment includes a total of six person months (50% effort) of protected research time. The start-up package provided to him included laboratory space, equipment and research funds needed to launch his investigative program. The package was sufficient to yield the preliminary data needed for this, his first R01 application. Support for a graduate student was initially provided by his department. That student is now funded through an individual NIH fellowship. Support for the post-doctoral research fellow, Jason Albright, that is requested in this application was also provided by the PI's department so that a highly qualified individual could be recruited in advance of making this proposal. The same approach was used to recruit the technician, Alan Mellone, for whom support is also requested in this application (see *Personnel Justification* for both Albright and Mellone). In addition, the applicant has been provided with unrestricted access to a departmental flow-cytometry facility (see Facility subsection below), without which essential parts of the proposed research project could not be pursued. Administrative support is provided to the PI by a departmental administrative core. Important career-development programs are also available to him, including GSC 1497, a formal course on the ethical conduct of research; a College-sponsored workshop designed to develop proposal-writing skills; and a departmental editor who provides assistance with the development of manuscripts. His research falls under one of three University-wide priority research areas, which will help to ensure continued institutional commitment to him and his research program.

Facilities:

Laboratory: The PI is assigned a 1200 sq ft laboratory that is located in departmental space, adjacent to his office. It is subdivided into a general purpose area (800 sq ft), a positive-pressure cell-culture room (200 sq ft), a medium preparation area (100 sq ft) and a walk-in cold

room (100 sq ft). Minor equipment (cost < \$5K) in this space includes: *These laboratory facilities were specifically designed and equipped to support the continuum of research for which the project proposed here is the next step.*

Animal: Specific pathogen-free mice (C57BL6) will be purchased from the Jackson Laboratory, a supplier known for the high quality and reliability of the animals it provides. They will be housed in the institution's AAALAC-accredited animal-care facility, which is in a dedicated building adjacent to the one that houses the PI's laboratory (see above). Cages will be located on laminar-flow racks in a 100 sq ft room dedicated to this project. In addition to oversight by a board-certified laboratory-animal veterinarian, all animal technicians are rigorously trained and certified. Microbiological, clinical pathological and necropsy diagnostic facilities are available on site, with back up from the State's veterinary diagnostic laboratory. *Success of the proposed research is critically dependent on the acquisition and maintenance of mice in a pathogen-free state.* The facilities described will help assure such quality.

Clinical: Not applicable.

Computer: The PI has two computers: (1) Dell PC located in the PI's office (Windows XP Professional); and (2) a Compaq laptop model Evo N1000c (Pentium 4; 170GHz; 256 MB of RAM; Windows XP Professional). Each technician and student is equipped with a similar laptop. Skype for Windows (business version) telecommunication software and equipment is on hand for all members of the research team. *The combination of these information technologies contributes to the potential for success by assuring both efficient data handling and optimal communication among members of the research team.*

Office: The PI's 144 sq ft office is adjacent to his laboratory. It is equipped with desk, credenza, desk and task chairs, two 4-drawer filing cabinets and hardwired high-speed access. There is also access to the Internet through the University's wireless network. The students'/ technician's shared office space, which is 356 sq ft, has similar access and is equipped with four individual desks, four task chairs and four 2-drawer filing cabinets. *These facilities assure that the PI and his immediate research team will have the necessary space in which to formulate experiments, analyze results, and prepare manuscripts for publication.*

Other:

- Flow Cytometry Core Facility located on same floor as the PI's laboratory. He has access by appointment on a fee-for-service, 24/7 basis. The facility contains a total of 800 ft², which is divided into two analytical suites and an adjoining room for sample preparation. The latter contains Zeiss bright-field, fluorescence, and phase-contrast microscopes, as well as a dissecting microscope and Conner desk-top centrifuge. The director of the facility, Michael Legge, is certified by Accuri, the maker of the cytometers in the facility (see *Equipment* section). A certified technician is available to assist investigators with use of cytometers, if needed. This core has been designated as a reference facility by the American Cytometric Society. *Availability of this core contributes greatly to the potential success of this project, which includes flow cytometry as a core analytical approach.*
- Intellectual/Collaborative Resources: The following are funded investigators in the PI's research environment who are doing research that is complementary to what is proposed here. *They provide invaluable constructive criticism and informal intellectual input, without which the proposed project would have far less chance of success.*

INVESTIGATOR	AGENCY	GRANT NUMBER	TITLE
Jennifer D'Espagne	NIH/NIAID	R01AIXXXXXX	Innate Immune Responses Limiting Nosocomial Infections
Patrick Hayek	NIH/NICHD	R01HDXXXXXX	Hospital Neonatal Infections and Their Prevention
Steven McMullins*	NIH/NIA	R34AGXXXXXX	Bacterial Complications of Healing Decubitus Ulcers
James Wherry	NIH/NIAID	R21AIXXXXXX	Bacterial Communities in Hospital-Derived Eye Infections
Geoffrey Teagarten	NIH/NCCAM	R01ATXXXXXX	Alternative Therapy for Nosocomial Staph Infections

* Dr. McMullins is appointed at the University of XXXXX, which is located in the same city fifteen miles from the PI's university. The PI and Dr. McMullins reciprocally attend each other's laboratory meetings on a bimonthly basis and are coauthors of several peer-reviewed publications (see Biographical Sketch). The other four investigators are members of the PI's department.

EXAMPLE OF EQUIPMENT SECTION

EQUIPMENT – PRIMARY LOCATION, PRINCIPAL INVESTIGATOR

Assigned to the PI:

1. Standard professional audiocassette decks (3; Sony model 810) with heavy-duty transports, a three-head design and Dolby-noise-reduction systems B, C and S.
2. Video recorders/playback units (4; Frontier model 8C) with formats ranging from analog U-Matic to the latest digital configurations, including VHS, VHS-C, SVHS, 8mm, Hi8, time-lapse, 6mm digital, and 8mm digital.
3. [Continue listing major equipment]

Core Equipment:

The equipment in the core Audio Enhancement Laboratory, which has been described in the *Facilities and Other Resources* section, includes:

1. Digital-adaptive enhancement processor (Acoustic Engineering, model E) that allows implementation of the full range of filter algorithms, as well as compression and limiting functions.
2. Spectrum analyzer (Harmon model 1600) with fast-Fourier transform device (>16-bit resolution and frequency-display ranges adjustable from 0-100 Hz up to 0-20 kHz) and single-channel capability. It has at least 800 lines of resolution on any frequency range and zoom capability.
3. [Continue listing major core equipment]

Equipment Shared With Other Investigators:

The following pieces of equipment are in the laboratories of other investigators who have agreed to provide access 'on demand' (see letters of support from Oliphant and Kaplan) for the purpose of making and authenticating computer-based voice identifications. Use of the equipment will be granted within 24 hours of a request being made, with most access given immediately.

1. Analog sound spectrograph (DC Live / Forensics, model B), which is in the laboratory of Dr. Maynard Oliphant. It has up to 32,000 band graphic EQ; flashback review; real-time coefficient display; time domain adaptive filter and frequency; time stamp; DeClipper; and signal-triggered VOX recording.
2. High-speed IBM computer system (located in the laboratory of Dr. James Kaplan) with a fast processor, a large (32 inch) monitor, an input for digital video, and hard-drive storage sufficient (24 terabytes) to handle the video applications of this project.

The pieces of major equipment described in this section, together with minor equipment described under Facilities & Other Resources, collectively constitute an audio-video forensic laboratory that has the full range of capabilities needed to complete the proposed project.

CHAPTER 16

HUMAN SUBJECTS, VERTEBRATE ANIMALS, SELECT AGENT RESEARCH, CONSORTIUM / CONTRACTUAL ARRANGEMENTS, RESOURCE SHARING PLAN(S), ENVIRONMENTAL IMPACT, HISTORICAL PLACES and FOREIGN COMPONENTS

GENERAL CONSIDERATIONS

The parts of the application covered by this chapter may or may not be relevant to your proposal. If none of the parts named in the title is applicable to your needs, skip to the next chapter. If one or more of the parts is, the key to success in completing that(those) part(s) is careful reading of the detailed instructions that are contained in the *PHS SF424 (R&R) Application Guide*, which will not be repeated here. What will be provided here is assistance in finding those instructions and a few tips that are relevant to being fully responsive.

HUMAN SUBJECTS SECTIONS

Considerations relevant to use of human subjects are included in two different places in your application, the *Other Project Information* and the *PHS 398 Research Plan* components (sections 4.4 and 5.5 of the *PHS SF 424 [R&R] Application Guide*, respectively).

Other Project Information Component – Section 1, Are Human Subjects Involved?

The information needed to complete this component is relatively simple to provide, consisting of one-or-more boxes to check and two fields that may need to be filled in.

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 6/30/2016

1. Are Human Subjects Involved?

☐ Yes ☐ No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

If no, Is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date:

Human Subject Assurance Number:

2. Are Vertebrate Animals Used?

☐ Yes ☐ No

2.a. If YES to Vertebrate Animals

If no human subjects will be involved at any project/performance site, then you simply check "No" on line 1 and you are finished here. If human subjects will be involved at any project/performance site, you must check "Yes" on that line and respond to the remaining queries. Respond to the query regarding Institutional Review Board (IRB) approval. If approval has been obtained, check the "No" box and then fill in the IRB approval number in the field provided. If IRB approval has not been obtained, check the "Yes" box, even if you have not yet submitted your request for approval at the time that your proposal is submitted. If you check "Yes," leave the field for the IRB approval number blank. Although you have the latter option, we strongly recommend that, if feasible, you obtain approval *before* preparing your proposal. Doing so is a form of 'insurance' against the unlikely possibility that IRB approval cannot be obtained for the project at a later time. With respect to the Exemption Number, if the human subjects/materials in your study are exempt, check off the appropriate category after choosing the appropriate one from among the descriptions of the exemptions under Part III, U.S. Department of Health and Human Services, Public Health Service, Supplemental Grant Application Instructions for All Competing Applications and Progress Reports (http://grants.nih.gov/grants/funding/424/SupplementalInstructions.docx#Human_Subjects_Exemption.Cat): section 3, Definitions → Human Subjects Research Definitions and Terms → Exemptions (page III-50). If your institution has no Human Subject Assurance Number on file with the Office for Human Research Protections, enter "None" in the field provided. If you have such a number, enter only the 8 numerals, i.e., do not include the "FWA" prefix.

If you checked "Yes" for involvement of human subjects, now complete the parts of the *PHS 398 Research Plan* form that pertain to human subjects, as well as the separate *Planned Enrollment Report* and *Cumulative Enrollment Report*.

PHS 398 Research Plan – Human Subjects Sections

As is evident from the *Research Plan* form, there are up to four subsections that may need to be completed here if you checked "Yes" in section 1 of the *Other Project Information* form. They include: (1) Protection of Human Subjects; (2) Inclusion of Women and Minorities; (3) Inclusion of Children. Knowing which one(s) to complete will come from reading Part II of the *Supplemental Instructions* referred to above and/or the specific Funding Opportunity Announcement (FOA) to which you are responding. Part II of the *Guide* has been set up to present six scenarios that cover any kind of research that involves human subjects. After carefully reading the six and answering the five questions that are designed to indicate which scenario is applicable to your needs, complete the Human Subject sections that are relevant to your project. Follow the up-loading instructions that are contained in the Part I instructions (section 5.5.5-7 of the *Guide*) for each of the Human Subjects Sections that is relevant to the project you are presenting.

Planned Enrollment Report and Cumulative Enrollment Report

The very clear instructions regarding how to complete these two enrollment reports are contained in subsections 5.8.1 (*Planned Enrollment Report*) and 5.8.2 (*Cumulative Enrollment Report*) of Part I of the *Guide*. We have nothing to add to these well-written instructions.

VERTEBRATE ANIMALS

There are also two parts of the application that must be completed if you are using vertebrate animals (sections 4.4.2 and 5.5.8 of the *PHS SF 424 Application Guide*). They pertain to parts of the *Other Project Information* form and the *PHS 398 Research Plan* form, respectively.

Other Project Information Component – Section 2, Are Vertebrate Animals Used?

As with the Human Subjects subsection, if you check “No” on line 2 section of the *Other Project Information* form (see relevant part of the form, below) you will have completed this part of the application and will not need to enter anything more in the *PHS 398 Research Plan* form. If you check “Yes” regarding Vertebrate animals, complete all of the information in both sections.

RESEARCH & RELATED Other Project Information OMB Number: 4040-0001
Expiration Date: 6/30/2016

2. Are Vertebrate Animals Used? ☐ Yes ☐ No 

2 a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number:

3. Is proprietary privileged information included in the application? ☐ Yes ☐ No

After checking “Yes” regarding use of vertebrate animals, you need to indicate whether or not you have approval of your *Research Plan* by your Institutional Animal Care and Use Committee (IACUC). If you have approval, simply enter the date that it was given. If approval is pending, leave the “IACUC Approval Date” field blank. If you do not have approval, check “Yes” next to the question regarding whether approval is pending. You should check “Yes” even if the process to obtain approval has not been initiated. As we strongly advocated with Human Subjects IRB approval, we strongly encourage you here to get IACUC approval of your project before you get very far into writing your *Research Plan*. Doing so will prevent what could be a nasty surprise later. Enter your institution’s Animal Welfare Assurance Number in the field provided (institutions that have numbers are identified at: <http://grants.nih.gov/grants/olaw/assurance/300index.htm>). Note that it must be your institution, not the number held by a collaborating institution. If your institution has no Assurance number, enter “None” in the field. If vertebrate animals will be used and you do not provide this number it will result in an eRA Validation error.

PHS 398 Research Plan Form – Section 8, Vertebrate Animals

This part of the application, which has no page limit, is relatively easy to complete, but adequate detail must be included to make it credible. It is especially easy to complete if you have read the excellent NIH tutorial titled, “How to Write an Application Involving Research Animals, which can be found at: <http://www.niaid.nih.gov/researchfunding/sci/animal/pages/anitutorial.aspx>. The key is to be fully responsive to each of the five points that must be addressed (see section 5.5.8 of the *Application Guide*). Then, upload the PDF file using “Add Attachment” at the right of line 8 of the form (shown below at arrow).

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

////////////////////////////////////

Other Research Plan Sections			
8. Vertebrate Animals		 Add Attachment	Delete Attachment View Attachment
9. Select Agent Research		Add Attachment	Delete Attachment View Attachment

SELECT AGENT RESEARCH

If your research involves biohazardous agents, either at your institution or at a collaborating one, you must address the three points that are set out in the instructions for the *Research Plan* component (section 5.5.9 of the *Application Guide*). Definition of what constitutes a hazardous agent is given through a CDC URL (<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>), together with another URL for less virulent strains of the same agents which are exempt (<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html>). If you need to complete this section, create a PDF file and upload it using the "Add Attachment" button at the right of line 9 of the *PHS 398 Research Plan* form, which is shown at the bottom of the preceding page.

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

Consortial/contractual arrangements are covered under subsection 11 of the *PHS 398 Research Plan* form. NIH policy regarding consortia can be found in Part III, section 1.1 of the *PHS Supplemental Grant Application Instructions* (http://grants.nih.gov/grants/funding/424/SupplementalInstructions.docx#Human_Subjects_Exemption.Cat) and on the NIH website (http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch15.htm).

The following is a direct quote from the *Application Guide* (section 5.5.11): "The signature of the Authorized Organization Representative on the SF424 (R&R) Cover form signifies that the applicant and all proposed consortium participants understand and agree to the [statement in the text box, below]:

"The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy."

Many Principal Investigators make the mistake of setting up relationships with investigators at other institutions without administrators at those institution(s) knowing about it. This is not to imply that they are *consciously* doing something behind the backs of administrators at the other institutions. They are simply ignorant of the fact that there are rules and regulations which govern such collaborations, and that these rules/regulations are especially important if one or more investigators at the other institution(s) will be investing time in the proposed project when it is funded. Under such circumstances, the institution that is home to the collaborating investigators usually has the right to receive F&A (indirect cost) reimbursement at their negotiated rate. Rarely are such institutions willing to waive that right. Thus, the appropriate administrative officials at collaborating institutions must always be made aware that their investigator(s) is(are) involved. This approach will avoid potentially serious inter-institutional problems and conflict later and will keep your application in compliance with NIH policy, as stated in the text box, above.

If you have the need to set up a consortial relationship, once the details have been worked out among the investigators and the various administrations that will be involved, you must describe the programmatic, fiscal and administrative details of it in this subsection of the *PHS Research Plan* form. *If a substantial part of the proposed work will be done elsewhere, you must justify here why your institution and not the other one should be the grantee.*

RESOURCE SHARING PLAN(S)

Resource sharing is covered by subsection 13 of the *PHS 398 Research Plan* form. There are three parts: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genome-Wide Association Studies.

Data-Sharing Plan

You only have to worry about a data-sharing plan if one or more of your requested years has direct costs of \$500K or more associated with it – or the Funding Opportunity Announcement (FOA) to which you are responding requires it, regardless of the size of the budget. If you must create a data-sharing plan, it should be very brief – one paragraph – but it must be credible, i.e., not come across as an afterthought. NIH encourages you to consult your Program Officer or FOA contact person before creating this subsection. Additional help can be obtained by referring to <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>. Alternatively, read section 1.5.1, Data Sharing Policy, of Part III of the *Supplemental Grant Application Instructions* that were referred to on the preceding page.

Plan to Share Model Organisms

Any application that is likely to result in the development of a model organism must address how it will be shared and distributed. The NIH policy pertaining to sharing model organisms is given in section 1.5.2, Sharing Model Organisms, of Part III of the same *Supplemental Grant Application Instructions* that are referred to on the preceding page, as well as NOT-OD-04-042 (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>).

Genome Wide Association Studies (GWAS)

Applicants who propose a genome-wide association study (any investigation of genetic variation across the entire genome that is designed to identify genetic associations with observable traits [such as blood pressure or weight] or the presence or absence of a disease or condition) must provide a plan for how resultant data will be deposited into the NIH-designated GWAS repository. For details, refer to either (1) section 1.5.3, Policy for Genome-Wide Association Studies, of Part III of the *Supplemental Grant Application Instructions* referred to on the preceding page; (2) Policy for Sharing of Data Obtained in NIH-Supported or –Conducted Genome-Wide Association Studies (GWAS), which can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>; or (3) the NIH website at <http://grants.nih.gov/grants/gwas>.

If you need to create any of these plans, simply follow the clear instructions that can be found in section 5.5.13 of the *Application Guide* and upload this document using the “Add Attachment” button on line 13.

ENVIRONMENTAL IMPACT

This part of your proposal (see figure at the top of the next page) is required only when the Funding Opportunity Announcement to which you are responding stipulates that the National Environmental Policy Act (NEPA) applies. In most cases, therefore, you will check Section 4a on the *Other Project Information* component “No”. If there is such a stipulation in your FOA, check “Yes” for 4a and follow the instructions that are given in section 4.4.4 of the *Application Guide* to complete 4b through 4d. Although not required to, you should also complete this part of the application if you personally feel that your project could negatively affect the environment.

HISTORICAL PLACES

If any part of the performance site(s) is either designated as an historical place or is eligible to be so designated you must check "Yes" on line 5 of the *Other Project Information* component (see figure, below). Checking "Yes" requires that an explanation be uploaded into field 5a. If you need to do so, we recommend that your explanation detail the extent to which your project will affect the (potential) historical site.

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0301
Expiration Date: 6/30/2016

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No

4.b. If yes, please explain: _____

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No

4.d. If yes, please explain: _____

5. Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No

5.a. If yes, please explain: _____

6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No

6.a. If yes, identify countries: _____

6.b. Optional Explanation: _____

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments ☐

FOREIGN COMPONENTS

If your project is either being submitted from an institution that is outside of the United States of America or a substantial amount of the work will be conducted in another country you must check "Yes" on line 6 on the *Other Project Information* form. Doing so requires that you then complete 6a and 6b. It is unfortunate that line 6b is titled, "Optional Explanation." It is not optional for PHS organizations; you must provide such an explanation. Foreign travel for collaboration does not qualify as a "foreign component" (see section 3, Definitions, of Part III of the *Supplemental Grant Application Instructions* under "Foreign Component" - page III-47). Special resources or characteristics of the research (e.g., human subjects, animals, disease, equipment and techniques) must be described along with your opinion as to whether similar research is already being conducted in the United States. If there is such research, you must justify why more of the same kind of research is needed. Do not enter the information in field 6b. Rather, create your explanation as a separate PDF file and upload it using the "Add Attachment" button on line 12, "Other Attachments", of the *Other Project Information* form (see lower arrow in the figure, above). The attachment must carry the heading, "Foreign Justification", which must also be the name of the file.

DEVELOPMENTAL STEPS FOR CHAPTER SIXTEEN:

1. Answer the question on the *Other Project Information* form regarding involvement of human subjects. If "No," skip to bullet 5, below.
2. If "Yes", human subjects will be involved, obtain IRB approval for the project.
3. If "Yes", complete the relevant ones of the five considerations that are associated with the "Human Subjects Protection" section of the *PHS 398 Research Plan* form.
4. Answer the question on the *Other Project Information* form regarding involvement of vertebrate animals. If "No," skip to bullet 8, below.
5. If "Yes", vertebrate animals will be used, obtain IACUC approval of your project.
6. If "Yes", check to determine whether or not your institution has an Animal Welfare Assurance Number.
7. If "Yes", review the NIH tutorial, "How to Write an Application Involving Research Animals." Use what you learn to write the responses to the five considerations that must be addressed under section 8, Vertebrate Animals, of the *Research Plan* form.
8. Determine whether hazardous agents will be used in your project, either at your institution or in those parts of the project that will be performed at other institutions. If you are unsure of what constitutes a hazardous agent, refer to [http://www.selectagents.gov/ Select%20Agents%20and%20Toxins%20List.html](http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html)). If hazardous agents will be used, complete subsection 9 of the *PHS 398 Research Plan* form.
9. If investigators at other institutions will be investing time on your project, determine whether you will be required to set up an official consortial relationship with the collaborating institution. If yes, follow the instructions related to subsection 11 of the *PHS 398 Research Plan* form.
10. If applicable, create plans to share and distribute data and model organisms, which should be uploaded using subsection 13 of the *PHS 398 Research Plan* form.
11. Check the Funding Opportunity Announcement to which you are responding and determine whether or not the National Environmental Policy Act applies. If it does, check "Yes" on line 4a of the *Other Project Information* form and then complete parts 4b-4d
12. Determine whether one or more of the performance sites has been designated as or is eligible to be designated as an historical place. If so, explain what impact, if any, your project will have on that site. Upload that explanation using field 5a of the *Other Project Information* form.
13. If applicable, create an attachment covering research activities associated with your project that will be conducted outside of the United States and/or collaborators in other countries. Appreciate that this document must be uploaded using the "Other Attachments" section (line 12) of the *Other Project Information* form, not the 6b line, "Optional Explanation."



CHAPTER 17

SF 424 COVER FORM, PHS 398 COVER PAGE SUPPLEMENT FORM and APPENDIX MATERIAL

SF 424 COVER FORM

View Burden Statement		OMB Number: 4040-0001 Expiration Date: 6/30/2016	
APPLICATION FOR FEDERAL ASSISTANCE SF 424 (R&R)		3. DATE RECEIVED BY STATE	State Application Identifier
1. TYPE OF SUBMISSION ☐ Pre-application ☐ Application ☐ Changed/Corrected Application		4. a. Federal Identifier	
2. DATE SUBMITTED		b. Agency Routing Identifier	
Applicant Identifier		c. Previous Grants.gov Tracking ID	
5. APPLICANT INFORMATION			
Legal Name:			
Department: Division:			
Street1:			
Street2:			
City: County / Parish:			
State: Province:			
Country: USA: UNITED STATES ZIP / Postal Code:			
Person to be contacted on matters involving this application			
Prefix: First Name: Middle Name:			
Last Name: Suffix:			
Position/Title:			
Street1:			
Street2:			
City: County / Parish:			
State: Province:			
Country: USA: UNITED STATES ZIP / Postal Code:			
Phone Number: Fax Number:			
Email:			
6. EMPLOYER IDENTIFICATION (EIN) or (TIN):			
7. TYPE OF APPLICANT: Please select one of the following			
Other (Specify):			
Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged			
8. TYPE OF APPLICATION:			
☐ New ☐ Resubmission		If Revision, mark appropriate box(es):	
☐ Renewal ☐ Continuation ☐ Revision		☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration	
		☐ E. Other (specify):	
Is this application being submitted to other agencies? Yes No What other Agencies?			
9. NAME OF FEDERAL AGENCY:		10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:	
National Institutes of Health		TITLE:	
11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:			
12. PROPOSED PROJECT:		13. CONGRESSIONAL DISTRICT OF APPLICANT	
Start Date	Ending Date		

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION	
Prefix	First Name Middle Name
Last Name Suffix	
Position/Title	
Organization Name	
Department	Division
Street1	
Street2	
City	County / Parish
State	Province
Country USA: UNITED STATES	ZIP / Postal Code
Phone Number	Fax Number
Email	
15. ESTIMATED PROJECT FUNDING	16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?
a. Total Federal Funds Requested	a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON DATE
b. Total Non-Federal Funds	b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372, OR
c. Total Federal & Non-Federal Funds	☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW
d. Estimated Program Income	
17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001) ☐ I agree *The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.	
18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation Add Attachment Delete Attachment View Attachment	
17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001) ☐ I agree *The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.	
18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation Add Attachment Delete Attachment View Attachment	
19. Authorized Representative	
Prefix	First Name Middle Name
Last Name Suffix	
Position/Title	
Organization	
Department	Division
Street1	
Street2	
City	County / Parish
State	Province
Country USA: UNITED STATES	ZIP / Postal Code
Phone Number	Fax Number
Email	
Signature of Authorized Representative Completed on submission to Grants.gov	Date Signed Completed on submission to Grants.gov
20. Pre-application	Add Attachment Delete Attachment View Attachment
21. Cover Letter Attachment	Add Attachment Delete Attachment View Attachment

The two pages of the Cover form are reproduced on the preceding two pages. The Cover form can easily be completed successfully after reading and following the instructions that are included in the *PHS SF 424 (R&R) Application Guide* (section 4.2). It is mandatory that shaded, bordered fields be completed. Parts of the Cover form that have been modified for PHS proposals are denoted in the instructions by the logo of the Department of Health & Human Services.

There are some parts of the Cover form that require particularly careful reading of the instructions. Strict adherence is required. For example, Grants.gov will not accept five-digit ZIP codes; the full nine digits must be used. ZIP codes can be looked up at <http://zip4.usps.com/zip4/welcome.jsp>. Another example is field 14: do not use the "Suffix" subsection to enter your degrees. This part of your credentials will be provided later, in the *Senior/Key Person Profile* (chapter 12). Field 14 is meant for suffixes, such as 'Jr.'.

One of the form's subsections has been titled in a potentially confusing way. Field 5, "Applicant Information", is not about you. Information about the Applicant organization is what is sought here – which would be evident after reading of the instructions; it is the institution that submits the proposal, not you. Those who don't read the relevant instructions often fill in this part of the component incorrectly, i.e., with information about themselves.

Before creating the descriptive title for your application (field 11), please read the suggested approach to doing so that is described in chapter 18. This is an exceptionally important part of your proposal. Therefore, you should put extensive thought and effort into creating the kind of title that will make a positive first impression on your reviewers. Whenever possible, you should also use the title to help assure assignment of your application to the study section you have chosen.

The second page of the *SF 424 (R&R) Cover* form is shown on the preceding page. Again here, there are parts of it that are not intuitive. Field 16 is one of them. For NIH and other PHS agencies, the square labeled "Program is not covered by E. O. 12372" should be checked, "b. NO." Another is "Pre-application" (field 20), which should not be completed unless you are responding to a Funding Opportunity Announcement that requires it.

PHS 398 COVER PAGE SUPPLEMENT

In NIH applications the *SF 424 (R&R) Cover* Component just discussed is complemented by the *PHS 398 Cover Page Supplement*. It also consists of two pages, which are easily completed if the instructions in section 5.3 of the *Application Guide* are carefully read. A lot of what is sought is a matter of responding with a simple "Yes" or "No". For example, either you will have program income or you won't. You will either be using stem cells or you won't. Additional information is required if you answer any of the questions with a "Yes". In that case, simply follow the relevant instructions in the *Application Guide*.

APPENDIX MATERIAL

If you are going to submit appendix material, the *PHS SF424 Research Plan* form has the capacity to accept up to 10 PDF files. Use the "Add Attachments" button at the right of line 14 of the form (next page, arrow) to upload them, not the "Other Attachments" part of the *PHS SF424 Other Project Information* form. The latter section is not used in the development of NIH and other PHS agency proposals unless it is specifically called for by instruction in the Funding Opportunity Announcement to which you are responding. If you have more than 10 appendices,

combine all those after the ninth into a single PDF document and upload it as the tenth, and last, upload. Include only one copy of appendix material.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment

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Other Research Plan Sections				
8. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
9. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
10. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
11. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
12. Letters of Support		Add Attachment	Delete Attachment	View Attachment
13. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
Appendix (if applicable)				
14. Appendix		Add Attachments	Remove Attachments	View Attachments

Before deciding to include appendices, understand that such material can have a negative psychological impact on your assigned reviewers: the additional material usually means more work for them. To overcome this problem, if you decide to include appendices, it should be readily evident (e.g., from the title of each) that they contain information that is genuinely important to the review of your application. Appendices should never contain material that the reviewer must read in order to understand what is being proposed; everything needed by the reviewer to evaluate your proposal should be contained within the body of the grant application. Thus, you should never include something like a 'Methods' appendix. If NIH staff members decide that you are trying to circumvent the page limitation for the *Research Plan* by including appendices, they have the option to delay the review of your application. The instructions pertinent to this point are very clear, as can be seen in the text box at the top of the next page.

Application Guide instructions pertaining to Appendices: "Do not use the appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies.

Appendix material, if used, should facilitate the job of your assigned reviewers. In other words, it should be restricted to supporting documentation that you make available as a courtesy, should your reviewers choose to use it. A reviewer-friendly approach that is encouraged by NIH is to include a summary of the appendices that have been included – a 'table of contents' for the appendix section, if you will, which should be part of the first PDF file that is uploaded.

Several kinds of appendix material are allowed:

Publications

Application Guide instructions pertinent to publications: "Publications – No longer allowed as appendix materials except in the [three] circumstances noted below. Applicants may submit up to three of the following types of publications [see text, below]. Do not include unpublished theses, or abstracts / manuscripts submitted (but not yet accepted) for publication."

The three kinds of publications that are allowed are: (1) manuscripts and/or abstracts accepted for publication but not yet published; (2) manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available; and (3) patents directly relevant to the project. If you elect to provide one or more of these, the entire document must be uploaded as a PDF attachment.

Unpublished, but accepted, manuscripts that are not publicly available are good examples of what *should* be included as appendix material, because the reviewers would otherwise have no access to such information. It is especially important to include such manuscripts if they are a source of details related to preliminary data that you have summarized under the Justification and Feasibility subsection of one of your aims.

If you are a New/Early Stage Investigator who has written a dissertation as part of your training, because so much emphasis is placed on assessment of your background and training, we recommend that you include your dissertation abstract as one of your appendices – unless, of course, a free copy of it is available online.

Instruments

Application Guide instructions pertinent to instruments: Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.

It is sometimes necessary for reviewers to physically inspect instruments that will be used in the research project. Such 'blank forms' take up too much space in the body of the Research Strategy section, which is why they have been allowed as appendix material.

Other Allowed Materials

If you have either material that cannot be submitted electronically or that cannot be converted to PDF format (such as medical devices, prototypes, DVDs, CDs), do not include such things with the application when it is submitted and do not send it to the Center for Scientific Review under separate cover. Rather, wait until you are notified as to the review panel that will evaluate your proposal. The name of the Scientific Review Officer who is administratively in charge of that panel, together with his/her contact information, will be provided as part of that notification. Immediately contact the SRO to negotiate how such material can be included in the evaluation of your proposal.

What Not to Include as Appendix Material

Any publication that is publicly available cannot be submitted as an Appendix.

In the past, it was permissible to have small images in the body of the grant proposal accompanied by an enlarged image in the Appendix. That is no longer permissible. This does not pertain, of course, to images that are contained within attached publications.

DEVELOPMENTAL STEPS FOR CHAPTER SEVENTEEN:

1. Complete the *SF 424 Cover* form and *PHS 398 Cover Page Supplement* form after carefully reading the instructions that guide their preparation (sections 4.2 and 5.3, respectively).
2. Decide what Appendix material will be submitted, if any.
3. If you need to submit more than 10 appendices, combine all after the ninth into a single PDF document and upload it as Appendix 10.
4. Appreciate that Appendix material can have a negative psychological effect on reviewers, because it usually means more work in evaluating the application. Therefore –
5. Screen each potential Appendix using this litmus test: Is this being included as a courtesy to the reviewers – to make their jobs easier? If the answer is 'Yes,' retain that Appendix.
6. Understand clearly the three kinds of publications that can be included as Appendix material.
7. Be certain to include manuscripts in press as appendices.
8. Do not include stand-alone images as Appendix material, with the exception of those that are parts of included publications. They are allowed.

OVERVIEW: PART FOUR

MAXIMIZING YOUR APPLICATION'S COMPETITIVENESS

Small things can make a big difference in how well your proposal is received by reviewers.

This part of the *Workbook* addresses components and steps in the developmental process that are relatively minor in terms of the space/time that are related to them. However, they are critically important to maximizing the competitiveness of your proposal. These are the last things to be done, but they shouldn't be done in haste or at the last minute, because they are essential to the success of your application. Thus, you need to plan to have time enough at the end of the developmental process to complete these final steps.

Chapter eighteen offers strategies for the development of a compelling and informative title, which is what conveys the first impression of your application.

Chapter nineteen addresses how to safely include proprietary or privileged information in your proposal, as well as how to prepare the all-important *Project Summary/Abstract* and *Project Narrative* sections.

Chapter twenty will guide you through preparation of the Cover Letter that should accompany your application, as well as how to obtain letters of support that will maximally support your proposal.

Chapter twenty-one describes the final – and most important – step in developing a competitive application: pre-submission review of your final draft by knowledgeable colleagues.

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1904-1905

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CHAPTER 18

HOW TO CREATE A COMPELLING, INFORMATIVE TITLE FOR YOUR PROPOSAL

GENERAL CONSIDERATIONS

The title is critically important, because it will likely be the first thing that a reviewer will see. In other words, the title gives the first impression of your application — and we all know that you get only one chance to make a good first impression. The title is also important as one of the things that will be used by staff at the Center for Scientific Review to assign your application to a specific Scientific Review Group/study section for evaluation. Thus, it is in your best interest to make your title as eye catching and informative as you can.

TIP: Your title should emphasize the payoff — the product of the research.

It is particularly important that your title emphasize what the research will produce, i.e., the payoff of the research, not the process that will yield that product. You should never offer a generic, process-oriented title like, 'Investigations of *Bacillus megaterium*.' Applicants often write such a title because they have misinterpreted the instructions in the textbox at the top of the next page and mistakenly think that the title must be sufficiently generic to apply to all future renewal applications. Rather, your title should immediately convey to the agency and its reviewers what the mission-relevant payoff from the research will be. Thus, the objective of your application from the *Specific Aims* section and the description of your expected contribution from the Significance subsection of the *Research Strategy* section will be inform the development of your title.

You can also use your title to help steer your application to the study section of your choice. For example, let's say that you have chosen the Bacterial Pathogenesis Study Section (BACP) as the one which is most qualified to review your proposal. A layperson (highly qualified, but still a layperson) will make assignment decisions, based largely on his/her understanding of your proposal's title and the information you include in the Project Summary/Abstract. So help that person make the 'right' decision. 'Genetics of *Mycobacterium tuberculosis* Pathogenesis' reflects that the focus of the research is a bacterium, and the word "pathogenesis" is included. With that title it would be hard to imagine an assignment to some other study section than BACP.

TIPS ON CREATING YOUR TITLE

If you are going to capture the attention of your reviewers, the title must be maximally informative and should convey as much about the novelty of your idea as is possible. Titles with this kind of positive impact aren't often created in haste; time and effort commensurate with the importance of this part of your application must be invested.

As a strategy, we recommend that you create your title by using a modification of an approach that is often used by marketers to develop advertising slogans. They begin the selection pro-

cess with as many as 100 'catchy' slogans that they have created. Then, they narrow the number down to the most appealing one using focus groups. They invest this kind of effort in identifying the best slogan because millions of dollars will likely be riding on that slogan's subsequent capacity to capture the interest and attention of the marketer's target audience. *Your stakes as a proposal writer are no less great.* Therefore, it is smart business, in our opinion, to apply the same strategy to the development of the 'slogan' – the title – that will immediately catch the interest and attention of your target audience, the reviewers of your proposal.

Current Application Guide instructions pertinent to creating a title: "NIH and other PHS agencies limit title ... length to 81 characters, including the spaces between words and punctuation. Titles in excess of 81 characters will be truncated. Be sure to only use standard characters in the descriptive title: A through Z, a through z, 0 through 9, space and underscore. A "new" application must have a different title from any other PHS project with the same PD/PI. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A "revision" application must have the same title as the currently funded grant."

The admonition, above, to hold title length to no more than 81 characters and spaces, including punctuation, was based on what the capacity of NIH's eRA systems – 81 was the most that could be accepted. On March 17, 2014 an NIH eSubmission Items of Interest was published by the Office of Extramural Research. It announced that the capacity in eRA systems has been increased to 200 characters and spaces, including punctuation. In other words, titles that exceed 81, up to 200 characters and spaces including punctuation, will no longer be truncated. Our expectation is that this change will be reflected in the next iteration of the SF 424 *Application Guide* instructions.

As noted earlier, we respectfully take exception to one part of the instructions that appears in the text box, above: In our opinion, renewal applications should *always* have a title that is different from the grant that supports the current period of investigation. Even though the title of a renewal changes under our approach, its number at NIH will remain the same (except for the last two digits, which change annually to denote the year of funding). The reason that we recommend changing the title on renewal applications will become apparent later in this chapter.

Steps in Creating a Set of Titles

1. As noted above, the title of an NIH application is no longer restricted to 81 characters and spaces, including punctuation. You now have a limit of 200.
2. To begin, review your application and list all words/phrases that convey important information, significant impact, and/or the novelty of your project. Many of these will be things that you have highlighted in the text with italics. Pay particular attention to the application's objective in the *Specific Aims* section and the description of your expected contribution in the Significance subsection of the *Research Strategy* section. Those two components clearly denote what the intended payoff is. Also include key words from the name of the study section to which you want your proposal assigned.
3. Of these words and phrases, consider whether any of them have widely understood, standard abbreviations/acronyms that can be substituted, e.g., DNA for deoxyribonucleic acid or CNS for central nervous system. List such abbreviations and acronyms. *Under no circumstances should you use non-standard abbreviations or acronyms in your title,*

i.e., one(s) that you have coined and defined in the text of your application. Once you have listed all words and standard abbreviations/acronyms that might have a role in conveying information about your application, begin arranging them (or variations of them) in combinations and permutations that do not exceed the number of letters and spaces (including punctuation) that are allowed. For example, if you were writing an application about developing successful grant applications to NIH, and you had listed such key words as success/successful, grants, proposal writing, grantsmanship, NIH, creativity, and competitive, you might formulate titles like:

- Creative Formats for Writing Competitive Grant Applications to the NIH
- NIH Proposal Writing Made Simple: Creative Formats for Successful Applications
- Creative Ways To Develop Competitive NIH Grant Proposals
- Keys to Success for Writing Creative, Competitive NIH Grant Proposals
- Competitive NIH Grantsmanship Skills Made Simple and Successful

Create as many titles as you can in an hour. Then, reduce the number to what you think are your 'Top 10.' Print them.

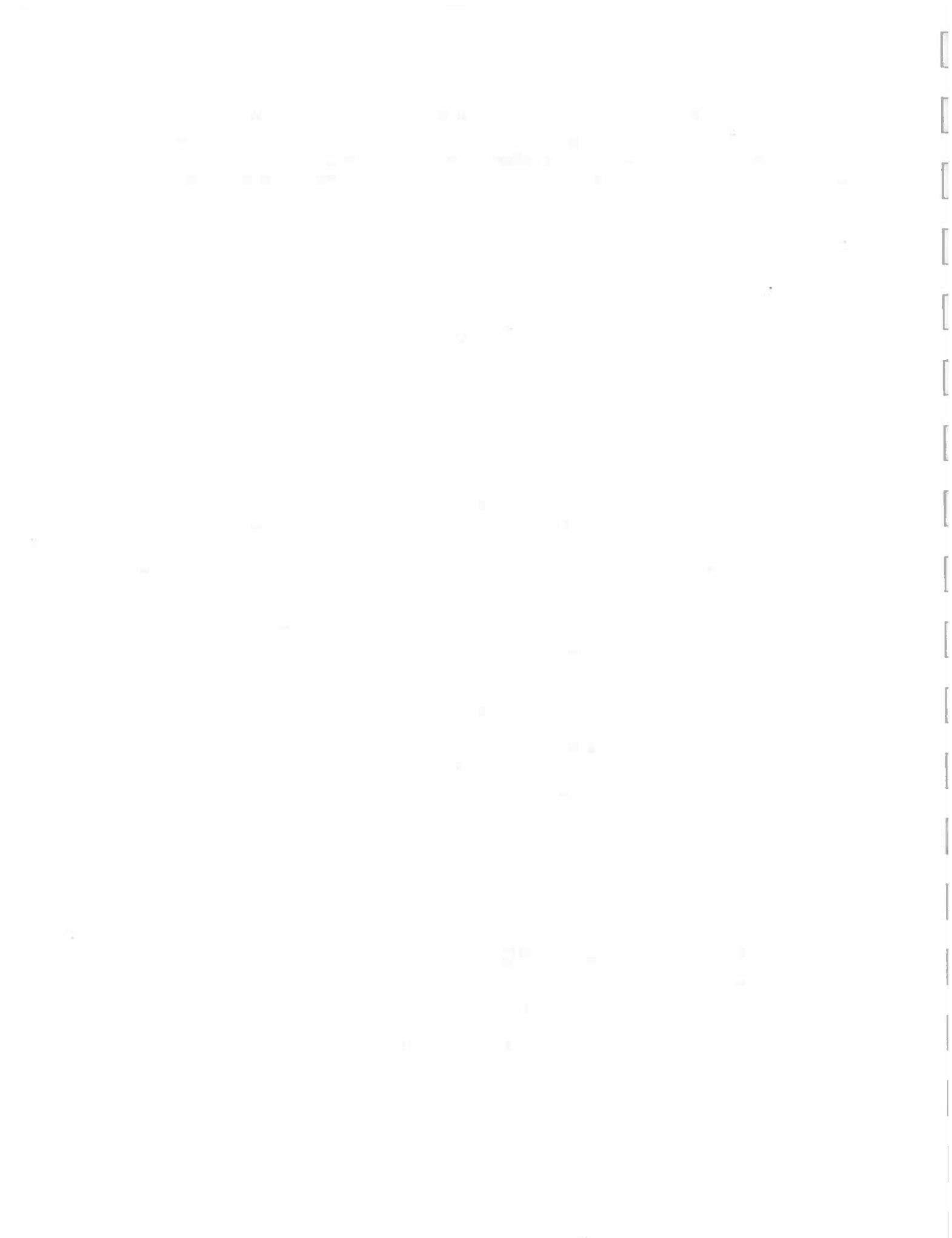
Steps in Identifying the Best Title

1. Show your list of titles to colleagues, both those who are closely related to your field and those who are strong academicians but not members of your field. With respect to choosing the latter, you will have identified the study section that is most qualified, in your opinion, to review your grant proposal (chapter 4) and will have documented the range of expertise that is held by its members. The individuals selected from outside your field should represent the fringe of the range of expertise that you expect to have on the review panel. Ask each individual you have selected to pick the one title that s/he thinks is maximally informative and most interesting. It has been our experience that most of your colleagues will select the same one or two, which should tell you that there is something especially appealing about that/those particular title(s).
2. Because titles have to be understood and used by laypersons, also take your list of titles to several such individuals -- a spouse or a neighbor, for example. Ask them to choose. You will probably find that they select the same title(s) that your colleagues chose.
3. Use the information that you have gathered in this manner to narrow the possibilities to no more than three titles. Further refine them until one begins to stand out clearly over the others because of its informative, novel, stimulating character. You will know it when you see it, because it will convey succinctly and compellingly what the payoff of the proposed research program will be. That's your title!

Now, enter the title that you have chosen in field 11 of your application's *SF 424 (R&R) Cover Component*.

DEVELOPMENTAL STEPS FOR CHAPTER EIGHTEEN

1. Appreciate that your title should emphasize the payoff from the proposed research.
2. Make a list of words and standard abbreviations that are candidates for use in your title.
3. Create a large number of titles, using combinations and permutations of the words and abbreviations you have selected. Select what you think are the top 10 from the list.
4. Ask colleagues and laypersons to select the most informative, interesting title.
5. Refine the final candidate(s) until it is possible to settle on one of them as your title.



CHAPTER 19

PROJECT SUMMARY/ABSTRACT, PROJECT NARRATIVE and PROPRIETARY/PRIVILEGED INFORMATION

PROJECT SUMMARY/ABSTRACT and PROJECT NARRATIVE

The *Project Summary/Abstract* and the *Project Narrative* will be concatenated after your application is submitted to produce the abstract for your proposal, which is referred to by NIH as the application's "Description." It will be read by every reviewer, most especially by non-assigned reviewers who have not looked at your application prior to the study-section meeting. In our opinion, the *Project Summary/Abstract* is the most important part of your proposal in terms of developing advocacy for funding it, especially among those who will be seeing your application for the first time at the study-section meeting. In addition, the *Project Summary/Abstract* and *Project Narrative* will be read by NIH staffers who will make important decisions regarding your proposal. These will include, but will not necessarily be limited to, those who will assign your application for review – both in terms of the review panel that will critique it and the persons on the panel who will be appointed as your reviewers; those who need to convey to legislators and the general public what NIH is funding; and NIH staff members who will catalog the application with respect to its content. As will be detailed later in this chapter, sensitive information must not be included in the *Project Summary/Abstract* and/or *Project Narrative* because these two sections will be published in the RePORTER database as your proposal's Description. NIH's instructions to the applicant, which are quoted in the text box, below, make this point unequivocally.

Application Guide Instructions pertinent to the Project Summary (section 4.4.7):
"This Summary must not include any proprietary/confidential information."

You also have to consider what is included in the *Project Summary/Abstract* and *Project Narrative* from the standpoint that your closest competitor will be able to read it when it is published in the RePORTER database. Thus, you walk a fine line when you write these parts of the application: you must include enough to get your reviewers genuinely excited, especially those who are seeing your application at the meeting for the first time, but not so much that you unnecessarily enable your competitors.

Tips on Creating the Project Summary/Abstract

The *Project Summary/Abstract* is created by adding an attachment of 30 lines or less. Exceeding 30 lines will generate an 'error' message during the initial validation of your proposal. The exception to this limitation is the K Award application, in which you have a full page for the Summary/Abstract, because proposed training must be summarized in addition to the science. The *Project Summary/Abstract*, which must be in the form of a PDF file, should be attached using the "Add Attachment" button for line 7 of the SF 424 *Other Project Information* form (below at arrow).

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 6/30/2016

1. Are Human Subjects Involved? ☐ Yes ☐ No
- 1.a. If YES to Human Subjects
- Is the Project Exempt from Federal regulations? ☐ Yes ☐ No
- If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
- If no, is the IRB review Pending? ☐ Yes ☐ No
- IRB Approval Date:
- Human Subject Assurance Number:
2. Are Vertebrate Animals Used? ☐ Yes ☐ No
- 2.a. If YES to Vertebrate Animals



7. * Project Summary/Abstract	Add Attachment	Delete Attachment	View Attachment
8. * Project Narrative	Add Attachment	Delete Attachment	View Attachment
9. Bibliography & References Cited	Add Attachment	Delete Attachment	View Attachment
10. Facilities & Other Resources	Add Attachment	Delete Attachment	View Attachment
11. Equipment	Add Attachment	Delete Attachment	View Attachment
12. Other Attachments	Add Attachments	Delete Attachments	View Attachments ☐

In addition to being informative of what is in the proposal, the *Project Summary/Abstract* must communicate this material with contagious enthusiasm.

The instructions that guide preparation of the *Project Summary/Abstract* are contained in section 4.4.7 of the *Application Guide*. They are, in part:

The *Project Summary* should be a self-contained description of the project ... [It] is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency** [NIH's emphasis]). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person."

Because of the amount of information that must be included in the 30 lines allowed for the Project Summary, it is one of the most difficult sections of the application to write. Assume that only essential information is included. For example, we recommend that you not follow the instruction quoted in the text box to include relevance to NIH's mission in the *Project Summary/Abstract*; it is a waste of space to do so, in our opinion. As will be seen later in this chapter, relating the project to public health, i.e., NIH's general mission, is the purpose of the *Project Narrative* part of your proposal. We recommend that specifics pertaining to NIH's mission be included there. (Remember, the *Project Summary/Abstract* and *Project Narrative* will be combined to create the application's *Description*.) Similarly, there isn't room enough to include descriptions of past ac-

complishments, which is why such information is explicitly prohibited by the instructions. For the same reason, background information should not be included. You have to assume that the reader, especially your assigned reviewers, will be sufficiently conversant with the field that background information is not needed in this part of the application.

Don't worry if there appears to be duplication here of other parts of your application, such as the Specific Aims section. Such duplication can't be – shouldn't be – avoided, because the *Project Summary/Abstract* must be a stand-alone document, i.e., one that does not need the rest of the proposal to be understood. If such duplication concerns you, decrease the perception of redundancy by paraphrasing what is in the Project Summary, i.e., avoid use of the same words.

Here are the steps that we recommend you take to develop your critically important *Project Summary/Abstract*:

1. The *Project Summary/Abstract* should not be written until you have completed the *Specific Aims* and *Research Strategy* sections. In other words, it should be written last – but not at the last minute.
2. You need every millimeter of space that you are allowed. Accordingly, use the smallest font allowable (i.e., 11-points). Line spacing should be the minimum allowed: 6 lines per vertical inch. *Use left and right margin settings of 0.5 inch here, rather than the 1 inch that we recommend for the Research Plan.* A small amount of additional space can be gained by auto-hyphenating the document (manual hyphenation can be a problem if word location is shifted when you create the PDF version of this document). Use of full justification will sometimes save a bit more.
3. Do not write this section in the first person. The instructions prohibit doing so.
4. Do not worry if you initially write more than the 30 lines that are allowed; there will be an editing phase after the first draft has been written.
5. Open the *Project Summary/Abstract* with a sentence that succinctly describes the gap in the knowledge base or unmet need that will drive the application.
6. Copy and paste into the file the sentences in the *Specific Aims* section that contain words that you highlighted in italics. They are designed to set up a compelling progression of logic when they are juxtaposed, one after the other.
7. Add your specific aims and the primary methods/approaches that will be used to accomplish them.
8. Conclude the *Project Summary/Abstract* with a combination of the 'contribution' sentence and statement of significance from the Significance subsection, and the statement of innovation from the Innovation subsection. These subsections are found at the beginning of the *Research Strategy* subsection.
9. Edit the file to no more than 30 lines.
10. Highlight key words in the edited *Project Summary/Abstract* using either italics or, if you are using Arial or Helvetica, underlined italics.

Tips on Creating the Project Narrative

Line 8 of the SF 424 *Other Project Information* component (see figure on the preceding page) allows you to attach a separate PDF file of no more than 2 or 3 sentences, which are meant to complement the *Project Summary/Abstract*. They will ultimately be combined with your *Project Summary/Abstract* as an integral part of the "Abstract" that is published in the RePORTER database. Despite what its name implies, the *Project Narrative* in an NIH proposal is meant to reflect the relevance that the proposed work has to public health. It should also reflect how the proposed research relates to the mission of the PHS component that you are targeting. To en-

sure that reviewers connect with the purpose of this part of your proposal, we recommend that you begin the first sentence with something like, 'The proposed research is relevant to public health because ...' Conclude with a sentence that relates either to NIH's mission or to that of the awarding component at NIH which you are targeting (e.g., NICHD). That sentence might begin with either, 'The project is relevant to NIH's mission because ...' (see chapter 1 for NIH's mission statement) or a modification of that opening which would be appropriate for one of NIH's institutes or centers.

To write these sentences, we recommend that you synthesize them from what you have written in the last, 'positive impact' part of the *Specific Aims* section; the third, 'benefits' part of the Significance subsection of the *Research Strategy* section; and the third, 'new horizons' part of the Innovation subsection, also a part of the *Research Strategy* section.

PROPRIETARY / PRIVELEGED INFORMATION

Information that is either proprietary, potentially patentable, a trade secret, or privileged / confidential commercial or financial information can be included in your grant application – but you should think twice before doing so. Such information should never be included in the *Project Summary/Abstract* or *Project Narrative*, however, because when it is funded, you know that those parts of your proposal will be published in the RePORTER database. In other words, it will enter the public domain. In addition, you have to remember that any funded federal grant can potentially be obtained in its entirety through the Freedom of Information Act. Therefore, putting sensitive information in the body of the proposal doesn't protect it, either.

If you must include sensitive material in your application in order to give reviewers a full appreciation of what you are proposing, we recommend that you make clear to NIH that your proposal contains such information. You do so by, first, checking "Yes" on line 3 of the *Other Project Information* component (arrow), the relevant part of which is reproduced below.

RESEARCH & RELATED Other Project Information	OMB Number: 4040-0001 Expiration Date: 6/30/2016
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1. Are Human Subjects Involved? ☒ Yes ☐ No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

If no, is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date:

Human Subject Assurance Number:

2. Are Vertebrate Animals Used? ☒ Yes ☐ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number:

3. Is proprietary/privileged information included in the application? ☒ Yes ☐ No

4 a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No

4 b. If yes, please explain:

4 c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or

To further inform NIH as to precisely which parts of your application are sensitive, you need to mark them clearly. We recommend that you do so using bolded brackets. This is the same approach that we recommend be used to mark changed parts of resubmitted applications. If you

are resubmitting a proposal you should use some other approach to mark the location of sensitive information. Each appearance of sensitive information should also be preceded by a text-boxed statement that is similar to, but slightly different from the one that is suggested in the *PSH SF 424 (R&R) Application Guide* (section 4.4.3). The modified version that we recommend is: "The following information, which is marked with bolded brackets, is proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation." There are two parts of the NIH-suggested legend that should give you pause. One is the phrase "requests not be released." As noted above, any funded PHS grant is potentially obtainable through the Freedom of Information Act. Thus, 'requesting' that the information be protected and the reality of whether it will be protected are two different things. The second concerning part is the final phrase, "except for purposes of review and evaluation." That means that the information can and will be released to persons outside the government who are involved in the review process, i.e., reviewers. The vast majority of reviewers are highly ethical, reliable individuals. Unfortunately, rarely, that is not the case. A final reason for concern is the following PHS-specific disclaimer: "If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. Although the grantee institution and the PD/PI will be consulted about any such disclosure, the PHS will make the final determination." Given all of these ways in which proprietary/privileged information could be disclosed, our recommendation is that, before including sensitive information, first discuss doing so with the person at your institution who is responsible for protecting intellectual property. If s/he is not concerned, you probably shouldn't be, either. If s/he is, we recommend that the two of you directly contact the Scientific Review Officer of the panel that you are targeting. If s/he cannot answer your questions satisfactorily, keep asking higher levels of authority until you are satisfied that the NIH-recommended approach will (or will not) safeguard what you want to include.

DEVELOPMENTAL STEPS FOR CHAPTER NINETEEN:

PROJECT SUMMARY/ABSTRACT & PROJECT NARRATIVE

1. Do not write the *Project Summary/Abstract* and *Project Narrative* until after the Research Plan has been completed.
2. Write the *Project Summary/Abstract* – 30 lines or less – using the 11 steps offered above.
3. Review NIH's mission (or the mission of the Institute or Center you are targeting).
4. Write the *Project Narrative* – 2 or 3 sentences – emphasizing the importance that the proposed research has to public health, as well as its relevance to specific aspects of NIH's or the Institute's/Center's mission.
5. Show the final drafts of your *Project Summary/Abstract* and *Project Narrative* to several colleagues. Ask whether or not: (i) the flow of logic in them is clear; (ii) the gap or need to be addressed is well delineated; (iii) the importance of the proposed work and its positive impact on the field and on public health are evident; and (iv) whether or not enthusiasm is engendered.
6. Use the feedback you obtain to revise these components, if necessary.
7. Convert the (revised) *Project Summary/Abstract* and *Project Narrative* into PDF files.
8. Upload the *Project Summary/Abstract* and *Project Narrative* PDF files into your application using the "Add Attachment" buttons at the right of lines 7 and 8, respectively.

PROPRIETARY/PRIVILEGED INFORMATION

9. Assure that nothing sensitive is included in your *Project Summary/Abstract* and/or *Project Narrative*.

10. Decide whether it is necessary to include proprietary / privileged / confidential information in the body of your application. If so, mark such information using a vertical line in the margin and precede it with a legend similar to the one suggested in this chapter.
11. Consult the official at your institution who is in charge of protecting intellectual property regarding whether what you are considering meets with his/her approval.
12. If necessary, together with your institution's intellectual-property officer, contact an official at NIH, starting with the Scientific Review Officer of the review panel you are targeting. Determine officially the extent to which what you have included will / will not be protected.

EXAMPLE OF A WELL-WRITTEN PROJECT SUMMARY/ABSTRACT (Note half-inch margins)

There is a fundamental gap in understanding how variation in the expression of conserved appendage-patterning genes leads to the enormous range of morphological variation that is observed among animals, including human beings. Continued existence of this gap represents an important problem because, until it is filled, understanding of the genetic anomalies that lead to developmental abnormalities of the limbs will remain largely incomprehensible. The long-term goal is to better understand the genetic variation and architecture of the complex phenotypes that attend limb development, both within and between species. The overall objective in this application is to identify how hind-limb development and variation are genetically controlled in hemimetabolous insects – an excellent model, because their hind legs often exhibit dramatic species-specific morphological diversification. Such a difference is not characteristic of holometabolous species, such as the familiar *Drosophila* and *Tribolium* models. Most conspicuous is differential enlargement of the hemipteran's hind (T3) legs, compared to the two pairs of forelegs. The central hypothesis is that diversification of hind-limb development results from temporal and spatial changes in the expression of specific regulatory genes. This hypothesis has been formulated on the basis of preliminary data produced in the applicants' laboratories. The rationale for the proposed research is that understanding evolutionarily conserved fundamental mechanisms of limb differentiation has the potential to translate into better understanding of the pathogenesis of leg developmental defects that now afflict one out of every 124,000 babies born in this country. Guided by strong preliminary data, this hypothesis will be tested by pursuing two specific aims: 1) Determine the function and relative importance of Ubx in developing T3 legs; and 2) Identify the role of dpp and ds gene expression in regulating T3 leg development. Under the first aim, an already proven RNA interference (RNAi) approach, which has been established as feasible in the applicants' hands, will be used to inhibit expression of Ubx, after which T3-specific changes in structure and gene expression will be analyzed across a wide range of hemipteran insects. Antibodies and RNA-hybridization probes that are already on hand will be used. Under the second aim, homologs of the genes dpp and ds will be cloned and patterns of expression analyzed and related to T3 leg development using *in situ* hybridization. The approach is innovative, in the applicant's opinion, because it departs from the status quo by utilizing naturally occurring variation in the structure of insect legs to better understand the complexity of limb development in human beings. New research horizons are expected to become attainable as a result. The proposed research is significant, because it is expected to vertically advance and expand understanding of how natural variation in patterns of gene expression produces evolutionarily conserved complexity in the phenotype of hind-limb development. Ultimately, such knowledge has the potential to inform the development of genetic counseling that will help to reduce the growing problem of leg deformity in the U.S.

EXAMPLE OF A WELL-WRITTEN PROJECT NARRATIVE (Limited to 2-3 sentences)

The proposed research is relevant to public health because the discovery of evolutionarily conserved mechanisms is ultimately expected to increase understanding of the pathogenesis of developmental abnormalities of the legs of human beings, as well as risk prediction for such abnormalities. Thus, the proposed research is relevant to the part of NIH's mission that pertains to developing fundamental knowledge that will help to reduce the burdens of human disability.

CHAPTER 20

COVER LETTER ATTACHMENT and LETTERS OF SUPPORT

PHS 398 COVER LETTER ATTACHMENT

As the title of this section implies, the Cover Letter attachment is specific to NIH grant applications and those to other Public Health Service agencies.

Application Guide instruction pertinent to the Cover Letter attachment, Section 4.2.21:
“Applicants are encouraged to include a cover letter with the application. The cover letter is only for internal agency use and will not be shared with peer reviewers.”

As implied in the instructions above, with three notable exceptions that will be pointed out, below, this is an optional attachment. We join with NIH, however, in urging you to submit one. We do so because a well-written cover letter can accomplish a great deal positively with respect to assignment and review of your proposal. The “internal agency” referred to in the text box, above, is the Division of Receipt and Referral at the Center for Scientific Review – to which your cover letter should be addressed. The salutation should either be “Dear Sir/Madam,” “Dear Referral Officer,” or “To Whom It May Concern.”

The letter should concentrate on issues that are related to assignment and review, i.e., it should not contain such things as an overview of what is proposed in the grant application. CSR staff will get that information by reading the title, Project Summary/Abstract, Project Narrative and, perhaps, other parts of your proposal. The letter should be written so that it can be interpreted and understood by a highly qualified layperson. It is in your best interests to do everything that you can in the Cover Letter to help such a person make decisions that are favorable to the assignment and review of your proposal.

NIH wants you to list one piece of information/make one request per line. Using this approach will help assure that none of your requests are overlooked. Accordingly, the format of the letter will be a series of one-line requests, some of which may be followed by a subordinate paragraph in which you explain and justify the related request.

1. ***The Application's Title.*** See chapter 18 for tips on how to create a strong title for your proposal, which can help to steer your application to the study section that you prefer.
2. ***Title of the Funding Opportunity Announcement.*** This is the title of either the Program Announcement (PA) or Request for Applications (RFA) to which you are responding. Include its exact name and number. If you are self-initiating your proposal, i.e., it is not written in response to a specific solicitation, you should list the relevant Parent Announcement's name and number.
3. ***Request for Assignment to a Specific Awarding Component and Why.*** You can suggest which of NIH's awarding components (Institute, Center or Office – see chapter 1) should consider your proposal for funding after it has been reviewed and scored.

To make the request, write out the funding component's name in full, followed by a hyphen and its acronym; do not enclose the acronym in parentheses. If you are presenting a topic that is pertinent to the mission of more than one awarding component (a so-called 'cross-cutting' topic), you can (and should) request multiple assignments for your application. Doing so potentially gives you multiple chances at funding. Indicate in your Cover Letter which awarding component should be primary. Justify why in a paragraph that is subordinate to the request. Rank order the remaining ones (as many as are applicable), including justification for each. You should consider both subject applicability to the awarding components and the relative levels of enthusiasm of their Program Officers (see chapter 3) in making your prioritization. As an example, let's say that your topic is a cardiovascular disease that is seen exclusively in elderly persons. The relevant Program Officer at the National Heart, Lung and Blood Institute was very enthusiastic about the topic and has indicated how funding your idea would help the Institute accomplish its near and long-term goals. By contrast, the PO at the National Institute on Aging was definitely supportive, but somewhat less enthusiastic. Under such circumstances you would justify NHLBI as primary and NIA as secondary. With such a dual assignment, after its review, your proposal would first go to NHLBI for consideration of funding. If program staff there would opt to fund the proposal, that would be the end of the story – a happy ending. If, on the other hand, they elected not to fund your proposal it would automatically be made available to NIA for consideration.

4. ***Request for Assignment to a Specific Scientific Review Group and Why.*** Using the approaches described in chapter 4, you will have identified what you think is the most appropriate Scientific Review Group for your application. You should make a request for that SRG in your Cover Letter (name written out in full, followed by a hyphen and its acronym; the acronym should not be enclosed in parentheses), and provide justification as to why, in your opinion, it is the most appropriate choice. That would be done in a separate paragraph that would be subordinate to the one-line request. Usually, you would base your justification on the kinds and range of expertise on the panel. If two or more SRGs would be applicable to the review of your proposal, you should indicate that fact. As part of your justification, you should rank order them from most to least appropriate.

If the most qualified SRG is missing a kind of expertise that is necessary for you to receive a fair review, you should request, on a separate line, that the missing kind of expertise be added for the purpose of reviewing your proposal. In the related subordinate paragraph you would justify that request by pointing out that, even though the requested SRG is the most qualified, without the missing kind of expertise you could not get a fair review of your proposal.

5. ***List of Individuals Who Should Not Review Your Proposal, and Why.*** You should make clear in your Cover Letter who should not review your application. For example, while making your analysis of SRGs, if you were to discover that your closest competitor is a member of the most appropriate panel, you could point that out; it may not be fair for a variety of reasons for such a person to be involved in the review of your application. But, before you decide to exclude him/her, do the cost-benefit analysis that is recommended in chapter 4 (page 37): You may elect not to exclude him/her because s/he is would be the reviewer who is most able to appreciate what you would be proposing. You don't have to worry about offending someone by including his/her name in the list of those who shouldn't be involved in the review of your proposal. The Cover Letter will only be seen by NIH staff members. In other words, it will not be provided to reviewers.

If there are those outside the panel who should not review your proposal, they should also be named, because they might otherwise be selected to provide an outside review. The name of any person you include must be accompanied by credible justification, in a subordinate paragraph, as to why that individual should not be involved in the review of your proposal. Avoid subjective reasons, such as "She doesn't appreciate the importance of the area." Also avoid making allegations that reflect negatively on the person you are trying to exclude, e.g., "He would likely steal my idea." The least controversial approach is to simply state that the named individuals are close competitors.

You should also name anyone who has been involved in the development of your proposal, e.g., the members of your pre-submission review committee. For this reason you should avoid asking anyone to serve on your pre-submission review committee who would potentially be a sympathetic official reviewer. You should also name individuals who would have a conflict of interest for some reason.

6. ***Specific Information About the Timing and Cause of a Late Application.*** You cannot ask permission to submit a late application. But you can ask 'forgiveness' in your Cover Letter for being late. You should definitely take this approach if you have a legitimate reason for missing the deadline (e.g., the death of a close family member). If the cause for lateness is a natural or man-made disaster, NIH will often extend the submission deadline for those who have been affected. Such extensions are issued as official Notices, which will come to you automatically if you are a subscriber to either the NIH listserv or RSS feed that provides information about the preceding week's Notices, Program Announcements and Requests for Applications (see chapter 1). Alternatively, you can use the search engine on the NIH website to look for such an announcement. If such a Notice has been issued and you submit within the extension period, your application would not be considered late. Simply state in your Cover Letter that you are one of those who were affected by the event and cite the title and number of the extension Notice. Additional details regarding late applications are contained in the following Notices: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-155.html>; .../NOT-OD-08-027.html; and .../NOT-OD-07-083.html and associated updates to them.
7. ***Reason for a Changed/Corrected Application.*** If you submit a Changed/Corrected application, NIH requires that you write a Cover Letter that addresses the reason for the change/correction. All of the information in the previous Cover Letter must be included in the new Cover Letter – plus the required explanation.
8. ***Application With a Sub-Award Budget that is Not Active Across All Years of Proposed Support.*** This is another instance when the Cover Letter is required. If you have a sub-award budget that is not included in all years you must explain why.
9. ***Agency Approval Documentation*** also requires a Cover Letter. For example, if you are submitting a budget that exceeds \$500,000 in one or more years, that budget must be pre-approved by NIH. You would state that you have such approval in your Cover Letter and then append the NIH documentation as part of the uploaded PDF document. Similarly, you must have NIH approval to submit an R13 Conference Grant proposal or a U13 Cooperative Agreement application. You would state that you have the approval in the Cover Letter and append the supporting documentation to the Cover Letter file.

The contents of the Cover Letter should be organized and presented using the one-item-per-line format that is suggested by the *Application Guide* (see section 4.2.21, page I-55,

"Suggested Cover Letter Format"). The document should be converted to a PDF document and uploaded using the "Add Attachment" button at the bottom of page 2 (line 21) of the Cover form, which is reproduced below (see arrow). Give the file a clear and descriptive title when you save it onto your hard drive.

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

Page 2

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION			
Prefix:	First Name:	Middle Name:	
Last Name:			Suffix:
Position/Title:			
Organization Name:			
Department:		Division:	
Street1:			
Street2:			
City:		County / Parish:	
State:		Province:	
Country:		ZIP / Postal Code:	
Phone Number:		Fax Number:	
Email:			

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19. Authorized Representative			
Prefix:	First Name:	Middle Name:	
Last Name:			Suffix:
Position/Title:			
Organization:			
Department:		Division:	
Street1:			
Street2:			
City:		County / Parish:	
State:		Province:	
Country:		ZIP / Postal Code:	
Phone Number:		Fax Number:	
Email:			
Signature of Authorized Representative		Date Signed	
Completed on submission to Grants.gov		Completed on submission to Grants.gov	
20. Pre-application		Add Attachment	Delete Attachment View Attachment
21. Cover Letter Attachment		Add Attachment	Delete Attachment View Attachment

LETTERS OF SUPPORT

Letters of support are uploaded into your application using "Add Attachment" button for line 12, "Letters of Support" of the *PHS 398 Research Plan* form (top of the next page, arrow).

These letters are essential parts of your application, especially if they pertain to the commitment of individuals who have no measurable effort invested in the project (e.g., Other Significant Contributors). Without such letters reviewers would almost surely become concerned that the individuals named in the proposal are not committed in the ways that you describe.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims		Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy		Add Attachment	Delete Attachment	View Attachment
4. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment
////////////////////				
Other Research Plan Sections				
8. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
9. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
10. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
11. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
12. Letters of Support		Add Attachment	Delete Attachment	View Attachment
13. Resource Sharing Plan(s)		Add Attachment	Delete Attachment	View Attachment
Appendix (if applicable)				
14. Appendix		Add Attachments	Remove Attachments	View Attachments

A second way to judge when a letter of support is needed, is to think like a reviewer. Any relationship that you would be concerned about as a reviewer is one for which you should have a letter of support. For example, if another institution has agreed to use and help disseminate the findings of the research you are proposing, or another investigator has agreed to give you access to an important library of specimens, a letter to that effect from the person who has the authority to make that commitment should accompany your proposal.

You should draft the letters of support yourself. There are three reasons why you should do so. First, no one knows better than you why a given letter of support is needed, i.e., what it must specifically address. Second, you cannot afford to get a poorly written letter of support from someone. How would you go back to that person to get a better one? Finally, the draft that you give to the intended letter writer will, at the least, save him/her the time s/he would otherwise have had to spend in order to write a strong letter of support for you. Almost without exception, in our experience, the person will be grateful.

We recommend the following approach. Offer to draft an 'example' of what is needed. For most of your colleagues that will be an offer that they cannot refuse. Deliver it along with a disk and a clear expression that s/he can scrap it and start over, modify it, or use it as written. In most cases the choice will be to modify/embellish what you have provided, making the letter even stronger. At the least, you will get back exactly what you provided, which will specifically and precisely underpin what you want supported. The final version should be on the writer's letterhead. Each letter must read as though it was written by the person who has signed it. Therefore, when drafting more than one letter of support, make certain that you vary the style, choice of words, punctuation, and even formatting of each, thereby giving the impression that they were written by different persons. If the 'writer' of a letter decides to modify/embellish your draft, the likelihood is that such additions will help to overcome the problem of 'sameness.'

Scan the letters that you receive and combine them into a single PDF file before uploading them using the "Add Attachment" button at the right of line 12 of the PHS 398 *Research Plan* form (see arrow, above).

DEVELOPMENTAL STEPS FOR CHAPTER TWENTY:

Creating a Cover Letter Attachment

1. Address your Cover Letter to the Division of Receipt & Referral, Center for Scientific Review - Dear Sir/Madam (or Dear Referral Officer, To Whom It May Concern).
2. Include the title of your proposal as the first line of your Cover Letter.
3. If you are responding to an NIH Funding Opportunity Announcement, include its exact title - followed by a hyphen and then its identifying acronym.
4. Designate the Scientific Review Group(s) that should review your application and provide justification for the choice(s).
5. Determine whether the full complement of expertise needed to give your proposal a fair review is included among members of the selected SRG(s). If additional expertise is needed on the most appropriate panel, request and justify its addition. List persons who should not review your proposal and provide objective justification relevant to why each should be excluded.
6. Decide on the basis of subject applicability and Program Officer enthusiasm whether you should ask for assignment to more than one awarding component. If so, select one as primary and rank order the others, from most to least applicable, with justification provided for the inclusion of each.
7. If applicable, append any documents required to reflect NIH agreement to submission of your application.
8. Upload the Cover Letter Attachment and any appended documents using the "Add Attachment" button on line 21 of the *PHS 398 Cover* form.

Creating Letters of Support

9. Think like a reviewer and ensure that any aspect of your application that could be the subject of reviewer concern is supported by a brief letter of support.
10. Draft an 'example' for each letter of support, being careful to ensure that each gives the impression that it was written by a different person.
11. Ensure that each letter writer understands that s/he has the option to modify and build on your draft.
12. After receiving them, scan the letters and combine them into a single PDF document, which should then be uploaded into your application using the "Add Attachment" button on line 14 of section 2 of the *PHS 398 Research Plan* component.

EXAMPLE OF A ROUTINE COVER LETTER ATTACHMENT (LETTERHEAD STATIONERY)

Date

Division of Receipt & Referral
Center for Scientific Review
National Institutes of Health

To Whom It May Concern:

My grant proposal, which is entitled "Two Hundred Characters & Spaces, Including Punctuation", is enclosed.

I am responding to Program Announcement PA-13-313, "Academic Research Enhancement Award (Parent R15)".

I request that my application be reviewed by the Bacterial Pathogenesis Study Section - BACP.

In addition to the highly relevant disciplinary expertise held by the members of BACP, I request that an *ad hoc* reviewer with expertise in electron-spin-resonance spectroscopy be assigned to the review of my application.

Dr. James W. Dalton, Department of Medicine, University of Somewhere, should not be involved in the review of my application because of a conflict of interest.

For consideration of funding, I request primary assignment to the National Institute of Allergy and Infectious Diseases - NIAID, with a secondary assignment to the National Institute of General Medical Sciences - NIGMS.

The following are my justifications for the requests made above:

- (1) I request assignment of my proposal to BACP study section because, in my opinion, of all the related Scientific Review Groups, the proposed research is most relevant to the complement of expertise held by members of that study section.
- (2) In spite of the fact that the members of BACP are, in my view, the most qualified to review my proposal, there is one essential kind of expertise that is missing: No standing member has electron-spin resonance spectroscopy expertise, without which my application could not be reviewed fairly (ESR will be the primary analytical approach used in the research). I request, therefore, that an *ad hoc* reviewer with that expertise be assigned to my proposal.
- (3) Dr. Dalton has been directly involved in the development of my application.
- (4) The infectious-disease aspect of my proposal makes NIAID most appropriate, in my opinion, for consideration of funding. NIGMS would also be appropriate because the results will have fundamental applicability to understanding the structure/function of any kind of biological membrane. I have confirmed the programmatic relevance of my application to these two institutes by querying Drs. Jonathan Hall (NIAID) and Mary Kiltner (NIGMS).

Thank you for considering these requests.

Sincerely,

Your Name, Degree(s)
Faculty Rank

EXAMPLE OF A LETTER OF SUPPORT (LETTERHEAD STATIONERY)

Date

Your Name
Your Department
Your Institution
City, State ZIP

Dear (Your First Name),

This letter confirms my support of the studies outlined in your grant proposal, "Immunologic Prevention of Two Hundred Characters & Spaces, Including Punctuation".

As you know, I am a formally trained immunologist (Ph.D., University of Somewhere, 1997). I am currently a Professor in the Department of Immunology at Outstanding University. I have published 93 peer-reviewed papers in immunology journals. Most of those publications pertain to the development and clinical application of monoclonal antibodies.

As you also know, I created monoclonal antibody 1234 (MoAb 1234), which you propose to use in your research. It has been described in detail in my recent Journal of Immunology publication (ref). Extensive studies have been performed that confirm its specificity for antigen XYZ (refs).

MoAb 1234 is not yet publicly available. Therefore, I will provide you with sufficient MoAb 1234 to perform the experiments described under Specific Aim #2 of your Research Plan. I attest to your familiarity with use of the antibody as a result of the week that you spent working with it in my laboratory as a visiting investigator.

In the unlikely event that it would be necessary, I additionally commit to collaborate with you on interpretation of the data obtained.

I agree to do these things at no cost to your research project. My only request is that you not distribute the monoclonal to others without my permission.

I look forward to collaborating with you on the proposed research and wish you the best with respect to your project. I am looking forward to seeing your results.

Sincerely,

Consultant's/Collaborator's Name, Degree(s)
Faculty Rank

CHAPTER 21

PRE-SUBMISSION REVIEW AND SUBMISSION OF YOUR APPLICATION

GENERAL CONSIDERATIONS

If we could offer you only one thing that would make the difference between success and failure, it would be pre-submission review of your application by knowledgeable colleagues. Your colleagues have the capacity to pick up the same scientific and technical errors in your proposal that would otherwise be caught by the official reviewers. Why allow review-panel members to detect mistakes that could have been removed prior to submission?

If pre-submission review is so important, why don't most applicants take advantage of what it has to offer? In our opinion, it is usually because they haven't planned to have sufficient time before the deadline to do so. *Ideally, you should allow members of your pre-submission review committee two weeks to evaluate your draft, after which you should give yourself at least one week to respond to their criticisms.* Even if you are following a compressed schedule because of a close deadline, don't make the mistake of eliminating this important part the developmental process. You may have to shorten the time with which you and your committee members have to work, but don't delete this step.

If English isn't your first language, unless you have extraordinary facility with languages and don't need it, we recommend that you obtain help pre-submission in eliminating minor mistakes in English usage that you may have probably. You want reviewers to concentrate exclusively on the content of your proposal, not on mistakes in use of English. To eliminate such mistakes, you may want to turn to a colleague who is a native English speaker. However, we caution you to select such a person carefully because there are those who have difficulty writing English well, even though native-born. A second approach would be to determine whether your institution's English department has a graduate student or junior-faculty member who wants to make a little extra income by providing editorial assistance. As a third possibility, some institutions have one or more English editors on staff. Check with your Research/Sponsored Programs Office to see if that is the case at yours. As a final consideration, there are commercial organizations that are comfortable handling scientific and medical-research documents. They offer revising, editing and proofreading services that will help you to overcome problems related to grammar, vocabulary and style. Three that we learned about from the *Journal of Biological Chemistry* can be accessed at: (1) <http://www.biosciencewriters.com>; (2) <http://www.bostonbioedit.com>; and (3) <http://www.prof-editing.com>. English editorial assistance, if needed, should be obtained before you send your proposal to members of your pre-submission review committee.

CHOOSING THE MEMBERS OF YOUR PRE-SUBMISSION REVIEW COMMITTEE

There should be at least three reviewers on your pre-submission review committee. We recommend that two of them be very close to the subject you are offering, because they will be the ones who on whom you depend to pick up scientific and technical errors that you have made.

They are also the ones who can best assess whether or not the research proposed is as innovative and significant as you think it is. These reviewers do not necessarily have to be from your own institution. Take advantage of your network and utilize colleagues at other institutions, if necessary. Remember not to include anyone who could be a sympathetic formal reviewer. Involvement with the preparation of your application would create a conflict-of-interest situation for such a person. The third member of the committee should be representative of the fringe of expertise that will be on the study section that you plan to recommend to review your proposal. In other words, a strong scientist who is in the ballpark with respect to the topic you are presenting, but not an expert on that topic. The need to make this selection is another reason why it is so important to investigate, pre-submission, the range of expertise on the targeted study section (see chapter 4). In all likelihood, the generalist will not be able to constructively criticize the scientific and technical nuances that your expert committee members will be able to critique. But that's okay, because that's not why you have included him/her. You will be trying to determine through this person whether or not you have written a grant application that can only be understood and appreciated by an expert. If you have, you have written a poor proposal. Not everyone on the study section will be an expert on your topic. As a matter of fact, very few will be - and those reviewers have an equal vote on the fate of your proposal. That is why, if your generalist can't appreciate what you are proposing because s/he can't read between the lines and interpret what you are presenting, or if s/he can't understand the jargon, unclear abbreviations and acronyms that you have used, you have written a poor proposal. Any strong academician should be able to read the grant application of any other academician and, regardless of the field, become excited. The scientific and technical nuances may be missed, but the idea driving the proposal and its significance and innovativeness should be clear. Anyone reading your proposal should be able to appreciate that, when acted upon, your idea will make a vertical difference in the field.

In addition to their scientific expertise, the reviewers on your pre-submission review committee must have several other things to offer. First, they must be colleagues who you can trust. You will be giving them some of your best thinking, and you want to be as certain as possible that they won't 'take the idea and run'. Second, they have to be the kinds of individuals who are willing to give you sharp, even trenchant, constructive criticism, if it is justified. If you have an 'ugly baby,' you want to know that pre-submission. But it is very difficult to tell someone that s/he has an 'ugly baby.' So, when you give them your draft for review, you must emphasize that you are soliciting *meaningful, sharp* constructive criticism, if warranted. You need to underscore to them that your feelings won't be hurt, even if they are sharply critical. It is much better to hear tough criticism from members of your pre-submission review committee than from members of the official study section. Third and last, members of the committee need to be colleagues who will take/make the time to thoroughly review your draft. You need to emphasize that what you are giving them isn't a time-consuming rough draft. It's what you would submit if they weren't willing to review it pre-submission. In addition, you need to emphasize that you are only seeking constructive criticism of the science and technical aspects of the proposal, not the grantsmanship - unless, of course, one of them finds something that s/he thinks is egregiously out of line. There are many different ways to write successful grant applications. Ours is but one of them - and we know that it works. If you get drawn into trying to please everyone with respect to grantsmanship, the outcome usually reads like it was written by a committee, which can negatively affect how your application is received. Also make clear when you give them your draft that you will provide the same kind of input for them, should they ask for it at some future time. Hopefully, the recommended assurances and that *quid-pro-quo* offer will convince them to provide more than just a cursory read-through. Some institutions offer pre-submission review committee members compensation for their input, which helps motivate them to take/make the necessary time to give your proposal a full review. Check with your upper administration (e.g., department, college, Research/Sponsored Programs Office) to determine if your institution will do that.

OBTAINING PRE-SUBMISSION REVIEW

While the primary responsibility of members of your pre-submission review committee is to review your final draft, if you select them early on in the developmental process, you would be well 3333 and Significance and Innovation subsections from the *Research Strategy* section as an inter-mediary step. With respect to the latter review, we have found it to be very worthwhile because, if there is something fundamentally wrong with what is being proposed, discovering that fact early on in the developmental process is invaluable.

There are many different ways in which to approach the pre-submission review of your final draft. For example, you might take the approach of distributing it to the members of your pre-submission review committee with the request that each member evaluate it independently before they meet as a group. They would then give you both their individual critiques and a collective opinion, much as an NIH study section would. While this works for some, it is very formal and requires a lot of work and coordination on the parts of the reviewers. Alternatively, you can seek a brief, written review from each member (a summary of the most important problems), together with handwritten annotations on your draft. After analyzing the reviewers' comments obtain verbal clarification, if necessary, of anything that is unclear or with which you may disagree. In our experience, the second of these two approaches is the one that works best.

FINAL REVISION AND SUBMISSION

After receiving the comments and suggestions of your pre-submission committee members, you should make the revisions that you think are justified before submitting your proposal to the Center for Scientific Review at NIH. It will be considered 'on-time' if it is received by Grants.gov no later than 5 pm (your local time) on the deadline day. Your Authorized Organizational Representative (AOR) will be sent an e-mail message from Grants.gov indicating that your proposal has been received.

Received is not the same thing as accepted, however. To be accepted, your application must be error free (both Grants.gov and eRA Commons errors) in terms of its compliance (validation) review. That is why, after saving a copy of what you intend to submit (see left arrow, next page), you should make use of the "Check Package for Errors" button on the first page of the application kit, under "Select Forms to Complete" (see right arrow, next page). If, in spite of taking this precaution, it is not error free when submitted, you would be notified as to what the source of the problem(s) is(are). Your proposal would not be accepted until the errors would be corrected. That is why we recommend that you not submit your proposal at the last minute. If you would do so and errors would be found during the compliance review, you would most likely not have time to correct them and resubmit. In other words, you would likely be forced to wait for the next round of submissions. To be safe, therefore, we recommend that you submit your proposal at least two business days in advance of the actual deadline. We also recommend that you make certain that your corrections are complete and that you strictly follow the instructions that you would have received with respect to the errors. Even with the two-day cushion that we recommend, if you don't get the corrections right the first time, it is unlikely that you would have time to resubmit a second time.

Once your proposal has been accepted, i.e., it has passed the initial compliance review, you and the AOR will be sent an e-mail message confirming that fact.


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SF424 (R & R)
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At this point, you're done. Accordingly, there is only one last thing left for us to do, and that is to give you our congratulations. Although we realize that this has not been an easy process, we assure you that the investment you have made will pay dividends: Most applicants don't go to the trouble that you have gone to, which is why most applicants go unfunded. We wish you and your application well. Congratulations, again, on having completed the process!!!!

DEVELOPMENTAL STEPS FOR CHAPTER TWENTY-ONE:

1. If English is not your native language, consider obtaining editorial assistance to remove errors in grammar, choice of wording and style. Do so before submitting your draft to your pre-submission review committee.
2. Choose the members of your pre-submission review panel early in the developmental process – at least two experts and one generalist. Obtain their independent, informal feedback on the significance and innovativeness of the idea you plan to develop into a grant application.
3. Submit the two-page template or master plan (*Specific Aims* section and the Significance and Innovation subsections of the *Research Strategy* section) to members of your committee. Revise, if necessary, based on their feedback to eliminate any flaws that exist at this early stage.
4. Obtain critical evaluation of your final draft by the members of your pre-submission review committee. Emphasize that you want their constructive criticism and set up the way that you will receive their feedback. Ideally, give them two weeks in which to perform their reviews.
5. Revise your final draft based on their feedback.
6. Submit your application through Grants.gov by following the instructions that are contained in Part I, section 2.10 of the *PHS SF 424 (R&R) Application Guide*.
7. Repay your pre-submission reviewers at some later time by acting as a pre-submission reviewer for applications that they develop.

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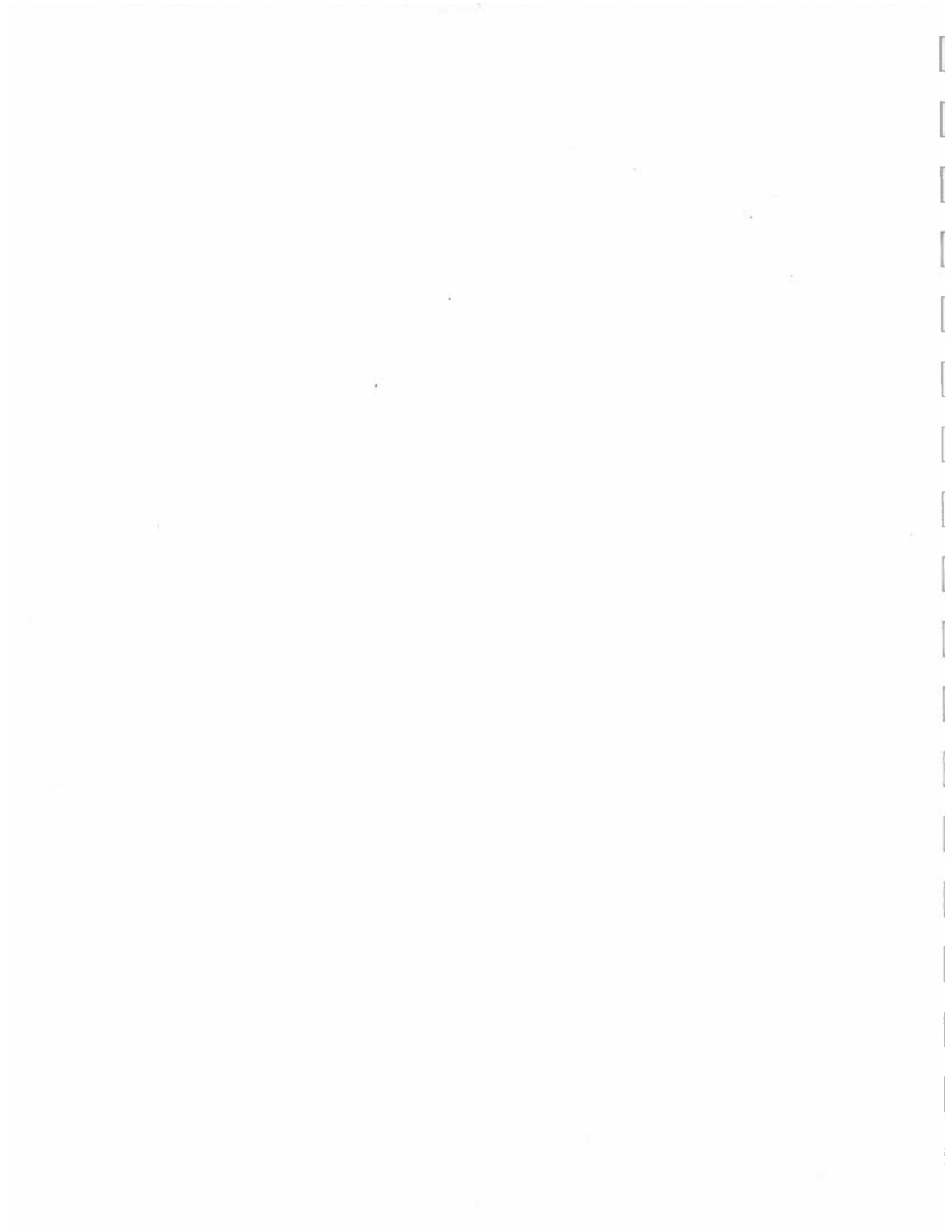
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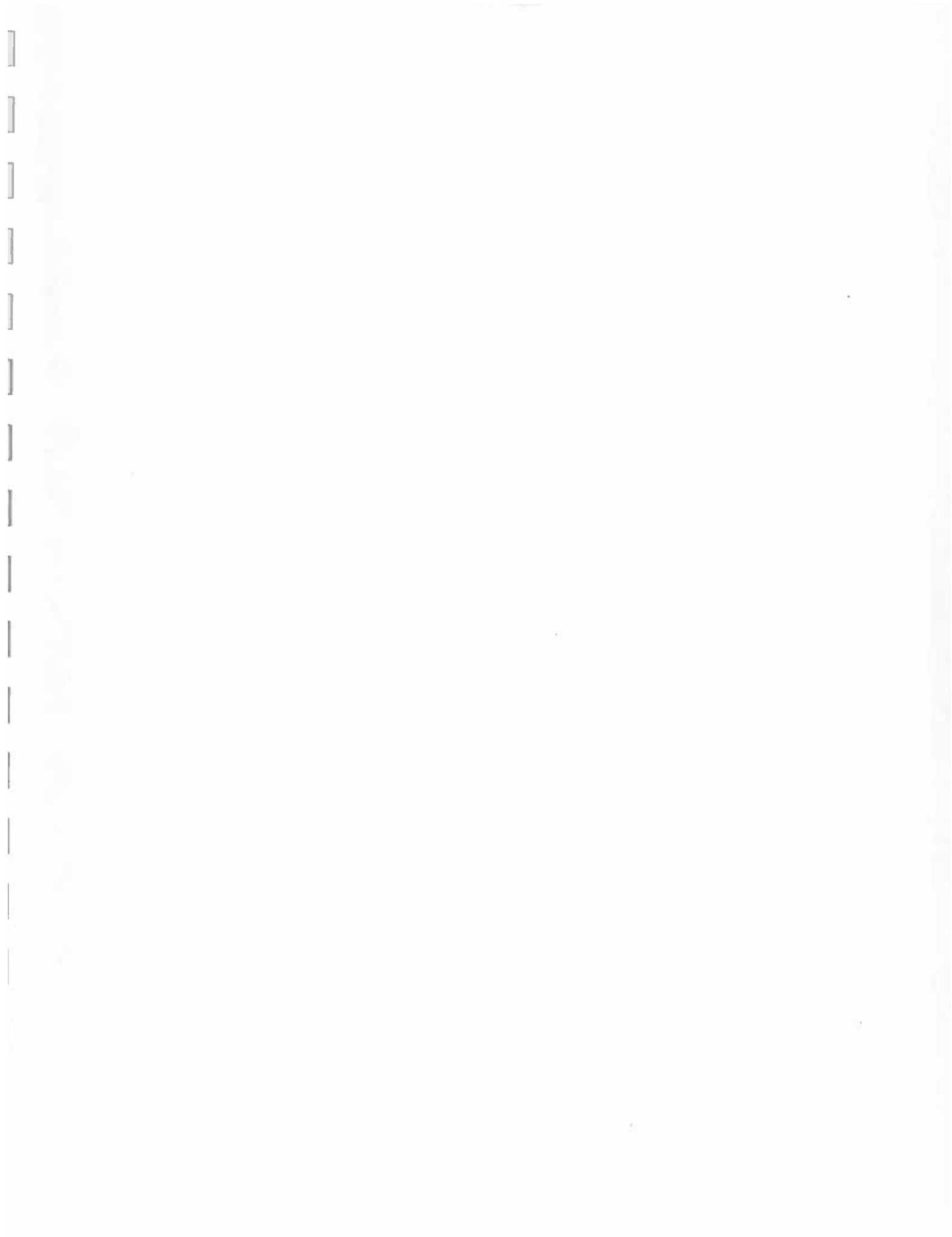
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