



PETER V. CHIN-HONG, M.D.
PROFESSOR OF MEDICINE
ACADEMY ENDOWED CHAIR FOR INNOVATION IN TEACHING
DIRECTOR, PROGRAM IN TRANSPLANT INFECTIOUS DISEASES
DIRECTOR, PATHWAYS TO DISCOVERY PROGRAM IN CLINICAL
AND TRANSLATIONAL RESEARCH
UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO

513 PARNASSUS AVENUE, S-410
SAN FRANCISCO, CALIFORNIA 94143-0654

TEL: (415) 502-9585 FAX: (415) 476-9364
E-MAIL: peter.chin-hong@ucsf.edu

July 27, 2016

To: Participants in "Designing Clinical Research (one month)" Epi 150.03 (Summer 2016)

From: Peter Chin-Hong and Miriam Kuppermann

We look forward to seeing you on **Monday, August 1, 2016** for the Designing Clinical Research course. The lectures will be held every Monday and Wednesday August 1st - 24th from 9-10:15am in HSW 302 (Health Sciences West building) on the Parnassus Campus. Small group sessions will follow the lecture from 10:30 – noon. Small group assignments will be announced during the first lecture. An additional peer review session is scheduled for Wednesday, August 24th from 10-noon.

Based on prior student feedback, we are also introducing 3 (high-yield but optional) brown-bag lunch talks on August 5th, 12th and 19th at 12 noon-1pm in S-214. We will give more details about these sessions once class gets started.

This year we are pleased to offer this course online as well. The general description and instructions below apply to all students. Those of you taking the course online will receive separate additional instructions.

The lectures and small group sessions are designed to teach you the basic principles of clinical research and to help you develop a research question and protocol. We cover quite a bit of ground over a short period of time, but most students have found this course very useful for understanding clinical research in general and developing their projects in particular. In order to get the most out of this course, we ask for the following.

- Please be on time for the lectures. We are fortunate to have outstanding faculty deliver the course lectures – you won't want to miss these.
- Please be prepared for your small group sessions and participate in commenting on the protocols of others in your group. The small group sessions are crucial for helping you develop your protocols and becoming familiar with critiquing the work of others.
- Please turn in your assignments on time. Our goal is to help you develop your research ideas into a more complete research protocol, and each of the assignments builds towards this goal. In order to give the instructors time to comment on the protocols, these assignments need to be turned in on time.
- Please attend all of the sessions. Only one excused absence is allowed during the month.

Here is your first assignment (not applicable to PUP and SF-BUILD scholars), due at the start of the small group session on August 1st:

- Read the Introduction and Chapters 1 and 2 of the *Designing Clinical Research* textbook (Hulley et al.) purchased from the publisher or an online vendor such as Amazon.com. Note that we are using the **4th edition** of the text.
- Identify the research mentor who is willing to work with you on your proposal. Typically such a person is engaged in clinical research or may be someone who can provide access to a relevant database.
- Think up a research question for which you might design a study, and **write a one sentence version of your research question** to bring to your small group session on August 1st. We strongly encourage you to think of a real question that is of interest to you and can be feasibly answered by a trainee at your level.
- Familiarize yourself with the literature related to your research question using PubMed and **write 3-5 sentences explaining the significance of your research question**. This initial draft of a “Significance Section” can take the form of a paragraph or logic statements as outlined in the sample protocol in the *Designing Clinical Research* textbook.
- Plan to learn Endnote or RefWorks, reference management software that will be very useful as you in your research. Information on how to get started with these programs is offered by the UCSF library.

Don't worry if your research question is not perfect---that is normal at this stage and is one of the reasons you are taking the course. Settling on a good research question is often the hardest part of the course, and many students will change topics entirely before the course is over. Your mentor should be able to help you develop your research ideas as you go along.

Below is the schedule for this intensive course. This schedule, as well as the course syllabus, presentations, and readings will be posted (and updated as necessary) on the course website (check the upper left corner for schedule menu). If you have not registered to take the course, please also do so through the website. If you are taking the course for credit, you will need to register on the website AND with the UCSF Registrar's Office.

http://www.epibiostat.ucsf.edu/courses/schedule/clin_research_predocs.html

The *requirements* for successful completion of this course are the same for all participants (except PUP and SF-BUILD scholars):

1. Full participation in lecture and small group discussions. Only one excused absence is allowed during this month-long course.
2. Completion of the **four** assignments. The first is due on the first day of class. The due dates for the other assignments will be posted on the website.
3. Completion of a five-page protocol, due **Monday, August 22nd**.
4. Participation in the peer-review process on **Wednesday, August 24th**.

We look forward to seeing you on August 1st in Room HSW 302. Please contact Olivia Deleon (olivia@epi.ucsf.edu) if you have questions. You may also contact the course director Peter

Chin-Hong (peter.chin-hong@ucsf.edu) or co-director Miriam Kuppermann (kuppermannm@obgyn.ucsf.edu) if you are a resident enrolled in this course.

We look forward to seeing you next week.
Peter Chin-Hong and Miriam Kuppermann

Designing Clinical Research (one month)-Epi 150.03, Summer 2016

(Due dates for the students enrolled in the online section vary slightly. Please stay tuned for the exact times. **There will also be three optional Friday brown-bag lunch talks on weeks 1-3)**

Date	Lecture title	Lecturer	Chapters in "Designing Clinical Research"
Week One			
Mon 8/1	The Research Question	Newman	1, 2
Mon 8/1	SMALL GROUP: Discussion of Assignment One (due at start of class)		
Wed 8/3	Subjects and Variables	Bauer	3, 4
Wed 8/3	SMALL GROUP: Discussion of Assignment Two (Final version of Assignment Two due electronically 8/6)		
Week Two			
Mon 8/8	Study designs	Bibbins-Domingo	7, 8, (12, 13, 18)
Mon 8/8	SMALL GROUP: Discussion of Assignment Three		
Wed 8/10	Causal inference/clinical trials	Grady	9, 10, 11
Wed 8/10	SMALL GROUP: Continued Discussion of Assignment Three (Final version of Assignment Three due electronically 8/13)		
Week Three			
Mon 8/15	Sample size and power	Cummings	5, 6
Mon 8/15	SMALL GROUP: Discussion of Assignment Four		
Wed 8/17	Introduction to statistics	TBA	6, 11
Wed 8/17	SMALL GROUP: Continued Discussion of Assignment Four (Final version of Assignment Four due electronically 8/20)		
Week Four			
Mon 8/22	Questionnaires/Qualitative Methods	Kuppermann	15, 16
Mon 8/22	SMALL GROUP: Discussion of Questionnaires		
Mon 8/22	FINAL PROTOCOL DUE 5 pm		
Wed 8/24	FINAL PEER REVIEW SESSION 10-12		

Citation Management classes: Citation management is an important tool for managing literature and citing appropriately. Both Endnote and RefWorks are used on campus. The Library has outlined the advantages to each produce and offers courses in both.

<http://www.library.ucsf.edu/help/citemgmt> Note that an advantage of RefWorks is that it is free to UCSF staff, faculty and students. Sign up for classes online at

<http://www.library.ucsf.edu/help/classes>.