



To: Enrollees in “Designing Clinical Research” One-Month Course (July/August/September 2021: Track 1 and Track 2)

Welcome to Designing Clinical Research! This course is designed to introduce you to the core principles underlying clinical research and guide you in developing a research protocol for your own research project. The course involves a combination of on-line lectures, textbook readings, written assignments, and interactive small group discussion.

You can view the course lectures, complete readings, and work on assignments in your own time, but you will need to attend your small group discussion section at your assigned time. **Please consult the attached roster now for your section assignment.**

Track 1: Your first small group section will take place on **Wednesday, July 28th**

Track 2: Your first small group section will take place on **Wednesday, August 11th**

However, your participation in this course starts *before this section*. Please begin watching the lectures and completing the readings for the first course topic (“The Research Question”) before the first class. You will use the concepts introduced in those lectures and readings to prepare your pre-course assignment, **due at the first small group section**.

To make sure that the course covers multiple important topics within a one-month period, we cover quite a bit of ground in a short period of time. This means that students need to work at a brisk pace. In particular, we ask that you:

- View the lectures and complete readings *before your small group sections* each week. These are designed to inform the assignments and discussion for that week.
- Be an active participant in your discussion section. The sections are crucial for helping you develop your research protocol and provide feedback to others.
- *Turn in assignments on time*. Our goal is to help you develop a complete research protocol, and each course assignment builds sequentially towards this goal. To provide useful feedback, section leaders need to receive assignments on time.

Here is your pre-course assignment to tackle before the first section:

- **Log on to the on-line syllabus** (<https://courses.ucsf.edu/course/view.php?id=8598>) using your MyAccess username and password to access the course materials. If you can't get access, contact Christian Leiva at Christian.leiva@ucsf.edu immediately.
- **Read Chapters 1 and 2** of the *Designing Clinical Research* textbook (Hulley et al.), purchased, borrowed, or rented from the publisher, the UCSF Library, or a vendor such as Amazon.com. Note that we are using the **4th edition** this year.
- **Identify and meet with a research mentor** who has agreed 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.

- Work with your mentor to identify a research question for which you might design a study, and **draft a one sentence version of your question** to bring to your first section.
- If you're planning to analyze existing data, **request early access to the dataset** you'll be using. For some course assignments, you will need to explore (or ask your mentor to help you explore) the measures used to assess your key study variables as well as examine the distribution of data for these variables.
- Familiarize yourself with the literature related to your research question using PubMed and **draft a paragraph explaining the significance of this question**. If it's challenging for you to start with a full paragraph, try developing logic statements as outlined in the sample protocol in the Designing Clinical Research textbook.
- Plan to obtain and learn to use either Endnote or Zotero (free), reference management software that will be very useful in preparing your protocol. The Library outlines the advantages and shortcomings of both: (<https://guides.ucsf.edu/referencemanagers>).

Don't worry if your research question is not perfect---that's normal at this stage and is one of the reasons you are taking the course! Settling on a good research question can be challenging, and many students will modify their questions before the course is over.

The *requirements* for successful completion of this course are:

1. Full participation in small groups-- only one excused absence is allowed.
2. Completion of **three** assignments. A draft for the first assignment is due at the first small group section.
3. Completion of a 5-page protocol, **due by August 20th, 5:00 PM, for Track 1, and due by September 3rd, 5:00 PM, for Track 2.**

We also encourage you to take part in the optional peer-review process of final protocol.

On the next page, you will find the schedule for this intensive course. This schedule, as well as the syllabus, presentations, and readings will be posted (and updated as necessary) on the on-line syllabus: (<https://courses.ucsf.edu/course/view.php?id=8598>)

Please contact Christian Leiva (Christian.Leiva@ucsf.edu) if you have questions about the course logistics or access to course materials. For questions about course content and how it applies to your own protocols, consult your section leader. Contact course director Alison Huang (Alison.Huang@ucsf.edu) or Megie Okumura (Megumi.Okumura@ucsf.edu) to provide feedback about the content or operations of the course. We look forward to seeing you in July and August!

Alison Huang, MD, MAS
Professor of Medicine

Christian Leiva
Resident Research Training Program

Megumi Okumura, MD, MAS
Associate Professor of Pediatrics, Medicine
and Health Policy

[see course schedule and overview on the next page]

Designing Clinical Research, Track 1 and 2 Overview

Date		Lectures, Sections, & Assignments	Readings
Week 1		TOPICS: THE RESEARCH QUESTION	
Track 1	Track 2		
Wed 7/28	Wed 8/11	LECTURES: "The Research Question" (Jacoby) SECTION: Discussion of Assignment 1, part 1	DCR chapters 1, 2
Due 7/29	Due 8/12	<u>ASSIGNMENT 1</u> : E-mail to section leader by 5 pm	
Week Two		TOPICS: STUDY DESIGNS, SUBJECTS & VARIABLES,	
Track 1	Track 2		
Mon 8/2	Mon 8/16	LECTURES: "Observational Study Designs" (Bibbins-Domingo) "Introduction to Randomized Blinded Trials" (Kanaya) "Studies of Medical Tests" (Newman) SECTION: Discussion of Assignment 2, Part 1	DCR chapters 7, 8, 10 plus pick one: 11, 12, or 13
Wed 8/4	Wed 8/18	LECTURES: "Subjects & Variables" (Bauer) SECTION: Discussion of Assignment 2, part 2	DCR chapters 3, 4
Due 8/5	Due 8/19	<u>ASSIGNMENT 2</u> : E-mail to section leader by 5 pm	
Week Three		TOPICS: STATISTICS AND SAMPLE SIZE	
Track 1	Track 2		
Mon 8/9	Mon 8/23	LECTURES: "Statistics for Life" (McCulloch) SECTION: Discussion of Assignment 3, part 1	DCR chapters 5, 6
Wed 8/11	Wed 8/25	LECTURES: "Sample Size and Power" (Cummings) SECTION: Discussion of Assignment 3, part 2	Also: "Statistical Interpret. of Data"
Due 8/12	Due 8/26	<u>ASSIGNMENT 3</u> : E-mail to section leader by 5 pm	
Week Four		TOPICS: CAUSAL INFERENCE and QUESTIONNAIRES & QUALITATIVE RESEARCH	
Track 1	Track 2		
Mon 8/16	Mon 8/30	LECTURES: "Causal Inference" (Grady) SECTION: Discussion of remaining protocol sections	DCR chapter 9
Wed 8/18	Wed 9/1	LECTURES: Qualitative Research & Questionnaire Design" (Kuppermann) SECTION: Discussion of remaining protocol sections	DCR chapters 15, 16
Due 8/20	Due 9/3 (see week 5)	<u>ASSIGNMENT</u> : Final Protocols Track 1 due by Friday Aug. 20, by 5 pm—upload directly onto the on-line course website Final Protocols Track 2 due by Friday Sept 3, by 5 pm—upload directly onto the on-line course website	
Week Five		TOPICS: ETHICAL CONSIDERATIONS	
Track 1	Track 2		
Mon 8/23	[Labor Day Holiday 9/6]	LECTURES: "Ethics in Research" (Grady & Chiong) "Responsible Conduct of Research" (Grady) "Data & Safety Monitoring" (Huang) SECTION: Track 1 : Discussion of unique ethical cases in research Track 2 : No final section for this track, given the Labor Day holiday, but students opting to take part in protocol review can work on their comments	DCR chapters 14, 17
Due 8/25	Due 9/8	<u>ASSIGNMENT</u> : Students opting to take part in the protocol review should expect to receive written protocol feedback from an instructor and student outside of their usual section by midnight this day; they should also send their own written comments by that time.	