

Welcome!!

Randomized Clinical Trials Course (EPI 205)

Course Logistics for 2022



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Welcome!!

Clinical Trials Course (EPI 205)

- **Objectives**: detailed understanding of experimental design options well as methods of carrying out and interpreting randomized controlled trials
- **11 lectures (9 lecturers)**
 - Dennis Black (course director)
 - Adam Boxer (MD, PhD)
 - Steve Cummings, MD
 - Alison Huang, MD
 - Joan Hilton, PhD
 - David Glidden, PhD
 - Deborah Grady, MD
 - Patrick Phillips, PhD
 - Vinay Prasad, MD
- **Four (live) small-group discussion section meetings**
 - 3:15 to 4:45 Tuesdays (1/25, 2/8, 2/22, 3/8) (Required, MH)
- **9 Workshops. Controversies, quandaries, etc. Interactive.**

Pre-Recorded Lectures and Live Workshops

- This year lectures will be pre-recorded
- Videos of lectures to be posted on Course website each Monday, 12pm
- Try to watch before Wednesday night
- Live sessions most Thursdays at 8:45-10:15

Discussion sections (meets 4 times)

- Small groups 8-10 students (live/Zoom). Each student to develop own protocol for a clinical trial
- A key part of course, strongly advise attendance to all sections

In section

- Discuss protocol and those of others
- Each student to present at least once (3-5 per section)
- Please attend all 4 sections....(important part of learning and of grade)
 - Section participation is part of your grade.
 - If you cannot attend a section, let section leader know ahead of time

“Live” workshop sessions

- Live interactive sessions are scheduled for almost all Thursdays from 8:45 to 10:15
- Please try to attend (live) as many as you can (MH 1401/02). All will emphasize the material covered in lecture that week
- **Your opportunity to interact with the faculty (most of whom have very deep experience in randomized trials)**
- Workshop formats:

Interesting real-life examples and controversies mostly built around weekly lecture topics. Short (very) presentations with “curated” discussion.

- There will be questions on the final from the workshops.

Workshops 1 (1/6 at 845 am) will be zoom only. Also workshop 2 (1/13). All others will be live in Mission Hall Room 1401/02.

Course Website

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

- **Course information regularly updated**
 - **Syllabus (aka Course Plan)**
 - List of lectures, discussion sections, Workshop/Q&A sessions
 - Dates for all sessions and when assignments due
 - **Lecture Recordings**
 - Readings (online)
 - RCT papers (usually specific parts)
 - Chapters from 2 books
 - **Workshop topics**
 - **Slides (powerpoint and video versions)**
 - **Homework assignments** (answers posted after assignment is graded and returned)
 - Protocol assignments

Assignments

Dates in Syllabus

Five Protocol Assignments (email to section leader)

- 5pm on Friday, January 7th (#1) – research question
- 12pm on Thursday, January 20th (Protocol assignment #1)
- 12pm on Thursday, February 3rd (Protocol assignment #2)
- 12pm on Thursday, February 17th (Protocol assignment #3)
- 12pm on Thursday, March 4th (Protocol assignment #4)

Eight (appx) Lecture Exercise Assignments (email to TAs by 5pm)

Mon, 1/10

Mon, 2/7

Tues, 1/18

Mon, 2/14

Mon, 1/24

Mon, 2/28

Mon, 1/31

Mon, 3/7

Submission of Assignments

DO NOT submit assignments through CLE website

Submit assignments via email:

- Homework assignments to TAs: UCSFClinicalTrials2022@gmail.com
- Section assignments: submit to your section leader
- Expect that everything is submitted on time..no late assignments accepted

What's coming up soon...



First Protocol Assignments (email to section leader)

– DUE THIS FRIDAY!

– 5pm on Friday, January 7th – research question

First Lecture Exercise Assignment (email to TA)

– DUE NEXT MONDAY

– 5pm on MONDAY, January 10th (#1)

Grading

Basis for grades

- **Lecture homework (25%)**
- **Protocol development and protocol critiquing in sections (50%)**
- **Final exam (25%) (posted to website 3/17, 12pm)**

Course Content and Overlap

- Some overlap with previous courses

eg. DCR and Biostat

- 2022: adjustments to maximize uniqueness of the moment
- Appreciate any feedback on duplication, content of course, etc.
(dennis.black@ucsf.edu)
- PLEASE COMPLETE EVALUATION AT END OF THE COURSE!!!!

TICR Professional Conduct Statement

Clarifications for this class

- I will maintain the highest standards of academic honesty
- I will neither give nor receive aid in examinations or assignments unless such cooperation is expressly permitted by the instructor
- I will conduct research in an unbiased manner, reports results truthfully, and credit ideas developed and work done by others
- I will not use answer keys from prior years
- I will write answers in my own words, and, when collaboration is permitted, acknowledge collaborators when answers are jointly formulated