

Course Title: Clinical Trials
Course Number: Epidemiology 205
Winter 2021

A. Objectives

The objectives of this course are to provide a detailed understanding of experimental design options; methods of randomization; blinding; developing interventions and controls; measuring outcomes and adverse effects; follow-up; compliance and post-randomization problems.

B. Prerequisites

Designing Clinical Research (Epi 180.04) and possession of a M.D., Ph.D., D.D.S. or Pharm.D. or equivalent doctoral degree. Exceptions to these prerequisites may be made with the consent of the Course Director, space permitting.

C. Faculty

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D. Format

Lectures: Eleven (11) Pre-Recorded Lectures. These lectures will be uploaded to the CLE website every Monday at 12pm PT (noon). The lectures that will be uploaded on Monday to the CLE website should be watched by the upcoming Thursday of that week.

Small group/Discussion Sections: Four (4) Tuesdays 3:15pm – 5:00pm PT on January 26, 2021; February 9, 2021; February 23, 2021 and March 9, 2021. All sections will be held via zoom. The zoom link will be provided by your section leader.

Q/A & Workshops: Every Thursday, 8:45am – 10:15am PT, will have either a Q&A session with the instructor, or a live workshop with an instructor or guest lecturers presenting on an interesting short discussion. You are strongly urged to attend the Workshops and also the Q&A sessions.

E. Textbooks

DO NOT PURCHASE (Available for download online via UCSF library)

- Designing Clinical Research, Fourth Edition, by Stephen B Hulley, et al (Philadelphia, PA: Lippincott Williams & Wilkins, 2013), ISBN-13: 978-1608318049
<http://ovidsp.dc2.ovid.com/ovid-b/ovidweb.cgi?QS2=434f4e1a73d37e8c27b9cfc56b4e7847a8f596c1815c570bb06114a234e64501570d6d35ac499d3ac5a284e719855a36b6cd7ce7b827703f8301ce6dc28e22a2ade5480f7fbc8dda6dc3468b2343907ae391245213e40da6b93fec03554834286cb46d12d09b8e7bad450cc9594264154f5d6a908c927669d4d235faa62af35ec95d243cca97a91b59810431a58ed41c140dc8577507fd4a9b98b0dde15dcb54a58813efd9dabf4e776662d9eb1aa4e7e000aebec77200ba37095b6fb0125dc8f0a69e9e9c3a1fea7170680f4c340a1fab5636ddd2c54210bd0d7579c647e4ba5936040326f65bfe6214720a10794922ab8e0bd1ed2696f0235073c6b762bd4674a9aa5251a8164>
- Fundamentals of Clinical Trials, Fifth Edition by Lawrence M. Friedman, Curt D. Furberg and David L. DeMets (New York, NY: Springer, 2015). This is as close to a bible as we have for clinical trials. Thorough presentations on many of the topics that we introduce in the lectures.
<https://ucsfcat.library.ucsf.edu/search~S0/?aDemets/ademets/1%2C1%2C9%2CB/frameset&FF=ademets+david+l+1944&9%2C%2C9/indexsort=->
- Data monitoring in clinical trials: a practical perspective, Second Edition by Susan S. Ellenberg, Thomas R. Fleming, David I. DeMets (Hoboken, NJ: John Wiley & Sons, Inc. 2019)
<https://ucsfcat.library.ucsf.edu/search~S0/?aDemets/ademets/1%2C1%2C9%2CB/frameset&FF=ademets+david+l+1944&4%2C%2C9/indexsort=->

F. Homework

Lecture homework is due by **5pm PST on the Monday** (*Note: Monday, January 18, 2021 is MLK Holiday and homework for that week is due on Tuesday, January 19, 2021 by 5pm PST*) following the lecture where the homework is assigned. Homework must be emailed to the Teaching Assistants. No late homework will be accepted. Homework will be graded and returned. Questions on homework assignments will be addressed in the sections.

Reading Assignments: It is expected that all required reading assignments will be completed prior to the lecture or section. This year we have made significant reductions in the reading so please try to complete the readings prior to lectures. Please note that most reading assignments specify certain PAGES, or SECTIONS of journal articles to read, not the entire article. Refer to the reading assignment with each lecture and section to determine what parts of a chapter or journal article are required.

G. Protocol Assignment

The major focus of the small group discussion sections is to develop a protocol for a randomized trial. The protocol will be based on your own research question. Contact your mentor, section leader or Dr. Black if you cannot come up with an idea for a research question for a clinical trial or consult with your mentor about refining a protocol that is currently in development. You are expected to present to your discussion section at least once during the quarter.

Email your research question(s) to **your Section Leader by 5pm on Friday, January 8, 2021** and your cumulative protocol assignment to your section leader according to the following schedule:
by **12pm (noon) on Thursday, January 21** for Section 1 on Tuesday, January 26

by **12pm (noon) on Thursday, February 4**, for Section 2 on Tuesday, February 9
 by **12pm (noon) on Thursday, February 18** for Section 3 on Tuesday, February 23
 by **12pm (noon) on Thursday, March 4** for Section 4 on Tuesday, March 9

H. Final Exam

There will be a required take home final exam. The exam will be posted on the course website on March 18, 2021, and will be due to the Teaching Assistants by **10am on Friday, March 26, 2021**.

Summary of Sessions, Assignments and Due Dates

Week of	MON	TUE	WED	THU	FRI
1/4/2021				Workshop1 8:45am	Research Question, 5pm*
1/11/2021	HW 1, 5pm			Q&A Session 8:45 am	
1/18/2021	<i>MLK Day</i>	HW 2, 5pm		Workshop2 8:45am Protocol 1, 12pm*	
1/25/2021	HW 3, 5pm	Section 1, 3:15pm			
2/1/2021	HW 4, 5pm			Workshop3, 8:45am Protocol 2, 12pm*	
2/8/2021	HW 5, 5pm	Section 2, 3:15pm		Workshop4, 8:45am	
2/15/2021	<i>Presidents Day</i>			Workshop5 8:45am; Protocol 3, 12pm*	
2/22/2021		Section 3, 3:15pm		Workshop6, 8:45am	
3/1/2021	HW 8, 5pm			Q&A, 8:45am; Protocol 4, 12pm*	
3/8/2021		Section 4, 3:15pm		Workshop7, 8:45am	
3/15/2021				Final Exam posted	
3/22/2021					Final Exam Due
Send to	Teaching Assistants			*Section Leader	Teaching Assistants

I. Grading

Grades will be based on total points achieved on homework (25%), protocol development and critiquing of protocols in the discussion section (50%), and the final exam (25%). ***Late assignments are not accepted.***

Clinical Trials Course

Winter 2021

Syllabus (for updates, https://ticr.ucsf.edu/courses/clin_trials.html)

Week	Date/Time	Faculty/ Session	Title/Content	Assignment
1		D. Black <i>Recorded Lecture</i>	Lecture 1 Design, Subjects and Randomization <i>Definition and importance of randomized controlled trials (RCT); examples of RCTs; disadvantages; alternatives; reasons for doing RCTs; randomization; inclusion/exclusion criteria; study designs including classical RCT, cross-over designs, matched pairs, cluster or grouped randomization</i>	Required Reading: Designing Clinical Research (4 th Edition), Chapter 10, pages 142-147 and Chapter 11, pages 151-158. Baden et al. "Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine" N Engl J Med 2020. Baden et al. "Research Summary: Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine" N Engl J Med 2020. Scan the Moderna trial protocol summary and read the "randomization" and "inclusion/exclusion" sections of the summary. Read abstract and watch a 3 min video abstract of a cluster randomized, international study. Schwalm et al. A community-based comprehensive intervention to reduce cardiovascular risk in hypertension (HOPE 4): a cluster-randomised controlled trial. Lancet, 2019 Oct 5;394(10205):1231-1242 https://www.sciencedirect.com/science/article/pii/S014067361931949X?via%3Dihub Optional Reading: Manson JE, et al. Vitamin D Supplements and Example of large, simple trial: Prevention of Cancer and Cardiovascular Disease. N Engl J Med. 2019 Jan 3;380(1):33-44. Another cluster randomized study (in China): The Chirpy Dragon study (Li, et al. 2019 PLOS) Fundamentals of Clinical Trials (5th Edition), Chapters 4, 5, and 6. Available via download for free. Homework: Exercises from Lecture 1 are due Monday, January 11, 2021 by 5pm: email to Teaching Assistants. Email your research question(s) to your Section Leader on <u>Friday, January 8, 2021 by 5pm</u> .
	Thursday, 1/7/2021, 8:45am – 10:15am PT	D. Black <i>Zoom link provided on CLE</i>	Workshop 1	This live/Zoom session will discuss issues about RCT participant inclusion/exclusion (topic in lecture 1) using examples from one of the Remdesivir Covid trials as well as other Covid trials. The session will also include a brief review and time for Q&A about lecture and course logistics

Week	Date/Time	Faculty/ Session	Title/Content	Assignment
1	Friday, 1/8/2021, 5pm PT	Section Leaders	Research Question Due	Email your research question to your assigned section leader.
2		D. Grady <i>Recorded Lecture</i>	Lecture 2 Blinding, Intervention and Controls <i>Definition and importance of blinding; strategies if the study can't be blinded; strategies to evaluate blinding; considerations when choosing the intervention; multiple interventions; importance of the control or placebo; advantages and disadvantages of equivalence trials</i>	Required Reading: Designing Clinical Research (4 th Edition), Chapter 10, pages 147-149. Noseworthy H, et al. The impact of blinding on the results of a randomized, placebo-controlled multiple sclerosis clinical trial. <i>Neurology</i> 1994;44: 16-20. Kirkley A, et al. A randomized trial of arthroscopic surgery for osteoarthritis of the knee. <i>N Engl J Med.</i> 2008 Sep 11;359(11):1097-107. Optional Reading: Fundamentals of Clinical Trials (5th Edition), Chapter 7. Lecture 2 Homework: Exercises from Lecture 2 are due Tuesday, January 19, 2021 by 5pm: email to Teaching Assistants.
	Monday 1/11/2021, 5pm	Teaching Assistant	Lecture 1 Homework Due	Exercises from Lecture 1 are due Monday, January 11, 2021 by 5pm: email to Teaching Assistants (UCSFClinicalTrials2021@gmail.com)
	Thursday, 1/14/2021, 8:45am – 10:15am PT	D. Black <i>Zoom link provided on CLE</i>	Q&A Session	
3		D. Black <i>Recorded Lecture</i>	Lecture 3 Measuring Outcomes and Adverse Effects <i>Clinical outcomes and alternatives. Defining adverse events; elicited vs. volunteered; nuisance adverse events; pitfalls of attribution of cause; FDA adverse events classifications</i>	Required Reading: Designing Clinical Research (4 th Edition), Chapter 10, pages 140-142, Chapter 11 page 162. Psaty BM, Lumley T. Surrogate end points and FDA approval: a tale of 2 lipid-altering drugs. <i>JAMA.</i> 2008 Mar 26;299(12):1474-6. Bent S, et al. Brief communication: Better ways to question patients about adverse medical events: a randomized, controlled trial. <i>Ann Intern Med.</i> 2006 Feb 21;144(4):257-61. Lecture 3 Homework: Exercises from Lecture 3 are due Monday, January 25, 2021 by 5pm: email to Teaching Assistants.
	Tuesday 1/19/2021, 5pm PT	Teaching Assistants	Lecture 2 Homework Due	Homework: Exercises from Lecture 2 are due Monday, January 19, 2021 by 5pm: email to Teaching Assistants (UCSFClinicalTrials2021@gmail.com)
3	Thursday 1/21/2021, 8:45am – 10:15am PT	D. Black <i>Zoom link provided on CLE</i>	Workshop 2	In this interactive, live/zoom discussion session we will focus on quandaries and controversies about efficacy and safety outcomes related to Covid-19 trials

Week	Date/Time	Faculty/ Session	Title/Content	Assignment
	Thursday 1/21/2021, 12pm PT	Section Leaders	Section I Assignment Due	Email your protocol to your Section Leader by 12pm (noon) on Thursday, January 21, 2021; bring a copy to Section I.
4		D. Black <i>Recorded Lecture</i>	Lecture 4 Statistical Issues in Randomized Trials; Review of data analysis for RCTs; Factorial RCT designs and analysis approaches; Subgroups and multiple comparisons: implications for inference from RCTs. Also most informative statistical graphic techniques for RCTs.	Required Reading: Designing Clinical Research (4th Edition), Chapter 11, pages 164-166 Wang R, Lagakos SW, Ware JH, Hunter DJ, Drazen JM. Statistics in medicine--reporting of subgroup analyses in clinical trials. N Engl J Med. 2007 Nov 22;357(21):2189-94. Polack et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 DOI: 10.1056/NEJMoa2034577 <i>Please read/review the abstracts from the following 2 papers. For this lecture, review please read the excellent Wang article which has set the standard for evaluating RCT subgroup analyses</i> Manson JE, et al. Marine n-3 Fatty Acids and Prevention Cardiovascular Disease and Cancer. N Engl J Med. 2019 Jan 3;380(1):23-32. Manson JE, et al. Vitamin D Supplements and Prevention of Cancer and Cardiovascular Disease. N Engl J Med. 2019 Jan 3;380(1):33-44. Homework: Exercises from Lecture 4 are due Monday February 1, 2021 by 5pm: email to Teaching Assistants UCSFClinicalTrials2021@gmail.com)
	Monday, 1/25/2021 5pm PT	Teaching Assistants	Lecture 3 Homework Due	Homework: Exercises from Lecture 3 are due Monday, January 25, 2021 by 5pm: email to Teaching Assistants UCSFClinicalTrials2021@gmail.com)
	Tuesday, 1/26/2021, 3:15pm – 5pm PT	Section Leaders <i>Zoom</i>	Section 1	Bring to Section 1: -Email your protocol to your section leader by 12pm (noon) on Thursday, January 21, 2021; bring a copy to section meeting. -Bring your Lecture 1-3 homework for review
	Thursday, 1/28/2021, 8:45am – 10:15am PT		No live/zoom session this week	No session

Week	Date/Time	Faculty/ Session	Title/Content	Assignment
5		D. Black <i>Recorded Lecture</i>	Lecture 5 5a. Follow up, Adherence to the Protocol, Intention to Treat, Consort guidelines Post-Randomization, 5b. Introduction to Sample Size Planning <i>Follow-up in RCTs; what happens after randomization; patient compliance or adherence; effect of incomplete follow-up; strategies to enhance compliance; intention-to- treat and per-protocol analyses; analysis based on post-randomization; subgroup analysis</i>	Required Reading: Designing Clinical Research (5 th Edition), Chapter 6, pages 55-59 and Chapter 11, pages 160-162. Hollis and Campbell. What is meant by intention to treat analysis? Survey of published randomized controlled trials. BMJ. 1999;319:670-4. Homework: Exercises from Lecture 5 are due February 8, 2021 by 5pm; email to Teaching Assistants. (UCSFClinicalTrials2021@gmail.com)
	Monday 2/1/2021 5pm PT	Teaching Assistants	Lecture 4 Homework Due	Exercises from Lecture 4 are due Monday February 1, 2021 by 5pm; email to Teaching Assistants (UCSFClinicalTrials2021@gmail.com)
	Thursday 2/4/2021 8:45-10:15am	D. Black <i>Zoom link provided on CLE</i>	Workshop 3	This live interactive session will focus on case studies of follow-up and adherence challenges
	Thursday, 2/4/2021, 12pm PT	Section Leaders	Section 2 Assignment Due	Email your protocol to your Section Leader by 12pm (noon) on Thursday, February 4, 2021; bring a copy to Section 2.
6		V. Prasad <i>Recorded Lecture</i>	Lecture 6 Non-Inferiority Trials <i>Non inferiority trials are studies that seek to show a new treatment, compared to an established treatment, is no worse than by some amount. That amount is called the margin or delta. Equivalence trials are subset of the non-inferiority design</i>	Required Reading: Prasad V. Non-Inferiority Trials in Medicine: Practice Changing or a Self-Fulfilling Prophecy? J Gen Intern Med 2018 Jan;33(1):3-5. doi: 10.1007/s11606-017-4191-y. Kudo M et al. Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomised phase 3 non-inferiority trial. Lancet 2018 Mar 24;391(10126):1163-1173. Homework: No homework assignment for lecture #6
	Monday 2/8/2021, 5pm PT	Teaching Assistants	Lecture 5 Homework Due	Exercises from Lecture 5 are due Monday February 8, 2021 by 5pm; email to Teaching Assistants (UCSFClinicalTrials2021@gmail.com)
	Tuesday, 2/9/2021; 3:15pm – 5pm PT	Section Leaders <i>Zoom</i>	Section 2	Bring to Section 2: -Email your protocol to your section leader by 12pm (noon) on Thursday, January 21, 2021; bring a copy to section meeting. -Bring your Lecture 1-3 homework for review

Week	Date/Time	Faculty/ Session	Title/Content	Assignment
6	Thursday 2/11/2021 8:45am – 10:15am PT	V. Prasad <i>Zoom</i>	Workshop 4	In this zoom/live session, Dr. Prasad will lead a discussion about the pitfalls of non-inferiority. Who defines the delta? What happens if the older treatment is delivered sub-optimally? Can a trial be non-inferior, but actually worse? And, finally, what percentage of NI trials are non-inferior?
7		D. Grady <i>Recorded Lecture</i>	Lecture 7 Nuts and Bolts – Conducting a Trial <i>Should one do a trial; pilot studies; funding sources; contracts; budgets; the study team; team management; space; recruitment of study subjects; starting the protocol; forms; compliance and follow-up; final visit and post-trial</i>	Required Reading: Designing Clinical Research (4 th Edition), Chapter 11, pages 158-159 and Chapter 17. Homework: There is no homework assignment for Lecture 7.
	Thursday 2/18/2021 8:45-10:15am PT	S. Cummings <i>Zoom</i>	Workshop 5	In live/Zoom session, Dr. Steven Cummings will lead an interactive session focusing on the use of new technologies to perform “Trials from home”: trials without clinical centers. This is fundamentally changing the way trials can be done.
	Thursday 2/18/2021 12pm PT	Section Leaders	Section 3 Assignment Due	Email your cumulative protocol to your Section Leader by 12pm (noon) on Thursday, February 18, 2021; bring a copy to Section 3.
8		A. Huang J. Hilton <i>Recorded Lectures</i>	Lecture 8 Ethics and Monitoring considerations for RCTs (Huang) and Statistical Aspects of Interim Monitoring (Hilton) <i>Ethical issues in clinical trials, including implications of interventions, eligibility criteria, randomization, and measures; Principles and approaches to data and safety monitoring in clinical trials</i> <i>Why alter/stop a clinical trial early; what parameters should be monitored and how often; what statistical methods should be used; who should decide to stop the trial.</i>	Required Reading: Lo B. Ethical issues in clinical trials, pages 1-7. Fundamentals of Clinical Trials (5th Edition), Chapter 16 “Monitoring Committee Structure and Function” Chapter 17 “Statistical Methods Used in Interim Monitoring” Optional Reading: Data monitoring in clinical trials: a practical perspective, (2 nd Edition), Chapter 9 “Determining When a Data Monitoring Committee is Needed” Homework: Exercises from Lecture 8 are due March 1, 2021 by 5pm; email to Teaching Assistants. (UCSFClinicalTrials2021@gmail.com)
	Tuesday, February 23, 2021, 3:15pm – 5:00pm PT	Section Leaders <i>Zoom</i>	Section 3	Bring to Section 3: -Email your cumulative protocol to your section leader by 12pm (noon) on Thursday, February 18, 2021; bring a copy to section. - Bring your Lecture 5, 6 homework for review
	Thursday, February 25, 2021, 8:45am – 10:15am PT	A. Huang <i>Zoom</i>	Workshop 6	In this live/zoom session, Dr. Huang will lead an interactive session about recent ethical issues in clinical trials.

Week	Date/Time	Faculty/ Session	Title/Content	Assignment
9		J. Hilton <i>Recorded Lecture</i>	Lecture 9 Adaptive and Cluster Randomization Trials	Required Reading: Brown AW, Li P, Bohan Brown MM, Kaiser KA, Keith SW, Oakes JM, Allison DB. Best (but oft-forgotten) practices: designing, analyzing, and reporting cluster randomized controlled trials. <i>Am J Clin Nutr</i>. 2015 Aug;102(2):241-8. doi: 10.3945/ajcn.114.105072. Epub 2015 May 27. PMID: 26016864; PMCID: PMC4515862 Coronado GD, Petrik AF, Vollmer WM, et al. Effectiveness of a Mailed Colorectal Cancer Screening Outreach Program in Community Health Clinics: The STOP CRC Cluster Randomized Clinical Trial. <i>JAMA Intern Med</i>. 2018;178(9):1174–1181. doi:10.1001/jamainternmed.2018.3629 Optional Video: Covariate balancing strategies: https://rethinkingclinicaltrials.org/news/february-9-2018-linking-design-to-analysis-of-cluster-randomized-trials-covariate-balancing-strategies/ Homework: No homework assignment for lecture 9.
	Monday, March 1, 2021, 5pm PT	Teaching Assistants	Lecture 8 Homework Due	Exercises from Lecture 8 are due March 1, 2021 by 5pm; email to Teaching Assistants. (UCSFClinicalTrials2021@gmail.com)
	Thursday, March 4, 2021, 8:45am – 10:15am	J. Hilton <i>Zoom</i>	Live Q&A Session	Bring your questions for Dr. Hilton about statistical issues in interim monitoring and adaptive designs.
	Thursday, March 4, 2021, 12pm PT (noon)	Section Leaders	Section 4 Assignment Due	Email your cumulative protocol to your section leader by 12pm (noon) on Thursday, March 4, 2021; bring a copy to section.
10		D. Glidden P. Phillips <i>Recorded Lecture</i>	Lecture 10 10a. Trials of COVID Interventions 10.b Global Health Trials <i>Dr. Glidden will discuss the issues that have presented themselves in COVID-19 therapeutic trials.</i> <i>Dr. Phillips will discuss global health trials.</i>	Required Reading: Science Magazine: “WHO's treatment megatrial is at a standstill” https://science.sciencemag.org/content/371/6533/972 New York Times: “How the Search for Covid-19 Treatments Faltered While Vaccines Sped Ahead” https://www.nytimes.com/2021/01/30/health/covid-drugs-antivirals.html Homework: No homework assignment for lecture 10

Week	Date/Time	Faculty/ Session	Title/Content	Assignment
10	Tuesday, 3/9/2021, 3:15pm – 5pm PT	Section Leaders <i>Zoom</i>	Section 4	Bring to Section 4: -Email your cumulative protocol to your section leader by 12pm (noon) on Thursday, March 4, 2021; bring a copy to section.
	Thursday, 3/11/2021; 8:45am – 10:15am PT	P. Phillips <i>Zoom</i>	Workshop 7	In this live/zoom session, Dr. Glidden or Dr. Phillips will lead a live discussion.
11		D. Black <i>Recorded Lecture</i>	Lecture 11 Multicenter Studies and Industry-Sponsored Trials <i>The anatomy and physiology of multicenter trials; how to work effectively and make use of data from such trials; how industry trials operate; pros and cons of participation in industry sponsored trials and principles that may minimize bias</i>	Required Reading: Fundamentals of Clinical Trials (5th Edition), Chapter 21 (Other readings may be distributed before the lecture.) Homework: There is no homework assignment for Lecture 11.
	Thursday 3/18/2021 8:45-10:15am		No live session.	
	Thursday 3/18/2021 12pm		Final Exam Posted	Take Home Final Exam to be posted on course website on March 18, 2021; and is due by 12pm on Friday, March 26, 2021. Email to Teaching Assistants.
12	Friday, 3/26/2021, 12pm PT	Teaching Assistants	Final Exam Due	Take Home Final Exam due by 12pm on Friday, March 26, 2021. Email to Teaching Assistants.