



Syllabus

PGS 292F Clinical Research Methods II

Spring 2017

All Classes McD 3.348 (Tower Conference Room) Monday through Friday 12:00 Noon–2:00 PM

Course Director: [Stephen R Saklad, Pharm.D., BCPP](#)
Office: UT Health Science Center San Antonio
Pharmacotherapy Education and Research Center (PERC)
McDermott Clinical Sciences Building
7703 Floyd Curl Drive, MSC 6220
San Antonio, TX 78229-3900

Office Telephone: 210-567-8355
Mobile/Text: 210-326-9086 (*Emergencies 24/7*)
FAX: 210-567-8328
Email: Saklad@uthscsa.edu (preferred)
Office Hours: Anytime by prearrangement or when office door is open

Course Faculty: [Kelly R. Reveles, Pharm.D., Ph.D.](#)
210-567-8345
kdaniels46@utexas.edu

[Jim Koeller, MS Pharm.](#)
210- 567-8339
koeller@uthscsa.edu

Course Competencies

By the end of the course, students will be able to:

1. Propose study designs for prospectively addressing clinical research questions including translational research questions.
2. Assess the strengths and weaknesses of possible prospective study designs for a given clinical research question (cohort studies, conventional clinical trials, and adaptive designs).
3. Identify existing appropriate measures (assessments of baseline characteristics and outcomes) of clinical research.
4. Assess threats to study validity (bias) including problems with sampling, recruitment, randomization, and comparability of study groups.
5. Assess internal validity in any planned or completed clinical or translational study, including selection bias, misclassification, and confounding.
6. Define criteria for inferring causation from observational investigations.
7. Describe strategies to improve subject retention in a clinical trial.
8. Design strategies for monitoring progress in a randomized controlled trial.
9. Delineate strategies for minimizing bias in cohort studies and randomized controlled trials.
10. Describe the processes and purposes of using propensity scoring in cohort studies
11. Compare and contrast the uses, strengths, and weaknesses of different clinical trial designs.

12. Critically appraise research reports of cohort studies and randomized controlled trials.
 - a. Use the STROBE guidelines for assessing an observational study
 - b. Use the CONSORT statements for assessing a clinical trial
13. Describe the steps in conducting a meta-analysis.
14. Demonstrate knowledge of community-engaged research approaches, including strategies for identification, development, and maintenance of community partnerships.
15. Compare the feasibility, efficiency, and ability to derive unbiased inferences from different research study designs (cohort studies and clinical trials).
16. Describe the basic principles and practical importance of random variation, systematic error, sampling error, measurement error, hypothesis testing, type I and type II errors, and confidence limits.
17. Defend the significance of data and safety monitoring plans.
18. Explain the uses, importance, and limitations of early stopping rules in clinical trials.
19. Describe the roles of comparative effectiveness research in the organization of health care and health care policy

Required Textbook



Designing Clinical Research 4th Edition. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB., Lippincott Williams & Wilkins, Philadelphia, PA ©2013. ISBN [978-1608318049](https://www.amazon.com/Designing-Clinical-Research-4th-edition/dp/1608318049)

Additional readings will be provided for some topics.

Prerequisite

Good standing in the graduate school and completion of the PGS 292E Clinical Research Methods I, or consent of the Course Director, Graduate Advisor, and Division Head.

Course Management Software

Canvas is the official online resource for this course.

Library Resources

Students are reminded that they have access to library resources at both UT Health Science Center San Antonio and UT Austin. Since we are >50 miles from Austin, we are provided free scans of print-only materials and interlibrary loans.

Recordings of Lectures

Students may record lectures to facilitate learning. Any recordings made are the private property of the lecturer and may not be distributed to third parties without the explicit written permission of the lecturer *in advance*. If permission to distribute is granted, unless otherwise specified by the lecturer in writing, all class materials and recordings are licensed under the terms of Creative Commons 4.0 BY-NC-ND International License. If lecture materials are otherwise copyrighted and not included under the Creative Commons license, students will need to obtain permission

from the license holder to reproduce the material. To view a copy of this license, see <http://creativecommons.org/licenses/by-nc-nd/4.0/>.

Examinations

There will be no formal exams in this course. There will be several assignments, given one week and due the next, or to be completed during class that will be assigned scores. These scores will be used to determine your final grade. Additional work may be assigned for extra credit upon request.

Academic Dishonesty

The “Statement on Scholastic Dishonesty of the College of Pharmacy” (November 8, 2010) reads in part:

Pharmacy practitioners enjoy a special trust and authority based on the profession’s commitment to a code of ethical behavior in its management of patient-centered pharmaceutical care. The inculcation of a sense of responsible professional behavior is a critical component of professional education, and high standards of ethical conduct are expected of pharmacy students and faculty. Violators of University rules on scholastic dishonesty are subject to appropriate disciplinary penalties. Since dishonesty harms the individual, fellow students, and the integrity of the University and the College of Pharmacy, policies on scholastic dishonesty must be strictly enforced. <www.utexas.edu/pharmacy/students/handbook98/3code.html#policy> <www.utexas.edu/pharmacy/nso/honor.pdf>

Students with Disabilities

The University of Texas at Austin provides upon request appropriate academic accommodations for qualified students with disabilities. All University rules concerning accommodations must be followed, including the student arranging for special accommodations prior to each class where needed. In the absence of such prearrangement, the student will be assumed that the student is not requesting special accommodations for that class, and will be expected to participate with the rest of the class at the regularly scheduled time. For more information, contact the Office of the Dean of Students at 512-471-6259, 512-471-4641 TTY. <deanofstudents.utexas.edu/>

Emergency Evacuation

The following has been requested to be added to all UT Austin syllabi by Dr. Robert Harkins, Associate Vice President for Campus Safety and Security. Supplementary information can be found at <http://www.utexas.edu/emergency>. While this information does not completely apply to students located in San Antonio, similar advice is to be implemented on those campuses <<http://research.uthscsa.edu/safety/emergencyresponse.pdf>>. You should download and review this document as you are located on this campus.

Occupants of buildings at The University of Texas at Austin or UT Health Science Center San Antonio are required to evacuate buildings when a fire alarm is activated. Alarm activation or announcement requires exiting and assembling outside.

- Familiarize yourself with all exit doors of each classroom and building you may occupy.

Remember that the nearest exit door may not be the one you used when entering the building.

- Students requiring assistance in evacuation shall inform their instructor in writing during the first week of class.
- In the event of an evacuation, follow the instruction of faculty or class instructors.
- Do not re-enter a building unless given instructions by a duly authorized incident commander or designee.

It is now common for government units (country, state, county, city, etc.), university campuses, health-care facilities, and agencies responsible for public safety and welfare to have emergency alert notification systems, usually sending email or text messages. Please sign up for those where *you* are located. To find these, just do a search for *emergency alert* or *emergency notification system* and where you live or have rotations. If you have signed up previously, please take the time to verify that your registration is current.

Class Attendance:

- Attendance in every lecture is mandatory.
- Absence is only excused due to illness, *bona fide* family emergency or life-cycle events, or participation in a university-sanctioned activity such as attending a professional meeting.
- If the UT Health Science Center San Antonio is closed for weather or other reason, that day's class is cancelled unless you are notified in advance of an alternate location or means of participating by Dr. Saklad or another faculty member. You are forbidden to take any risk that an informed and prudent person would avoid to attend class. Any cancelled class will be rescheduled or replaced to be sure to cover all topics.
- Documentation will be required for the absence to be excused.
- Contact Dr. Saklad (see beginning of this syllabus for contact info) *by Canvas or email in advance* for a university-sanctioned activity, or *as soon as possible* if you are absent from class for another reason.
- Depending upon your individual circumstances, the *excused* absence may be made up by additional individualized instruction or additional assignments. The most appropriate option will be determined by Dr. Saklad.
- Each *unexcused* absence will result in a 10% reduction in total score (equivalent to a one letter grade decrease) for the class that can't be made up with additional work.

Schedule of Topics (assigned readings may be changed prior to class)

Class #	Date	Topic	Faculty
1	01-10-2017	Orientation to course. Cohort Studies, Uses and Principles, Inception Cohorts, Retrospective and Prospective Designs (Chapter 7: Designing Cross-Sectional and Cohort Studies pages 88-96)	Saklad
2	01-12-2017	Clinically based cohort studies	Reveles
3	01-13-2017	Principles for Inferring Causation (Chapter 9 – Enhancing Causal Inference in Observational Studies, pp 117-136; Bradford-Hill, A. A Short Textbook of Medical Statistics (1977). Chapter 24 – <i>Statistical Evidence and Inference</i> , pp 285-296, Hodder and Stoughton, London)	Reveles
4	01-17-2017	Reading the Literature #3 – Cohort Studies (Cohort Study: Nishihara R, Wu K, Lochhead P et al. Long-term Colorectal-Cancer Incidence and Mortality after Lower Endoscopy. <i>New Engl J Med</i> 2013; 369(12):1095-1105. DOI: 10.1056/NEJMoa1301969; Supplemental Material from <i>New Engl J Med</i> Website: http://www.nejm.org/doi/suppl/10.1056/NEJMoa1301969/suppl_file/nejmoa1301969_appendix.pdf ; JP, Von Elm E, Altman DG, Gøtzsche PC, Mulrow CD, Pocock SJ, et.al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. <i>Ann Intern Med</i> 2007; 147:W163-W194.)	Reveles
5	01-18-2017	Propensity Scores in Cohort Studies	Reveles
6	01-20-2017	Comparative Effectiveness Research	Koeller
7	01-23-2017	Multi-center Clinical Trials; Monitoring Trial Progress and Early Termination (Chapter 11 – Alternative Trial Designs and Implementation Issues, pp. 163-182)	Koeller
8	01-24-2017	Retrospective Clinical Data Design and Analysis	Saklad
9	01-25-2017	Group Interventions – Community Studies (Chapter 18, Community and International Studies, pp 268-276)	Saklad

Class #	Date	Topic	Faculty
10	01-26-2017	Retention of Subjects and Minimizing Bias in Prospective Studies (Chapter 7, table 7.3 – page 95; Chapter 11 – Alternative Clinical Trial Designs and Implementation Issues, pp. 151-170; Review National Death Index Information at: http://www.cdc.gov/nchs/ndi.htm)	Saklad
11	01-27-2017	Drug Development – Phase I Trials (Roberts TG, Jr., Goulart BH, Squitieri L, et.al., Trends in the Risks and Benefits to Patients with Cancer Participating in Phase 1 Clinical Trials. <i>JAMA</i> 2004; 292:2130-2140.)	Saklad
12	01-30-2017	Randomized Controlled Trials; Uses and Principles; Randomization Schemes (Chapter 10 – Designing a Randomized Blinded Trial, pp. 147-162)	Saklad
13	01-31-2017	Conducting a Meta-Analysis (Chapter 13 – Research Using Existing Data, pp. 192-207.) (Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0 [updated March 2011] Ed: Higgins JPT and Green S < http://handbook.cochrane.org >	Saklad
14	02-01-2017	Adaptive Research Designs Adaptive Design Clinical Trials for Drugs and Biologics < http://www.fda.gov/downloads/Drugs/Guidances/ucm201790.pdf >	Saklad

Class #	Date	Topic	Faculty
15	02-02-2017	<p>Guideline Development (Stone NJ, Robinson J, Lichtenstein AH, Bairey-Merz CN, Blum CB, Eckel RH, Goldberg AC, Gordon D, Levy D, Lloyd-Jones DM, McBride P, Schwartz JS, Shero ST, Smith SC, Watson K, Wilson PWF. 2103 ACC/AHA Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. <i>Circulation</i> 2013; 01.cir.0000437738.63853.7a published online before print November 12 2013, doi:10.1161/01.cir.0000437738.63853.7a; Gibbons GH. NHLBI adopts new collaborative partnership model of clinical practice guidelines development. June 19, 2013: <http://www.nhlbi.nih.gov/about/directorscorner/messages/nhlbi-adopts-new-collaborative-partnership-model-for-clinical-practice-guidelines-development.html> Institute of Medicine. Clinical Practice Guidelines We Can Trust. March 2011. Brief Report and Standards.)</p>	Saklad