Course Title: Designing Clinical Research

Summer 2018

Time: Tuesdays 3-5pm, July 10, 2018 - August 29, 2018 (lectures and small group), final project due 9/5/18 (or 9/12/18)

Course instructor:
Bernice Ruo, MD, MAS
8939 Villa La Jolla Dr.
La Jolla, CA 92037
Division of General Internal Medicine, Department of Medicine, UCSD
bruo@ucsd.edu
Office hours: TBD (Tuesdays 3-4pm)

Course description:
This course is an introduction to the process of clinical research, defined broadly as patient-oriented, translational, epidemiologic, comparative effectiveness, behavioral, outcomes, or health services research (i.e., any research that has individual human beings or groups of human beings as its unit of observation). Students are exposed to overarching concepts and essential vocabulary for designing and interpreting clinical research. This is primarily accomplished by instructing students in the creation of a research protocol that is intended to address a relevant research question in their specific area of interest.

Course organization: 1 hour interactive lecture followed by 1 hour of small group discussion weekly for 8 weeks

Course goals: To introduce the process of clinical research so that students understand the concept and vocabulary to design and interpret clinical research. To enable students to design a study to answer a clinical research questions. To allow students to practice creating a research protocol of their own to address a relevant research question in their specific area of interest.

Course objectives:
The objectives for this course are for participants to:

- acquire skills for designing and interpreting clinical research
- produce a 5 page clinical research protocol, including background, sampling, measurements, and data analysis

Prerequisites:

- Possession of at least an undergraduate degree
- An idea for a research question in clinical research that preferably has been discussed with an experienced investigator or research mentor.
- Proficiency with word processing software, biomedical literature searching with Pubmed, and reference management software (Endnote, RefWorks or other software).

Required materials:
Course Schedule: (see attached)

Course Component:
- Attendance and participation in small group
- Completing homework assignments in preparation for small group sessions
- Submission of final 5 research protocol

Exams/Final Project:

No exams.

Final project: Submission of 5 page research protocol at the end of the course

Grading policy:

S/NS

Criteria for pass:

1. Attendance in lecture and small group. Allowed for 1 missed lecture and 1 small group session with giving at least 24h advanced notice to course director

2. Completing homework each week. Bring your completed homework assignment to small group, you may submit each week's homework assignment by the following day after small group by midnight if you want to make revisions after receiving feedback in small group.

3. Participating in small group by reading and giving feedback on fellow students' research

4. Submission of a final research protocol

Course Policy and Expectations:

Attendance policy: Your attendance in lecture and small group is expected. You are allowed 1 excused absence for 1 lecture and 1 small group with prior approval. Please do not use your cell phones during class. Please use laptops only as related to class activities.

Academic Integrity (Plagiarism): http://academicintegrity.ucsd.edu/

Late work submission policy: 1 homework assignment may be submitted late. The final research protocol must be submitted on time.

Communication with lecturers: The best way to reach the course director is by email. We will try to respond within 24 hours.

Student Evaluation of Course and Faculty: Course and faculty evaluations provide important feedback to instructors to improve course content and teaching methodology. Teaching evaluations are also an important factor in faculty behavior. To facilitate ease of completion of evaluations an electronic format has been implemented in Survey Monkey. Please see the TritonEd page for the link.

Accommodations: If you have a disability that may impact your academic performance, you may request accommodations by submitting documentation to: https://students.ucsd.edu/well-being/diability-services/
### LECTURE SCHEDULE

**Course:** Designing Clinical Research  
**Course Coordinator/Main Instructor:** Bernice Ruo, MD, MAS  
**Quarter:** Summer 2018  
**Class Time:** 3-5pm  
**Class Location:** UCSD Extension: University City Center (UCC) - 6256 Greenwich Dr., San Diego, CA 92122 Room # 118

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<th>Lesson (Date)</th>
<th>Topic</th>
<th>Learning Objectives</th>
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| 7/11/18       | Introduction to clinical research and research questions | • To understand the “Anatomy” and “Physiology” of research  
• To know the essential components of a research protocol  
• To learn how measurements in a sample are used to draw inferences about a population | Chapters 1-2  
Homework Guidelines | TBD |
| 7/18/18       | Literature review/ Systematic reviews | • To learn about doing a thorough literature review to understand the background to your study question  
• To learn about how a systematic review and meta-analysis differ from a literature review  
• To learn basics about how a systematic review is done | TBD | Research question |
| 7/25/18       | Study design | • To understand the different types of study designs including cross-sectional studies, cohort studies, case-control, and trials  
• To be able to choose what type of study design would best answer a specific clinical question | TBD | Research question and significance section w/ references |
|               | Subjects and variables | • To know how to describe the target and accessible populations to best answer a research question  
• To understand and know how to describe inclusion and exclusion criteria | Chapters 3-4 | |
<p>| 8/1/18        | Sample size, p values, and confidence intervals | • To understand the basic concepts and information needed to estimate sample sizes for various types of studies | Chapters 5-6 | 1 page study protocol and study subjects section | Bernice Ruo, MD |</p>
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| 8/8/18       | Observational designs and studies of diagnostic tests | • To understand the study design of these types of studies  
• To recognize the advantages and limitations of these types of studies | Chapters 7-8  
Either chapter 12, 13, or 18 | Sample size justification |
| 8/15/18      | Questionnaires, data collection forms, and data management | • To understand how to development of paper and online questionnaires and data collection forms  
• To know the limitations of spreadsheet programs (e.g. Excel) for database management.  
• To learn about some alternative software platforms for data collection and management. | Chapters 12, 13, 15, 16 | Measurements section, and a new 1p study outline |
| 8/22/18      | Causal inference and randomized trials | • To understand what patterns allow for causal inference  
• To learn about the different types of randomized trials | Chapters 9-11 | 1 page data collection form, corresponding data dictionary, data management plan |
| 8/29/18      | Career examples | • To learn how to design a study, implement and disseminate the results to make a difference  
• To see some examples of successful careers in clinical research | Chapters 17, 19 | Enhancing inference in your study, write about pre-testing plan and unsettled issues |
| 9/5/18 Or 9/12/18 | n/a | • Final research protocol due (5 pages) | | |

*Invited Speakers name/title and contact information*

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