

**DESIGN OF CLINICAL RESEARCH STUDIES
EPID 804**

Spring Semester, 2014

- Instructor:** Laura Loehr, MD, PhD, MS
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Office hours: After class or by appointment
lloehr@email.unc.edu
- TA:** Kumi Smith, kumi.smith@unc.edu
- Time:** 2:00–3:15 Tuesday, and Thursday
- Place:** Hooker Room 3005
- Website:** <https://sakai.unc.edu/portal> (You must have a UNC ONYEN account to access the website)
- Objectives:**
- 1) To develop a strong fundamental understanding of the design of clinical research studies
 - 2) To understand appropriate approaches to the development of clinical research studies.
 - 3) To understand selection of study populations.
 - 4) To understand the choice of appropriate measures for clinical research studies.
- Lectures:** The lectures/discussions are the core of the course. The lectures are intended to be participatory. It is more important that you speak up and give a reasonable answer than to be right. Many times, an incorrect answer provides greater learning opportunities than just giving the right answer. **Everyone** is encouraged to participate.
- Handouts are provided for most lectures and will be posted on Sakai when they are made available.
- Text:** Recommended, but optional text is: Hulley, Cummings, et al. Designing Clinical Research
- The Hulley text is an excellent resource for clinical researchers. It isn't perfect, but it is extremely useful. Not all of these chapters will match the lecture exactly, but they will provide important information for a clinical researcher.
- Readings:** Additional readings will be posted throughout the semester. On Thursdays, we will have "lab" which is meant to be even more participatory than class. We will discuss the design of selected papers. It is most important that you read the introduction and methods sections for lab than the other parts of the papers. In addition, you may want to read the conclusions, and the strengths/limitations usually reported in the discussion section. Please read all of the 2 articles in which you will lead the discussion.
- Labs:**
- Group Project**
- A major activity in this course is the group project which will be part of the Thursday "lab" sessions. Working in groups of 2-3 students, groups will design a clinical research project to answer a research question of their choosing. The research question should be current and amenable to a feasible clinical study. The study can be any clinical research design, except preferably not a randomized clinical trial (as RCT's are covered in a separate class). Groups will be assigned (by the instructor) based on research interests and experience with the goal of achieving diversity of research interests within each group. There are at least three periods during class time set aside to meet with your group.
- The project will be completed in three parts and end with a final oral presentation (and lively discussion) on the last day of class. The first 2 parts require write-ups of **no more than 3 pages** single spaced each (Arial 11 pt font, 1 inch margins). One person should assume lead responsibility for at least one of the four parts. Ideally, all students participate in all 3 parts, and

then lead at least one part. The roles of each person in each phase should be explicitly determined and stated on the cover page of the write-ups. Only one write-up will be turned in per group and one grade is given for the group. More details will come later.

Part 1: Statement of research question, brief background (no more than one-two paragraphs), statement of significance, and a description of the study design, study population, and principal measurements

Part 2: Further refinement of the description of the study design, study population, and principal measurements.

Part 3: Description of pilot and formative research proposed with this study. Self- assessment of the biases and limitations inherent in the proposed study.

Part 4: Oral presentation (written not required) with refinement of the proposal based on feedback.

Oral presentation with discussion: ~15 minutes, may use Power Point, there will be an additional 5-10 minutes allowed for questions and answers.

Leading Discussions

Please choose 3 articles from your area of research (or broadly from your area) that are examples of 3 different types of study designs (see assignment for details). Some or all of your articles may be used for discussion in lab. You will be asked to fill out a worksheet and lead the discussion for 2 articles.

Grades:

The grades for the course will be based on the below distribution.

Article Selection (3) and worksheet:	10%
Group project (Part I – IV)	10% X 4 (40% total)
Leading of papers discussion in lab:	10% X 2 (20% total)
Individual review of another groups project	15%
Participation and attendance:	15%

Final grades are based on the standard graduate school scale (H,P,L,F). The breakdown is H: $\geq 95\%$; P: 70 – 94%; L: 65 – 70%; F: $< 65\%$. No incompletes will be given except under special circumstances agreed upon by the student and instructor.

Please let me know if you have unavoidable and upcoming class absences.

Tuesday Session	Thursday Lab Session	Assignments due
	1/9 Introduction to class/lab, Laura Loehr	
1/14 Pilot studies, Mark Weaver	1/16 Papers discussion of Pilot Studies with Laura/Kumi	First lab assignment due by 1/21 by 2pm
1/21 Introduction to study design, Laura Loehr	1/23 First Group Meeting	
1/28 Cohort studies, Laura Loehr	1/30 Papers discussion #1, Doll (Bristow) and Hupp (van de voorde)	Written Part #1, due by 5pm on 1/30
2/4 Ancillary studies & secondary data, Laura Loehr	2/6 Papers discussion #2	
2/11 Case control studies, Andy Olshan	2/13 Second group meeting	
2/18 Diagnostic tests, Bill Miller	2/20 Papers discussion #3, Wu (Fauchais), Bice (Ahmed)	Written Part #2 due by 5pm 2/18
2/25 Comparative effectiveness research, Alice White	2/27 Papers discussion #4 Doll (Gruenigen)	
3/4 Bias inherent in CER, Bradley Layton	3/6 Papers discussion #5, Bice (Steingrub)	
3/11 Spring Break!	3/13 Spring Break!	
3/18 Randomized controlled trials, Mark Weaver	3/20 RCT Papers discussion with Mark	
3/25 Cluster Randomized Trials, Daniel Wallace	3/27 Papers discussion #6, Herce (Baird) and Hupp (Guerin)	
4/1 Formative research, Amy Corneli, FHI	4/3 Third Group Meeting	
4/8 Outcomes research, Anna Kucharska- Newton	4/10 Papers discussion #7 Wu (Erkan)	Written Part #3 due by 5pm on 4/10
4/15 TBA	4/17 Fourth Group Meeting	Individual Reviews due by 4/17 at 2pm
4/22 Studies of biomarker/laboratory measures, David Ransohoff	4/24 Final Project Presentations	

Group 1, Herce, Hupp, and Doll; Group 2, Bice, Wu