Block Institute for Clinical and Translational Research

“Design and Conduct of Clinical Research”
Winter - Spring 2016- 2017

SYLLABUS

Time:   Tuesdays and Thursdays (beginning December 6), 5:00-6:30 PM
Location:   Forchheimer Building, Education Center Rooms 1A/B (unless otherwise noted)
Albert Einstein College of Medicine campus

Course Leaders:
   Paul R. Marantz, MD, MPH; email:  paul.marantz@einstein.yu.edu; Block/Mazer 517
   Patricia Friedmann, MS; email:  patricia.friedmann@einstein.yu.edu; Block/Mazer 613

   Office hours: By appointment

Course Description
This seminar course aims to introduce students to clinical research with a focus on epidemiology and study design. The course uses an introductory clinical research text, along with a critical assessment of papers from the scientific (clinical and epidemiologic) literature, in order to learn about study designs: their strengths and weaknesses and how such studies are conducted. Topics to be covered include: basic epidemiology, measures of association, basic statistics, cohort studies, case control studies, clinical trials, causal inference, and research ethics.

Course Overview
The course will be taught by a team of 2 faculty members. Some classes will involve computer-based exercises, and will require students to bring their laptops to class.

IMPORTANT NOTE: All classes will require advance preparation and active participation. In general, this will mean careful reading and reflection on the assigned textbook chapters before coming to class. Classroom discussions will be designed to elucidate concepts covered in the reading, and the faculty will presuppose that the students are all prepared. Students should anticipate and plan for approximately 1-3 hours of reading/reflection each week.

Learning Objectives
At the end of the course, students will be able to:
Describe what makes a good research question.
List the major elements of a cohort (prospective and retrospective cohort) study.
Critique a case-control study, and describe alternative observational designs.
Explain the advantages and disadvantages of specific study designs for specific research questions.
Design, interpret, and critique a randomized clinical trial.
Distinguish internal and external validity in research.
Explain the role of significance testing and interpret P values and confidence intervals.
Interpret the major measures of association used in epidemiologic research.
Describe the estimates and assumptions involved in sample size determination, and perform simple calculations.
Identify ethical challenges in clinical investigation, and propose solutions to those challenges.
Distinguish between associations and causal connections in etiologic research.

Course Requirements & Grading
The course will be graded “Honors/Pass/Fail”. (As per graduate school regulations, a grade of “incomplete” may be allowed if absolutely necessary at the discretion of the Professors.) We plan to use a criterion standard for grading: i.e., Honors > 90%, Pass 65-90%, Fail < 65%. However, we reserve the right to ‘curve’ these cut-points if necessary.

The grade will be determined using the following formula:
- Final examination: 70%
- Attendance and class participation (preparation, contribution to discussion): 30%

Readings
There will be assigned readings to be completed before each class. These will include chapters from the textbook, Hulley et al (below), as well as original source materials (journal articles, etc.). Some assignments are listed on the Course Calendar page of this Syllabus, but other readings may be assigned throughout the course. The textbook must be purchased prior to December 1; non-textbook readings will be available on the course page established on the Canvas learning management system.

Textbook

Final Exam
There will be a take-home final exam, short answer/short essay format, to be submitted by February 16.

Canvas
Canvas will be used as the main platform for posting course materials and communicating with students. All students must have their Canvas credentials established, and access confirmed, prior to December 1.

Course Calendar on next page
COURSE CALENDAR

All classes 5:00-6:30 PM (Faculty Key: PF=Patricia Friedmann; PM=Paul Marantz):
All Chapters are from Hulley et al. Other reading assignments will be available on Canvas. Other readings (required and/or recommended) may be added as the course proceeds.

<table>
<thead>
<tr>
<th>Month</th>
<th>Tues</th>
<th>Thurs</th>
<th>Faculty</th>
<th>Topic</th>
<th>Reading Assignment</th>
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<tbody>
<tr>
<td>Dec</td>
<td>6</td>
<td>PF/PM</td>
<td>The Rise and Fall of Hormone Therapy</td>
<td>Gary Taubes, “Do we really know what makes us healthy?”, Sunday NY Times Mag, Sept 2007</td>
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<td></td>
<td>8</td>
<td>PF/PM</td>
<td>Developing a research question</td>
<td>Chapters 1 and 2</td>
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<tr>
<td></td>
<td>13</td>
<td>PF</td>
<td>Sampling and Recruitment</td>
<td>Chapter 3</td>
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<td></td>
<td>15</td>
<td>PF</td>
<td>Measurement</td>
<td>Chapter 4</td>
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<td>Jan</td>
<td>3</td>
<td>PF</td>
<td>Hypothesis testing and sample size estimation</td>
<td>Chapters 5 and 6</td>
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|       | 5    | PF    | Sample size and Power Laboratory | In-class exercise  
**NOTE: THIS LABORATORY CLASS WILL BE HELD IN THE ‘TRAINING ROOM’ OF THE EINSTEIN LIBRARY: FORCHHEIMER BUILDING, ROOM 119N** |
| Jan   | 10   | PM    | Observational studies I | Chapter 7 |
|       | 12   | PM    | Observational studies II | Chapter 8 |
|       | 17   | PM    | Causal inference | Chapter 9 |
|       | 19   | PM    | Research using existing data | Chapter 13 |
|       | 24   | PF    | Experimental studies I | Chapter 10 |
|       | 26   | PF    | Experimental studies II | Chapter 11 |
|       | 31   | PM    | Evaluating diagnostic tests | Chapter 12 |
| Feb   | 2    | PM    | Research ethics | Chapter 14 |
|       | 7    | PF/PM | Review session | |
|       | 9    |       | | |
|       | 14   |       | | |
|       | 16   |       | **FINAL EXAM DUE** | |