Public Health 446
The Design, Conduct and Analysis of Clinical Trials
Spring Quarter 2015
1.0 Credit

Time: Thursdays 6-9pm
April 2, 2015 – June 11, 2015

Location: 633 N Saint Clair, 18th Floor Classroom (18-055)

Instructor: Domenic J. Reda, MS, PhD

e-mail: redaph446@gmail.com

Office hours: By appointment either immediately before or after class

I. Course Description

Introduction to fundamentals of clinical trials, including design, conduct, analysis and interpretation of trial results. Topics include designs for early phase and definitive trials, methods for randomization, blinding and sample size determination, choice of controls, operational issues, data management and data quality issues, interim analysis methods, critical review of clinical trial proposals and published results and statistical techniques for analyzing clinical trial data.

II. Learning Objectives

This course is designed to familiarize students with clinical trials, including design, conduct, analysis and interpretation of trial results. After completion of the course, students should be able to:

a. Describe the rationale and ethical principles for designing and conducting randomized clinical trials (RCTs)
b. Identify differences between RCTs and other types of biomedical and public health research
c. Describe the design principles of RCTs and the different types of RCT designs
d. Describe the different types of randomization and construct simple randomization schemes.
e. Apply the principles and techniques of sample size calculation and determine sample sizes for trials of simple designs.
f. Identify operational aspects of RCTs, potential problems that may occur in the conduct of RCTs and useful strategies to address these problems
g. Apply appropriate statistical techniques for the analysis of data from clinical trials.
h. Use clinical trial reporting guidelines expected by medical journals to critically review the published results of a clinical trial.

III. Texts and Readings


The text will be supplemented by journal articles and other documents.
Canvas™
The syllabus and selected readings will be posted on the course’s Canvas site, if you are registered for the course.

IV. Class Assignments, Projects, Quizzes, Tests
There is an expectation that students will have read assignments and come to class prepared to discuss the material in the reading assignments. There will be 3 homework assignments, several quizzes, a mid-term examination, and a class presentation.

The oral presentation will be a 15-20 minute presentation accompanied by Power Point slides summarizing a key study or group of studies, key issues that arose and lessons learned. Following the presentation will be a 5 minute class discussion of the presentation in which the presenter answers questions raised by the teacher and the other students.

V. Student Evaluation
Students will be evaluated based on:

- Homework and Quizzes (25%)
- Mid-Term Examination (25%)
- Oral presentation of a Key Study or Group of Studies (25%)
- Critical Review of a Published RCT (25%)

VI. Course Evaluation
The Program in Public Health administers web-based course evaluations to students for each course near the end of the quarter. *Your completion of both the unit (course) and faculty evaluation components is required; failure to complete either of the evaluations will result in an incomplete grade until the evaluations are submitted.* You will be sent the web link and instructions via email later in the quarter. You will have about two weeks to complete the evaluations before grades are submitted.

VII. Academic Integrity
Every Northwestern faculty member and student belongs to a community of scholars where academic integrity is a fundamental commitment. The Program in Public Health abides by the standards of academic conduct, procedures, and sanctions as set forth by The Graduate School at Northwestern University. Students and faculty are responsible for knowledge of the information provided by The Graduate School on their Web page at [http://www.tgs.northwestern.edu/academics/academic-services/integrity/index.html](http://www.tgs.northwestern.edu/academics/academic-services/integrity/index.html).

Academic misconduct includes, but is not limited to
1. Receiving or giving unauthorized aid on examinations or homework
2. Plagiarism
3. Fabrication
4. Falsification or manipulation of academic records
5. Aiding or abetting any of the above

The PPH follows The Graduate School’s procedure for evaluating alleged academic misconduct, as outlined on the TGS website. [http://www.tgs.northwestern.edu/academics/academic-services/integrity/dishonesty/index.html](http://www.tgs.northwestern.edu/academics/academic-services/integrity/dishonesty/index.html)
Faculty reserve the right to use the “Safe Assignment: Plagiarism Detection Tool” that is part of the Course Management System to evaluate student assignments. Information about this tool can be found at [http://www.it.northwestern.edu/education/course-management/support/assessments/safeassignment.html](http://www.it.northwestern.edu/education/course-management/support/assessments/safeassignment.html)

### VIII. Class Schedule

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Reading (course textbook)</th>
<th>Assignments/Projects/Tests</th>
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| 1    | April 2| • History of Clinical Trials  
• Overview of Clinical Trials  
• Ethical Issues          | Chapters 1-2              |                                                                  |
| 2    | April 9| • What is the Question?  
• Outcomes  
• Interventions  
• Study Population        | Chapters 3-4              |                                                                  |
| 3    | April 16| • Study Design                                                | Chapter 5                 |                                                                  |
| 4    | April 23| • Randomization  
• Blinding                                                            | Chapters 6-7              | Design elements of a study from a published RCT                  |
| 5    | April 30| • Sample Size                                                  | Chapter 8                 | Midterm Examination (1.5 hours)                                  |
| 6    | May 7  | • Spirit Statement  
• Critical review of protocols                                        | Journal articles          | Sample Size Homework (Replicate sample size calculations for your paper, assess assumptions used for the sample size, other sample size calculations) |
| 7    | May 14 | • Baseline Assessments  
• Recruitment  
• Data collection and Quality Control  
• Participant Adherence  
• Adverse Events          | Chapters 9-12, 14         | Class presentations of a key study (or group of studies)         |
| 8    | May 21 | • Health-Related Quality of Life  
• Study Oversight and Monitoring Response Variables                  | Chapters 16-17            | Critical review of a published RCT                              |
| 9    | May 28 | • Issues in Data Analysis                                         | Chapter 18                |                                                                  |
| 10   | June 4 | • CONSORT Statements  
• Critical Review of published RCT                                    |                           |                                                                  |
|      | June 11|                                                                                           |                           | Critical review of a published RCT                              |