



## EPIDEMIOLOGY FOR CLINICAL RESEARCH

M88-588

Spring, 2018

Time: Mondays, 4:30 to 7:00 p.m.

Location: CRTC Center Classroom  
2nd floor, Wohl Building

Instructor: Robert Fitzgerald, Ph.D., M.P.H.  
Instructor of Psychiatry (Child)  
Office: 286-0151  
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Division of Child and Adolescent Psychiatry  
Department of Psychiatry  
Campus Box 8504

Office Hours: By Appointment (Contact Dr. Fitzgerald directly)  
Target audience: Graduate students, trainees, or junior faculty interested in conducting clinical research, including those enrolled in the Masters of Science in Clinical Investigation program and Applied Health Behavior Research program. Prior clinical research experience is helpful but not required.

Credits: 3

## Course Overview

*Introduction:* This course introduces principles of epidemiology with the goal of applying epidemiologic methods to answer clinical research questions. The course provides basic tools used in descriptive and analytical epidemiology, which are crucial for making informed decisions in the care of patients as well as evaluating the epidemiologic literature. Critical thinking and scientific/analytic competencies are emphasized throughout the course.

*Purpose:* This course will focus on common applications of epidemiologic principles and tools in clinical research, in clinical issues, and in understanding the medical literature concerning these issues. This will be accomplished via different modalities that will enhance the critical thinking and scientific/analytic competencies for the students who complete the course.

## Course Description

*Course Format:* The course format will include lectures, class discussion, problem sets, supplementary reading material, critiquing a research study, and writing a small study proposal.

### *Course Elements and Requirements for Students:*

- It is very important that students attend all classes. The information needed to master the course objectives will be presented and discussed in class. Students who miss three or more classes may be asked to withdraw from the course and to re-take the course at a later time. Arrangements for assignments that will be missed due to travel/conferences, etc. must be made ahead of the expected missed class.
- Students are expected to complete the assigned readings before each lecture. The readings have been selected to complement the lectures, and will provide additional examples for applying basic epidemiologic methods and tools in clinical research.
- Students should be prepared to discuss the exercises and any assigned readings at the start of each class and to participate in class discussion.
- Students are required to complete a written critique of a published research study. Students are also required to develop a small study proposal as described in more detail in the “grading determination and policy” section.

### *Course Elements and Requirements for the Instructors:*

- The instructor will usually be available during normal business hours to answer any questions that you may have about the course. If your schedule precludes you from meeting during normal business hours, he will make every effort to meet with you at times that may be more convenient for you. Please feel free to contact the instructor by telephone or via email to discuss any issues concerning the course.

- The instructor retains the right to change the order of the lectures and the content of the class to meet the needs of the students who are enrolled in the course.

*Readings:*

Fletcher RH, Fletcher SW, Fletcher GS. Clinical epidemiology. The essentials (5th edition). Lippincott Williams & Wilkins, Philadelphia, 2014.

*Assigned weekly readings:* Articles or book chapters will be emailed or posted on Blackboard. These articles are intended to supplement the text and are required to be read by all students.

*Grading Determination and Policy:* Each student will complete a 2-page written critique of a study (30%), 4 short problem sets (40%), and a 3-page study proposal (30%). The instructor will assign each student to critique a specific study. Grading will be based on the written critique. Late submissions will not be accepted, and critiques that are not completed independently by the student will not be graded.

The critique of the published study (30%) will be based on the following criteria. Please use the following separate headings in your critique.

- 1) Study objective, setting and participants (5 points).
- 2) Description of the study design (5 points).
- 3) Brief description of the study results and its implications (5 points).
- 4) Strengths and weaknesses of the study identified by you and by the authors (5 points).
- 5) How these weaknesses of the study affected the findings (15 points).
- 6) How the authors addressed the weaknesses of the study (10 points).
- 7) How the study could be improved (15 points)

For items 4-7, focus your critique on the issues of selection bias, measurement bias, confounding, and any other methodological issues pertaining to the type of study design used in the study that were discussed during class. Please use narrative to write your critique and submit via Blackboard by the assigned due date.

The 3-page study proposal is based on the format from the National Institutes of Health. It will only include the technical part of the proposal (budgets, biosketches, etc. are not required). The main subject headings for a study proposal are: A) Specific Aims (no more than ½ page), B) Significance (no more than ¼ page), C) Innovation (no more than ¼ page) and D) Research Design and Methods (about 2 pages). Preliminary Studies and Power and Sample Size sections are not required. Please complete the Bias Form that describes how bias may play a role in your proposed study. Please use 0.5 inch margins throughout and Arial 11 font size. Each student will be required to do each of the following items:

Submit drafts via Blackboard to Dr. Fitzgerald of:

- Specific Aims, Significance, and Innovation (due 3/12/2018)
- Research Design and Methods section (due 4/9/2018)

The final written proposal of the Specific Aims, Significance, Innovation, and the Research Design/Methods sections, due 4/30/2015, will constitute 30% of the final grade. I will provide you with comments on each section of the proposal prior to final submission for grading and return them to you in a timely manner to enable you to revise your proposal. Please also describe how you addressed each of the comments throughout your revisions using Track Changes and the “comment” facility in Microsoft Word. You are encouraged to select a topic that relates to your current or proposed area of interest. Late submissions will not be accepted, and proposals that are not completed independently by the student will not be graded.

The final grade will be based on the class distribution of 200 points from the written critique of a study (60 points), written study proposal (60 points), and 4 short problem sets (20 points each).

### Grading scale

<b>Grades/sub-grades</b>
<b>A (93% to 100%)</b>
A- (90% to 92%)
B+ (88% to 89%)
<b>B (83% to 87%)</b>
B- (80% to 82%)
C+ (77% to 79%)
<b>C (73% to 76%)</b>
C- (70% to 72%)

Total points available: 200

### Academic Integrity Policy

Students are expected to abide by and uphold the Academic Integrity Policy for Graduate Students from the Graduate School of Arts & Sciences. All students should have received this policy. Please contact the Office of the Dean of the School of Arts & Sciences to obtain copies of this document.

### Pagers and cellular phones

Although clinicians may be expected to be available by pager or cellular phone, please limit their use as much as possible during class.

### Students with disabilities

Washington University is committed to providing accommodations and/or services to students with documented disabilities. Students who are seeking support for a disability or a suspected disability should contact the Disability Resource Center (DRC) at 314-935-5970 or [disabilityresources@wustl.edu](mailto:disabilityresources@wustl.edu). The DRC is responsible for approving and arranging all accommodations for University Students.

## Course Calendar

Date	Week	Material
1/22	1	<p><b>Topic: Introduction and Course Overview</b></p> <p><b>Readings:</b> Fletcher Chapter 1</p> <p>Sackett DL. Clinical epidemiology: what, who, and whither. <i>J Clin Epidemiol</i> 55, 1161-1166, 2002.</p>
1/29	2	<p><b>Topic: Measurement in Epidemiology and Frequency of disease</b></p> <p><b>Readings:</b> Fletcher Chapter 2 – Frequency; Chapter 3-- Abnormality</p> <p>Gordis L. Chapter 3 - Measuring the occurrence of disease.</p>
2/5	3	<p><b>Topic: Determining a diagnosis</b></p> <p><b>Readings:</b> Fletcher Chapter 8</p> <p>Feinstein AR. Misguided efforts and future challenges for research on diagnostic tests. <i>J Epidemiol Community Health</i> 56, 330-332, 2002.</p> <p>Colditz GA. Improving standards of medical and public health research. <i>J Epidemiol Community Health</i> 56, 333-334, 2002.</p> <p>Choi BCK. Future challenges for diagnostic research: striking a balance between simplicity and complexity. <i>J Epidemiol Community Health</i> 56, 334-335, 2002.</p> <p><i>*Problem Set 1 due</i></p>
2/12	4	<p><b>Topic: Risk of disease</b></p> <p><b>Readings:</b> Fletcher Chapter 4</p>
2/19	5	<p><b>Topic: Causality</b></p> <p><b>Readings:</b> Fletcher Chapter 12</p> <p>Rothman, K. J., &amp; Greenland, S. (2005). Causation and causal inference in epidemiology. <i>Am J Public Health, 95 Suppl 1</i>, S144-150.</p>
2/26	6	<p><b>Topic: Reviewing and critiquing scientific literature</b></p> <p><i>Guest Lecture: TBD</i></p> <p><b>*Assigned: Manuscript critique</b></p> <p><i>* Problem Set 2 due</i></p>
3/5	7	<p><b>Topic: Cohort studies</b></p> <p><b>Readings:</b> Fletcher Chapter 5</p> <p>White E, Hunt JR, Casso D. Exposure measurement in cohort studies: The challenges of prospective data collection. <i>Epi Reviews</i> 20, 43-56, 1998.</p> <p>Vandenbroucke JP, von Elm E, Altman DG, Gotzsche PC, Multow CD, Poole C, Schlesselman JJ, Egger M, for the</p>

		STROBE initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Explanation and elaboration. PloS Med 4(10):e297, 2007
3/12	8	<b>SPRING BREAK – no class this week</b> <b>**Due: Draft of first sections of study proposal**</b>
3/19	9	<b>Topic: Prognosis of disease</b> <b>Readings:</b> Fletcher Chapter 7
3/26	10	<b>Topic: Prevention</b> <b>Readings:</b> Fletcher Chapter 10 <i>* Problem Set 2 due</i>
4/2	11	<b>Topic: Treatment I</b> <b>Readings:</b> Fletcher Chapter 9 and 13 Moher D, Hopewell S, Schulz KF, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Details of CONSORT guidelines from <a href="http://www.consort-statement.org">www.consort-statement.org</a> <b>*Article Critique due</b>
4/9	12	<b>Topic: Studying cases</b> <b>Readings:</b> Fletcher Chapter 6 Wacholder S, McLaughlin JK, Silverman DT, Mandel JS. Selection of controls in case-control studies. I. Principles. Am J Epidemiol 135, 1019-1028, 1992. Wacholder S, Silverman DT, McLaughlin JK, Mandel JS. Selection of controls in case-control studies. II. Types of controls. Am J Epidemiol 135, 1029-1041, 1992. <b>**Due: Draft of first sections of study proposal**</b>
4/16	13	<b>Topic: Statistical methods in epidemiology</b> <b>Readings:</b> Fletcher Chapter 11
4/23	14	<b>Topic: Interpreting Epi Data/Bias Analysis</b> <b>Readings:</b> Fletcher Chapter 15 <i>* Problem Set 4 due (in-class)</i>
4/30	15	<b>Modern Methods/Genetic Epi</b> <b>Readings:</b> Diez-Roux AV. Multilevel analysis in public health research. Annu Rev Public Health 21, 171-192, 2000. Sternthal MJ, Jun HOJ, Earls F, Wright RJ. Community violence and urban childhood asthma: A multilevel analysis. J Eur Resp Soc 2010 <b>**Due: Final study proposal**</b>