New Course Request

Check Appropriate Boxes: Undergraduate credit □ Graduate credit □ Professional credit □

1. School/Division Medicine I Doctoral Program 2. Academic Subject Code PBHL

3. Course Number E715 (must be cleared with University Enrollment Services) 4. Instructor Zollinger

5. Course Title Design and Implementation of Observational Studies

Recommended Abbreviation (Optional) Design & Implem of Obsv Studies

(Limited to 32 Characters including spaces)

6. First time this course is to be offered (Semester/Year): Fall 2010

7. Credit Hours: Fixed at 3 or Variable from 0 to 0

8. Is this course to be graded S-F (only)? Yes ☐ No ☑

9. Is variable title approval being requested? Yes ☐ No ☑

10. Course description (not to exceed 50 words) for Bulletin publication: This course examines fundamental aspects of designing and implementing observational epidemiology studies. The focus is on developing strategies to increase the validity of the study results by using techniques to control for possible confounding factors and biases. Topics include sampling methods, sensitivity, data weighting, standardization, selection of cases and controls, matching, data collection and project management.

11. Lecture Contact Hours: Fixed at 3 or Variable from 0 to 0

12. Non-Lecture Contact Hours: Fixed at 0 or Variable from 0 to 0

13. Estimated enrollment: 30 of which 100 percent are expected to be graduate students.

14. Frequency of scheduling: once time per year Will this course be required for majors? Yes

15. Justification for new course: Necessary component for the development of the PhD in Epidemiology curriculum.

16. Are the necessary reading materials currently available in the appropriate library? Yes

17. Please append a complete outline of the proposed course, and indicate instructor (if known), textbooks, and other materials.

18. If this course overlaps with existing courses, please explain with which courses it overlaps and whether this overlap is necessary, desirable, or unimportant.

19. A copy of every new course proposal must be submitted to departments, schools, or divisions in which there may be overlap of the new course with existing courses or areas of strong concern, with instructions that they send comments directly to the originating Curriculum Committee. Please append a list of departments, schools, or divisions thus consulted.

Submitted by: ___________________________ Date 5.28.10
Carole Kacius
Department Chairman/Division Director

Approved by: ___________________________ Date 6/8/2010
Pete Klem
Dean

Dean of Graduate School (when required)

University Enrollment Services

After School/Division approval, forward the last copy (without attachments) to University Enrollment Services for initial processing, and the remaining four copies and attachments to the Campus Chancellor or Vice-President.

University Enrollment Services Final—White; Chancellor/Vice-President—Blue; School/Division—Yellow; Department/Division—Pink; University Enrollment Services Advance—White
INDIANA UNIVERSITY SCHOOL OF MEDICINE
DEPARTMENT OF PUBLIC HEALTH
FALL SEMESTER, 2010

COURSE TITLE: Design and Implementation of Observational Studies
COURSE NUMBER: PBHL-E 715
LOCATION: 714 N. Senate, Room 235
DATE: Wednesdays, 6:00 to 8:40 pm

FACULTY: Terrell W. Zollinger, Dr. P.H.
Professor, Department of Public Health
Director, Epidemiology Division
Associate Director, Indiana University Bowen Research Center
Office: 714 N. Senate, Room EF 205
Phone: 278-0307 (direct line); 274-4242 (assistant)
E-mail: tzolling@iupui.edu
Office Hours: Tues. 2:00 – 5:00 pm (by appointment)

COURSE DESCRIPTION: This course examines fundamental aspects of designing and implementing observational epidemiology studies. The focus is on developing strategies to increase the validity of the study results by using techniques to control for possible confounding factors and biases. Topics include sampling methods, sensitivity, data weighting, standardization, selection of cases and controls, matching, data collection and project management.

PHD PROGRAM COMPETENCIES ADDRESSED IN THIS COURSE
1. Design investigations of acute and chronic conditions as well as other adverse health outcomes in targeted populations.

2. Differentiate special populations by race, ethnicity; culture; societal, educational, and professional backgrounds; age; sex; religion; disability; and sexual orientation.

3. Critically evaluate results of epidemiologic studies, including analyses, interpretation and conclusions.

4. Prepare written and oral reports and presentations to effectively communicate necessary information to professional audiences, policy makers, and the general public.

5. Prepare proposals for extramural peer-reviewed funding.

6. Promote and model ethical conduct in epidemiologic practice.

PREREQUISITES: This course is designed for students in the PhD program in Epidemiology. Advanced students in the Master of Public Health degree program, Epidemiology concentration may register for this course with the permission of the professor.
Prerequisite courses:
PBHL P517 Fundamentals of Epidemiology
PBHL P600 Epidemiology Research Methods

LEARNING OBJECTIVES: The students will be able to perform the following tasks at the completion of this course:

Primary Objectives:
1. Describe the basic epidemiology study designs along with their limitations.
2. Demonstrate an understanding of sampling methods.
3. Determine sample sizes needed for different study designs.
4. Recognize potential study biases and know how to control them.
5. Understand how to measure factors, outcomes and covariates.
6. Demonstrate the ability to design a study with an appropriate control group.
7. Explain when and how to match control cases to study cases.
8. Describe how to appropriately design pre- and post- program studies with a parallel control group.
9. List and describe the steps necessary to plan to implement a study.
10. Discuss processes necessary to prepare to analyze study data.

Secondary Objectives:
1. Develop advanced epidemiological research methods.
2. Demonstrate the ability to present information in a professional manner.

TEXTBOOKS:

Primary textbook:

Mark Woodward
ISBN: 9781584884156
Publisher: Chapman & Hall
http://www.crcpress.com/utility_search/search_results.jsf?conversationId=195263

Secondary textbooks:

Design of Observational Studies (2010)
Paul R. Rosenbaum
ISBN: 978-1-4419-1212-1
Publisher: Springer
http://www.springer.com/978-1-4419-1212-1

Paul S. Levy, Stanley Lemeshow
Publisher: Wiley

INSTRUCTIONAL METHODS: This course is designed to expose the students to the topics and concepts using lectures, discussions and exercises. Theory, reading material,
examples and exercises will be integrated to provide an optimal learning experience. The instructor will continuously integrate current developments into the classroom discussion and the students will be instructed to regularly search the World Wide Web for sites with relevant literature and other material. Lecture outlines will be made available on OnCourse (https://oncourse.iu.edu). Students are expected to routinely log onto this course site. The lecture outlines are designed to provide a guide for the lecture, identify the lecture objectives, and provide structure for the students’ notes. Exercises will be assigned that will help the students apply the concepts discussed in class.

EXERCISES:
Exercises will be assigned in conjunction with the lecture outlines. Students are encouraged to work together on the exercises, although each student is responsible for submitting his or her completed assignment. Exercises will typically be due one week after they are assigned. Late exercises will be accepted at the prerogative of the professor.

EXAMINATIONS:
There will be a final exam in this class to assess the students’ mastery of the concepts presented and terms used in the course.

PAPERS AND PRESENTATIONS:
Students will write two papers and make two class presentations on the key points of the paper. The first paper and presentation will be a prospectus for an epidemiologic research study. The final paper and presentation will focus on potential biases inherent in the student’s first prospectus along with specific remedies used to increase the validity of the project. Details will be given in assignment sheets.

EVALUATION AND GRADING SCALE
The students’ final grades will be determined as follows: prospectus presentation -- 1/4th; bias and correction presentation -- 1/4th; final exam -- 1/4th; and weekly exercises -- 1/4th. The scores received on each of these four items will be combined into a total score. The professor reserves the right to adjust scores to appropriately reflect the students’ level of subject mastery. Final grades may include a “+” or “-” and will be assigned using the following scheme and a numeric score below 80% indicates unsatisfactory performance, the course will have to be repeated and the current grade will not count toward degree requirement:

- A+  97 to 100%
- A   93% to 96%
- A-  90 to 92%
- B+  87 to 89%
- B   83 to 86%
- B-  80 to 82%
- C+  78 to 79%
- C   73 to 76%
- C-  70 to 72%
- D+  67 to 69%
- D   63 to 66%
D- 60 to 62%
F 59% or lower

A grade of "I" (incomplete) may be arranged for a student, who through circumstances beyond his or her control (such as illness, active military duty, etc.) is unable to complete the course on schedule. The instructor will require a written request from the student before a grade of "I" will be recorded. The student and instructor will develop a schedule for the student to complete the course requirements.

A grade of "W" (withdrawal) may be assigned, upon request to students who decide to drop the course, according to the University guidelines. A student who is failing the course will be given a grade of "F" if he or she withdraws from the course after the published deadline for automatic grade of "W".

ATTENDANCE
The professor will not take attendance. However, since this is a small class, the participation of all class members is needed to make the course a success.

STUDENTS WITH DISABILITIES
Students needing accommodations because of disability will need to register with Adaptive Educational Services (AES) and complete the appropriate forms issued by AES before accommodations will be given. The AES office is located in CA 001E; the office staff can be reached by calling 274-3241.

STUDENT COURSE EVALUATION
The Department of Public Health evaluates all courses. Student course evaluations will be conducted in a manner that maintains the integrity of the process and the anonymity of respondents.

ACADEMIC INTEGRITY
Academic and personal misconduct by students in this class are defined and dealt with according to the procedures in the Student Misconduct section of the IUPUI Code of Student Rights, http://live.iupui.edu/dos/code.htm.

The professor requires students to adhere to established ethical guidelines for behavior. Although students are encouraged to work together on exercises and in studying for the exams, collaboration and dishonesty on the exams will not be tolerated. The student research reports must be the student's own work. Submitting material written by others without proper citation is plagiarism and, consequently, will result in academic discipline. In fairness to all students, please refrain from such activities and any appearance of such activities.

STUDENT LEARNING OUTCOMES AND PERFORMANCE MEASURES:
1. By completing the reading assignments and participating in the classroom discussion, students will develop an understanding of the concepts and issues related to observational epidemiologic studies and methods.
2. By completing the assigned exercises, students will demonstrate the ability to identify and critique study techniques discussed in class.
3. By preparing and delivering the classroom presentations, students will develop an understanding of how to perform the steps necessary to conduct observational epidemiological studies.
4. The final exam will measure the students’ recall of terms, understanding of issues and concepts, and ability to perform tasks related to the topics presented in class.

PBHL E715: Schedule of Topics and Readings

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<tr>
<th>DATE</th>
<th>TOPIC AND READINGS</th>
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| Aug 25   | Lecture 1 (Objective 1) Course Introduction, Historical Foundation, Review of Basic Observational Study Designs, Fundamental Issues  
Readings: Woodward Chapter 1; Rosenbaum, Chapter 1 |
| Sept 1   | Lecture 2 (Objective 2) Sampling Methods I, Probability/Non-Probability Samples, Over-Sampling, Weighting, Ratio Estimation  
Readings: Levy/Lemeshow, Chapters 3-7) |
| Sept 8   | Lecture 4 (Objectives 2) Sampling Methods II, Complex Sampling, Multi-stage Sampling, Cluster Sampling, Variance Estimation with Complex Sampling  
Readings: Levy/Lemeshow, Chapters 8-12 |
| Sept 15  | Lecture 5 (Objective 3) Determining Sample Size, Confidence Level, Power, Sensitivity  
Readings: Woodward, Chapter 8; Rosenbaum, Chapter 14 |
| Sept 22  | Lecture 6 (Objectives 1 and 4) Prevalence Studies, Measurement Methods and Errors, Inclusion/Exclusion Criteria, Selection Bias, Non-response Bias  
Readings: Woodward, Chapter 2 |
| Sept 29  | Lecture 7 (Objective 5) Establishing the Research Question, Assessing Risk Factors, Dose of Exposure, Assessing the Outcomes, Measures of Severity  
Readings: Woodward, Chapter 3 |
| Oct 6    | Lecture 8 (Objectives 1 and 5) |
Cross-Sectional Studies, Risk Measures and Dose, Outcome Measures, Covariates and Confounding, Interactions, Standardization, Limitations

Readings: Woodward, Chapter 4

Oct 13  Mid-term Presentations

Oct 20  Lecture 9 (Objectives 1 and 6)
        Retrospective Studies, Selection of Cases and Control Groups, Nested Designs, Recalls Bias, Limitations

Readings: Woodward, Chapter 6

Oct 27  Lecture 10 (Objective 7)
        Matching Methods, Identifying Covariates, Individual vs. Group Matching, Outcomes in Matched Pairs, Over/Under Matching, Matching with Two Control Groups

Readings: Rosenbaum, Chapters 7-12

Nov 3   Lecture 11 (Objective 1)
        Prospective Studies, Lost to Follow-up, Life Tables, Person-years, Historical Cohort Designs, Limitations

Readings: Woodward, Chapter 5

Nov 10  Lecture 12 (Objective 8)
        Intervention Studies, Pre- and Post-Program Designs, Parallel Designs, Cross-over Designs, Sequential Designs

Readings: Woodward, Chapter 7

Nov 17  Lecture 13 (Objective 9)
        Planning the Implementation, Time-table, Milestones, Assemble Resources, Obtain Approvals, Task Assignments

Readings: TBD

Nov 24  Thanksgiving Break – class does not meet

Dec 1   Lecture 14 (Objective 10)
        Data Collection, Monitoring, Preparing for Analysis

Readings: TBD

Dec 8   Project Presentation

Dec 15  Final Exam