

PHCL 435 (2+1)
Research design and pharmacoepidemiology
Course Syllabus-2015-2016



Course Description

The aim of this course is to introduce the students to the concepts and methods of research, pharmacoepidemiology, and biostatistics through lectures, case scenarios, and case study.

Educational Objectives

At the completion of the course, students should be able to:

1. Understand the concept of pharmacoepidemiology.
2. Distinguish different types of research methodology and its contribution to pharmacy practice.
3. Apply appropriate statistical methods used in different research design.

Course Learning Outcomes

At the completion of the course, the student should be able to:

1. Compare and contrasts different study designs.
2. Distinguish methods of data collection and recording.
3. Understand issues involved in selecting sample and recruiting participants.
4. Discuss threats to validity and issues of interpretations.
5. Discuss applications of pharmacoepidemiological concepts and methods to pharmacy practice.
6. Explain measures of disease occurrence and association.
7. Demonstrate knowledge and understanding of statistical theory.
8. Select and apply appropriate statistical techniques for managing common types of medical data.
9. Interpret correctly the results of statistical analyses

Course Day & Times

Lecture: Monday 10-12 a.m.

Lab: Monday 1-4 p.m.

Course Resources

References and Textbooks

Yi Yang, Donna West-Strum. **Understanding Pharmacoepidemiology**. 2011

Beth Dawson, Robert G. **Basic & Clinical Biostatistics**, 4e

Raymond S. Greenberg, Stephen R. **Medical Epidemiology**, 4e.

Brenda Waning, Michael Montagne. **Pharmacoepidemiology: Principles and Practice**. 2001

- Other references or handouts can be provided during the course.

Course Outline

Lecture Topic (Tuesday)	Lab Activity (Sunday)
Introduction to pharmacoepidemiology (PE) and its Principles	No lab
Risk estimates and Descriptive Studies	Counting in PE The research process (Good research question)
Observational studies	Exercises on Risk estimates How to write a proposal (literature review)
Observational studies	Case reports example discussion+ Case control example discussion
Interventional study design	Plagiarism
Data source and collection	Mid Term Exam1 (covers Lect 1- 5) RCT examples discussion
Principles of sampling	Reference citation with EndNote Assignment #1 due (finalize the project goals and title)
Potential errors in studies (Bias, confounding)	Exercise on types of Bias
Types of variables. Validity and issues of interpretations.	Exercise on Confounding factors
Spontaneous Reporting system	Assignment#2 due: complete the introduction and aim & objectives part Sample size estimation
Descriptive and inferential statistics	Statistics calculation applications and assignments
Statistical concepts: confidence interval, hypothesis test, p value, statistical power	Midterm Exam 2 Statistics calculation applications and assignments
Automated database for pharmacoepidemiology	Final students proposal presentation
	Final students proposal presentation

The syllabus and schedule may be changed by the faculty if needed & students will be notified of these changes

Grade distribution:

Activity	Points
2 Midterm exams	30
Lab activities/assignments	15
Project Proposal	15
Final Exam	40
Total	100

COURSE POLICIES

A. COURSE FORMAT:

During this course the following mode of teaching can be used: formal and informal Lectures, discussion, self-directed learning.

COURSE TOOLS/REQUIREMENTS

This course requires the student to:

- Read the assigned material before coming to the lab
- Acquire personal lab top with wireless connection to the internet (be prepared to bring your computer in every lab.
- King Saud University email user name account
 - To access KSU library and to communicate about the course in particular, regarding the assignments.

B. ASSESSMENT TOOLS:

- Exams /quizzes
- presentations
- Research proposal
- Team assignments

B. EXAM FORMAT:

- Written exams mainly consist of, but not limited to: one correct answer multiple choice questions, short notes, matching, organize a list and fill in blanks. Questions can be direct recall of information, case scenario, and calculations.

C. LATE ASSIGNMENTS/HOMEWORK POLICY OR MISSED QUIZZES/MIDTERM EXAMS:

- Late assignments/homework will be penalized by **5% reduction** in grade **per each passing day**.
- the instructor **has the right** to determine the method for midterm/quiz make up by any of the following:
 - increasing the percentage of the remaining exams to cover the missed exam
 - assigning the final exam a higher percentage to cover the missed exam for the student
 - a make-up exam (mostly short note style)
 - In the final exam, the section relating to the missed examination material can be used as the grade for that missed exam.
 - Make up exam should be performed as per college policy. Valid documents about the absence MSUT be submitted by students within 2 weeks of the absence date.

D. ATTENDANCE POLICY:

- Students are expected to prepare for, attend and participate in all lectures and labs.
- Student must exercise **punctuality** in attending classes and labs.
- Students missing 25% or more on attendance are forbidden from setting in the final exam, per University Policy. Documents of proof of student absence MUST be submitted within 2 weeks.
- A student absent from class bears full responsibility for all material covered in class. Quizzes may be given anytime during the class period; therefore, please be on time and plan to attend the entire period. Missing a lab activity or a quiz due to **late arrivals or early departure will not be made up.**
- If you anticipate having to leave class early, please let your instructor know before the beginning of class.
- Unprofessional conduct including misbehavior during lectures/labs will not be tolerated and may result in actions leading up to dismissal from the course.
- Cell phone must be turned off or muted at all times during lecture and labs.

E. ACADEMIC DISHONESTY/PLAGIARISM/PROFESSIONALISM

- Students are expected to demonstrate **professionalism** and **honesty** during this course.
- Academic dishonesty includes, but is not limited to, cheating, plagiarizing, fabricating of information or citations, facilitating acts of academic dishonesty by others, having unauthorized possession of examinations, submitting work of another person or work previously used without informing the instructor, or tampering with the academic work of other students.
- Professionalism includes many aspects, among which: student act responsibly through their actions, attitude and appearance.

F. SYLLABUS CHANGES

- The course coordinator reserves the right to make changes as necessary to this syllabus. If changes are necessitated during the term of the course, the instructor will immediately notify students of such changes both by email communication and posting both notification and nature of change(s) on the course bulletin board.

G. ERRORS IN GRADING

- Errors in grading must be adjudicated by the instructor. If you believe that your work has been incorrectly graded (e.g. points were added up incorrectly), you must contact the instructor immediately in writing and clearly state the error you believe has occurred. The instructor of the course will always determine the final grade.

H.E-MAIL POLICY

Please note that the following applies to all emails sent to any member of PHCL 435 course teaching faculty.

- Students should include their full name, course number and lecture section in every email.
- All emails should be sent from your KSU account or an appropriately identifying email with student's NAME. Emails from alias emails (e.g. butterfly@, noufyloofy@etc) will NOT be responded to.
- Every email must have a subject title indicating the purpose of the email
- When writing emails please use proper courtesy and use PROPER Arabic or English.
- If you are submitting an assignment, all your identifying information should be inside the text of the attachment
- Emails should not be used to discuss personal problems, issues with grades, or problems with other students or other instructor. These emails will not be responded too, and these issues should be discussed in person.
- Emails not related to the course should not be sent to the instructors and if they are, no further email will be received from that email address, and the student may risk disciplinary actions per University Policy.

I. COURSE EVALUATION

- An evaluation of the full course and course faculty will be administered towards the end of the course. Additionally, individual faculty may ask for an evaluation of their lecture(s)

Course Binding Agreement (PHCL 435)

The Course binding agreement has to be signed by each student and returned through the class leader to the course instructor before the third lecture. *Failure to submit this paper will attest to the student had read and agreed on the information contained therein.*

“I have read this syllabus, understand its implications (and have sought clarification of those parts that were unclear to me), and will abide by it. I understand that the course coordinator has the right to make alterations to the class and exam schedule as needed.”

Name of Student: _____

University ID: _____

Signature of Student: _____

Date _____