**King Saud University**

**College of Pharmacy**

**PHCL 435**

**Course Syllabus Fall 2016/ First Semester 1437/1438**

1. **GENERAL INFORMATION**

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| **Course Number** |  |
| **Course Title** | Research Design and Pharmacoepidemiology |
| **Lecture Hours Per Week** | (2+1) |
| **Credit Hours Per Semester** | 3 |
| **Admission Particulars** | Pre-requisites: Introduction to Drug InformationCo-requisites: None |
| **Course Director:** | **Female Campus:****Hadeel Alkofide, MSc, PhD**Assistant Professor of Clinical PharmacyOffice Location: Building #8, 3rd floor, room #28Phone: +966 11 8056894Email: halkofide@ksu.edu.saOffice hours: by appointment**Male Campus:****Mansour Almetwazi, PharmD, PhD**Assistant Professor of Clinical PharmacyOffice Location: 1 A 201Phone:Email: mmetwazi@ksu.edu.saOffice hours: by appointment |
| **Clock hours & Locations:** | Days and time: Lectures on Mondays from 10 am-12 pm. Lab on Mondays 1 pm-2 pmFemale campus location: Room F49 for lectures and room S06Male campus location: TBA |

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| Participating Faculty |
| Monira Alwhaibi MSc, PhDTeaching FacultyOffice: Building 8, third floorEmail: malwhaibi@ksu.edu.saOffice hours: by appointment | **Abdulaziz Alhossan, PharmD, MPH, BCPS**Teaching Faculty Office: 1A237Email: alhossan@ksu.edu.saOffice hours: by appointment |
| Lab Instructors Female Campus |
| Hailah Almoghirah, MScClinical Lecturer Office Location: Building #8, third floorEmail: halmoghirah@ksu.edu.saOffice hours: by appointment | **Hanouf O. Aldeeb, BSc**Clinical Teaching AssistantOffice: Building #8, third floorEmail: haldeeb@ksu.edu.saOffice hours: by appointment |
| Hind Alrashidi, MScClinical LecturerOffice Location: Email: Office hours: by appointment |  |

1. **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.

1. COURSE OBJECTIVES

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

1. At the completion of the course, students should be able to:
2. Understand the concept of pharmacoepidemiology.
3. Distinguish different types of research methodology and its contribution to pharmacy practice.
4. Apply appropriate statistical methods used in different research design.
5. **COURSE ABILITY OUTCOMES**

**Following the successful completion of this course, a student will 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
10. **RESOURCES**

**REQUIRED TEXTBOOK:**

* Yi Yang, Donna West-Strum. Understanding Pharmacoepidemiology. 2011
* Beth Dawson, Robert G. Basic and 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.
* All supplemental materials will be available to the students, electronically through blackboard or distributed by faculty members via email or in class. Class handouts and patient cases (when applicable) will be posted on the KSU blackboard server (<https://lms.ksu.edu.sa/>), or handed to you by the lab instructors. It is the student responsibility to check the blackboard site regularly for any updates.
* Other reading materials will be distributed in the class as required.
1. **COURSE POLICIES**
2. **ACADEMIC DISHONESTY/PLAGIARISM**
* 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. Students found in violation of such policy are subjected to disciplinary actions as per University Policy.
* Please read the manual of study and tests for undergraduate students and operational rule

 (لائحة الدراسة والاختبارات للمرحلة الجامعية والقواعد التنفيذية المعتمدة) <http://dar.ksu.edu.sa/Regulations>

* Please read the manual of students rights and duties (لائحة تأديب الطلاب بجامعة الملك سعود) <http://dar.ksu.edu.sa/Regulationss>
1. **CLASS PARTICIPATION AND PROFESSIONALISM**
* It is expected that all students come to class prepared by completing where applicable all assigned readings, online homework, and other assignments before class and ready to actively participate in classroom activities. Faculty will clarify and expand on the reading material. Use of phones is prohibited during class.
1. **GUIDELINES FOR E-MAIL COMMUNICATION**
* E-mail is often perceived as an informal method of communicating, but some basic rules of style or etiquette are expected. In general, rules of common courtesy for interaction with people should be used for any situation and on the internet it is especially important where, for example, body language and tone of voice must be inferred.
1. **All emails should be sent from your KSU account** **ONLY**
2. Mail should have a subject heading which reflects the content of the message.
3. Your message should begin with an appropriate salutation, including the name of the person being addressed, and end with the full name of sender.
4. Use mixed case and proper punctuation.
5. Current e-mail addresses for all students must be maintained in the Blackboard system**.** Each student must edit this in the "Personal Information" section of "Tools". Faculty will not be able to contact you if your email address is not updated and you could miss important information about courses.
6. **Check your e-mail daily.** Most information and communication from instructors will come via e-mail or will be posted on Blackboard under announcements.
7. **Failure to check email/Blackboard may result in you missing important assignments and subsequently affect your grade.**
8. Direct your request to the appropriate person, as indicated below. Please note that discussion board posts are preferred whenever your questions do not involve personal matters to reduce the number of individual emails.
* **Questions concerning lecture content:**
* First, post your question on the **discussion board of Blackboard**. All faculty teaching in this course have access to blackboard and will reply to questions posted. Other students may have the same question that you have or may have the answer. Please allow adequate time for faculty to respond.
* Inquire if the faculty member teaching that lecture has office hours and try to attend.
* If neither of the above steps adequately answers your question, email the faculty member teaching that lecture.
* **General course questions or if you are unsure of where to direct questions**:
* Contact the Course Director if your question involves a personal matter. Post general course related questions on the **discussion board** dedicated to the overall course logistics.
* **DO NOT** send message to "All Instructors".
1. **ATTENDANCE AND EXCUSED ABSENCE**
* In the case of illness or prolonged absence, it is the student’s responsibility to notify the faculty member and/or the Course Director within 5 days from the first date of absence. Exceptions to the five-day notification period are rare and can only be approved by the Vice Dean of Academic Affair. With acceptable documentation from a student, an official memorandum will be issued notifying faculty of an excused absence. In the case of a legitimate excused absence, course instructors will make all reasonable attempts to assist the student to satisfy requirements of the course.
* Students missing 25% or more on attendance are forbidden from setting in the final exam per University Policy.
* If a student missed a midterm exam for an **ELIGIBLE** reason, Student must submit proper documentation within 2 weeks of scheduled exam time to the faculty member and the course coordinator.
* For any missed exams, student should fill a make-up exam form (pick up from department secretary) and obtain the necessary signatures and approvals from faculty member, the course director and head of the department.
* The faculty member has the right to determine the method for make-up exam, which can be 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 that student
	+ A make-up exam (the exam will be based on short answer questions)
	+ If the final is cumulative, the section relating to the missed examination material can be used as the grade for that missed exam.
* If a student missed an in class lab assignment with an **ELIGIBLE** reason, student must submit proper documentation within 2 weeks of scheduled assignment time to the faculty member and course coordinator. In case of absences with no reasons zero points will be given to the missed lab assignment. The lab instructor has the right to determine the method for make-up assignment.
1. **EXAMINATION AND GRADING CRITERIA**
2. **EXAMS/QUIZZES**
* Two midterm exams and a non-cumulative final exam will be administered throughout this course.
* Written exams mainly are based on case scenarios and consist of, but not limited to: one correct answer multiple choice questions, true/false, short notes, matching, organize a list and fill in blanks (one word).
* Random Quizzes will assess your understanding of general concepts found in the recommended class course materials. Each quiz will be administered randomly either in the class or through Blackboard.
* Make up quizzes will NOT be possible under any circumstance.
* The final course grade will be calculated based on the total number of points earned on each examination in addition to points earned through quizzes, assignments, and lab work, including formal case presentations, in comparison to the total number of points available.
1. **ASSIGNEMENT & SUBMISSION**
* Late assignments/homework (for both lecture and lab work) will be penalized by 30% reduction in grade per day late. Please follow the lab schedule and the lab lecturer’s instructions on assignments due dates. Absence in lab indicate a zero grade in that lab assignment.
1. **GRADE DISTRIBUTION**

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| **Midterms** | Two midterm exams each for 15%, based on case scenarios and consist of, but not limited to: one correct answer multiple choice questions, true/false, short notes, matching, organize a list and fill in blanks (one word).  | **30%** |
| **Lab**  | There are lab assignments throughout this course, they are mostly handled and answered during lab time | **15%** |
| **Project** | Two to three students in each group. There will be a write-up for the proposal and a presentation. Grades will be divided as: 8 for the write-up and 7 on your presentation | **15%** |
| **Final Exam** | Non-cumulative, based on case scenarios and consist of, but not limited to: one correct answer multiple choice questions, true/false, short notes, matching, organize a list and fill in blanks (one word) | **40%** |
| **Total** |  | **100%** |

**Note: Faculty can subtract up to two grades for any unprofessionalism**

1. **CONFLICT RESOLUTION:**
* Any issues related to this course teaching, examinations and grading should be resolved with the course instructor promptly to ensure healthy learning atmosphere.
* Unresolved matter should be directed to the course coordinator. If matter is not yet resolved, please direct your complaint to the department head/Vice Head.
1. **CHANGE IN THE COURSE SYLLABUS OR GRADE DISTUBITION:** students will be notified with any changes to the course syllabus or grade distribution.
2. **GRADING SCALE:** grades will be earned based on KSU grading policy. the following scale:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Letter Grade | Score Achieved |  | Letter Grade | Score Achieved |
|  A+ | > 95% |  |  C+ | 75 - 79.99 % |
| A | 90 - 94.99 % |  | C | 70 - 74.99 % |
|  B+ | 85 - 89.99 % |  |  D+ | 65 - 69.99 % |
| B | 80 - 84.99 % |  | D | 60- 64.99 % |
|  |  |  | F | < 60% |

1. **COURSE SCHEDULE**

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| --- | --- | --- | --- | --- | --- | --- |
| **Week** | **Date** | **Lecture Topic (Monday)** | **TF** | **Reference** | **Lab Activity (Monday)** | **Exams** |
| 1 | 19-Sep | Lecture 1:Introduction to pharmacoepidemiology (PE) and its Principles- Terminology | HA/MM | Book #1, chapters 1 and 2ERIC Notebook: Incidence vs Prevalence | Plagiarism/Referencing and the Use of Endnote | Mid 1/Final |
| 2 | 26-Sep | Lecture 2:Risk estimates and Descriptive Studies (introduction to study designs) | HA | Book #1, chapter 2ERIC Notebook: Statistics in Epidemiological Literature | Counting in PEThe research process (Good research question) | Mid 1/Final |
| 3 | 3- Oct | Lecture 3: Observational studies I | HA | Book #1, chapter 3ERIC Notebook: Case Control Studies, Cross Sectional and Ecological Studies | Exercises on Risk estimatesHow to write a proposal (literature review) | Mid 1/Final |
| 4 | 10- Oct | Lecture 4:Observational studies II | HA | Book #1, chapter 3ERIC Notebook: Cohort Studies, Confounding and Bias | Case reports example discussion+ Case control example discussion | Mid 1/Final |
| 5 | 17-Oct | Lecture 5:Interventional study design- Review article (Systematic reviews and meta-analysis) | AA | TBA | Cohort examples discussionsPlagiarism/Reference citation with EndNote exercise | Mid 2/Final |
| 6 | 24-Oct | Lecture 6:Potential errors in studies (Bias, confounding, effect modification) | AA | TBA | Intervention studies/ reviews examples and discussion**Assignment #1 due (finalize the project goals and title)** | Mid 2/Final |
| 7 | 31-Oct | Midterm 1 | HA/MM | Lectures 1-4 | Exercise on types of Bias |  |
| 8 | 7-Nov | Lecture 7: Types of variables. Validity and issues of interpretations | AA | TBA | Exercise on Confounding factors | Mid 2/Final |
| 9 | 14-Nov |  | Break |  |
| 10 | 21-Nov | Lecture 8:Descriptive and inferential statistics | MA | Book #1, chapter 5 | Statistics calculation applications assignments**Assignment#2 due: complete the introduction and aim & objectives part** | Mid 2/Final |
| 11 | 28-Nov | Lecture 9:Hypothesis testing | MA | Book #1, chapter 5 | Exercises on using statistics to describe a study sample | Final Exam |
| 12 | 5-Dec | Lecture 10:Introduction to regression analysis/Patient reported outcomes | MA | TBA | Exercises on power analysis and sample size calculation | Final Exam |
| 13 | 12-Dec | Lecture 11:Data source and collection/ Spontaneous Reporting system | MM | TBA | Exercises on patient reported outcomes/ Exercises on regression analysis**Assignment#3 due: complete the methodology and sample size estimation** | Final exam |
| 14 | 19-Dec | Midterm 2 | AA/MA | Lectures 5-8 | Exercise on data source and collection |  |
| 15 | 26-Dec | Lecture 12:The use of secondary data | MM | TBA | **Final student’s proposal presentation** | Final exam |
| 16 | 2-Jan | Lecture 13:Principles of Sampling | MM | TBA | **Final student’s proposal presentation** | Final exam |

MA: Monira Alwhaibi, MM: Mansour Almetwazi, HA: Hadeel Alkofide, AA: Abdulaziz Alhossan

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

1. **COURSE BINDING AGREEMENT**

The Course binding agreement has to be signed by each student and returned through the class leader to the course instructor before the second lecture. Failure to do that will prevent student from attending further classes.

#  **“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 course and exam schedule as needed.”**

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# **Name of Student: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# **University ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# **Signature of Student: \_\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# **Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_**