TSCI 5071
Patient Oriented Clinical Research Methods – 1

Fall 2017

CLASS DAYS and TIME: Tuesdays (August 22 – December 12, 2017), 3:00 – 5:00 pm

CLASSROOM: LIB 2.015

COURSE DIRECTOR: Byeongyeob Choi, PhD

OFFICE LOCATION and HOURS: ADM 314.14, Monday – Friday (8:00 am – 5:00 pm by appointment)

EMAIL: choib@uthscsa.edu

TELEPHONE: 210-567-0854

READ THIS DOCUMENT CAREFULLY – YOU ARE RESPONSIBLE FOR ITS CONTENTS

COURSE DESCRIPTION AND OBJECTIVES

This interdisciplinary course is the first in a two-semester sequence designed to train participants in the conduct of patient-oriented clinical research.

Pre-requisites – There are no pre-requisites for this course.
Semester credit hours – 2.0 SCH

By the end of this course, each student should be able to:

- Define a research question.
- Effectively conduct a systematic review of the scientific literature.
- Design strategies for recruitment into a study.
- Delineate strategies for minimizing bias in cross-sectional and retrospective studies
- Read and interpret research reports of cross-sectional and case control investigations.

COURSE ORGANIZATION

The main teaching modalities used in this course include:

1. Lectures
2. Class discussions requiring active student participation.

Materials:

No special materials are required for this course.

Computer Requirements:

Students are required to have a laptop computer that can connect to and operate over a wireless network.

Software required:

- Microsoft Office Suite (A personal copy of the latest version can be purchased at The UTHSCSA bookstore at student pricing with a student ID)

Laptops with an Apple based Operating System must be able to also operate using a Windows based Operating System. It may be necessary to purchase Windows (student pricing available at The UTHSCSA bookstore with a student ID) and virtualization software.

All laptops will connect to The UTHSCSA network via the HSCwave broadcast wireless connection. Authentication for wireless use is based on The UTHSCSA domain username and password.

Verification of proper operation **prior** to the start of class is highly recommended.

Assistance is available thru the IMS Service Desk

- Telephone:(567-7777
- E-mail (ims-servicedesk@uthscsa.edu)

Assistance is also available at the IMS Student Support Center (4.421T, DTL).

Reading Assignments – Reading assignments will be listed in the individual class sections of this syllabus.

ATTENDANCE

Attendance at scheduled classes and examinations is crucial to meeting course objectives. Therefore, regular attendance in class is expected of each student.

- Attendance is defined as being present within 15 minutes after the scheduled beginning of the class and until 15 minutes before the scheduled ending of the class.
- Excused absences may be granted by the Course Director in cases such as formal presentations at scientific meetings, illness, or personal emergency.
- Excused absences are considered on an individual basis and require electronic communication with the Course Director to request an excused absence. The e-mail request to the Course Director for consideration of an excused absence must provide details regarding the circumstances and specific dates.
- It is expected that students will provide *advanced notice* of absence for scheduled events.
- If a student has excessive unexcused absences in a given course, they will automatically receive a grade of *unsatisfactory* unless *makeup* has been approved by the Course Director.
- Makeup of absences (both excused and unexcused) is allowed at the discretion of the Course Director.
- Allowable unexcused absences will be determined by the credit hours of the course as follows:

Course Semester Credit Hours	Allowable Unexcused Absences
3.0	3
2.0	2
1.0	1

TEXTBOOKS

Required:

- **"Designing Clinical Research"**, *Fourth Edition*; Hulley SB, Cummings SSR, Browner WS, Grady DG, Newman TB; Lippincott Williams & Wilkins, a Wolters Kluwer Business, Philadelphia, PA 2015; **ISBN/ISSN: 9781608318049**

GRADING POLICIES AND EXAMINATION PROCEDURES

1. Class attendance is essential for anyone who wishes to obtain credit for the course. You must attend 14 of the 16 lectures in order to obtain credit for the course. You can make up any sessions missed due to unexpected schedule conflicts, professional travel, or other extenuating circumstances, provided you contact your course director as soon as you know you will need to miss a class. Any student who fails to meet this requirement will receive an UNSATISFACTORY grade for the course.
2. Three assignments are to be completed during the semester. These assignments are posted on Blackboard. Each assignment will be scored on a 100-point scale. ***You must complete and turn-in all 3 assignments on time and receive a minimum score of 70/100 points on each assignment in order to receive credit for the course.***
    a. A student who completes at least 2 of the assignments with 70/100 points, but fails to complete the 3rd assignment with a score of 70/100 points, will receive an incomplete.
    b. A student who completes less than 2 of the assignments with a score of 70/100 points will receive an UNSATISFACTORY grade for the course.
3. A student who receives an INCOMPLETE must meet with the Course Director and develop a plan of action to complete the outstanding work. All outstanding work must be completed within 6 months after the end of the course; otherwise the grade will be changed to UNSATISFACTORY.
4. A student who receives an UNSATISFACTORY grade must retake the course in order obtain a change of grade.

Grading System

The grading will be conducted on a pass fail basis and both assignments need a Satisfactory in order to pass the course.

S = Satisfactory U = Unsatisfactory

REQUESTS FOR ACCOMODATIONS FOR DISABILITIES

In accordance with policy 4.2.3, **Request for Accommodation Under the ADA and the ADA Amendments Act of 2008 (ADAAA)**, any student requesting accommodation must submit the appropriate request for accommodation under the American with Disabilities Act (ADA, form 100). To his/her appropriate Associate Dean of their School and a copy to the ADA Coordinator. Additional information may be obtained at http://uthscsa.edu/eeo/request.asp.

ACADEMIC INTEGRITY AND PROFESSIONALISM

Any student who commits an act of academic dishonesty is subject to discipline as prescribed by the UT System Rules and Regulations of the Board of Regents. Academic dishonesty includes, but is not limited to, cheating, plagiarism, collusion, the submission for credit of any work or materials that are attributable in whole or in part to another person, taking an exam for another person, signing attendance sheets for another student, and any act designed to give unfair advantage to a student or the attempt to commit such an act. Additional information may be obtained at http://catalog.uthscsa.edu/generalinformation/generalacademicpolicies/academicdishonestypolicy/

TITLE IX AT UTHSCSA

Title IX Defined:
Title of the Education Amendments of 1972 is a federal law that prohibits sex discrimination in education. It reads "no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance."

University of Texas Health Science Center San Antonio's Commitment:
University of Texas Health Science Center San Antonio (UTHSCSA) is committed to maintaining a learning environment that is free from discriminatory conduct based on gender. As required by Title IX, UTHSCSA does not discriminate on the basis of sex in its education programs and activities, and it encourages any student, faculty, or staff member who thinks that he or she has been subjected to sex discrimination, sexual harassment (including sexual violence) or sexual misconduct to immediately report the incident to the Title IX Director.

In an emergency, victims of sexual abuse should call 911. For non-emergencies, they may contact UPD at 210-567-2800. Additional information may be obtained at http://students.uthscsa.edu/titleix/

EMAIL POLICY

All correspondence will be sent to the student using the student's LiveMail address and CANVAS. All correspondence from the student to the course director should be sent to the course director's e-mail as listed on the first page of this syllabus.

USE OF RECORDING DEVICES

Only with course director's or instructor's permission.

ELECTRONIC DEVICES

Cell phones must be turned off during all class meetings and exams. Computers and electronic tablets are allowed only for participating in classroom activities (*e.g.*, viewing slides presented in lecture or conference materials). No texting, tweeting, e-mailing, web-surfing, gaming, or any use of electronic devices that is not directly connected with classroom activities is permitted.

TENTATIVE CLASS SCHEDULE

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Week	Date	Module	Title/Instructor(s)
1	08/22/2017	**Defining a Research Question**	Searching the Scientific Literature – Techniques and Databases – Gaspard - LIBRARY
2	08/29/2017		Electronic Reference Management – Software and Methods – Gaspard - LIBRARY
3	09/05/2017		Cross-sectional and Cohort Studies - Uses and Principles – Choi
4	09/12/2017		Defining Inclusion and Exclusion Criteria – Hazuda
5	09/19/2017		Defining a Research Question – Ferrer
6	09/26/2017	**Cross-sectional Studies**	Recruitment Strategies for Subject Enrollment – Hazuda
7	10/03/2017		Reading the Literature #1 – Interpretation of Systematic Reviews and Meta-analyses – Ferrer
8	10/10/2017		Analytic Approaches and Interpretation: Stratification, Standardization, and Risk – J Pugh
9	10/17/2017		Case-Control Studies – Uses and Principles – Choi
10	10/24/2017		Basic Principles of Survey Instrument Design - Espinoza
11	10/31/2017	**Case-Control Studies**	Diagnostic Test Evaluation – Michalek
12	11/07/2017		Case-Control Studies-Design Challenges – Matching and Control Selection – Choi
13	11/14/2017		Hypothesis testing – Choi
14	11/21/2017		Sample size calculation and R – Choi
15	11/28/2017		Bias in Evaluation of Diagnostic Tests - Ismail
16	12/05/2017		Causal Inference - Schmidt

Week: 1
Date: August 22, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Instructor(s): Chris Gaspard
Topic: Searching the Scientific Literature – Techniques and Databases
Learning Objectives and Competencies– Participants will be able to: 1. Develop a focused Medline search specific to their research project. 2. Describe the National Library Medicine tree structure for Medical Subject Headings (MeSH). 3. Set up an ongoing process for obtaining monthly reports of new literature germane to their research project. 4. Effectively search at least one other clinical information database – e.g. Cochrane Database of Systematic Reviews, Web of Science
Class Assignment: Librarians will work with participants to create your own customized searches.
Readings: Handouts at time of class

Week: 2
Date: August 29, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Instructor(s): Chris Gaspard
Topic: Electronic Reference Management – Software and Methods
Learning Objectives and Competencies– Participants will be able to: 1. Conduct a focused Medline search specific to their research project. 2. Have a working knowledge of reference management software: a. Local (resident on computer) – e.g., Endnote, Reference Manager b. Server based – e.g., Ref Works 3. Download references from search and effectively manage them in example software programs.
Class Assignment: Librarians will work with participants to create your own customized searches.
Readings: Handouts at time of class

Week: 3
Date: September 5, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Cross-Sectional and Cohort studies – Uses and Principles
Instructor(s): Byeongyeob Choi, PhD
Learning Objectives – Participants will be able to: 1. Describe the uses, strengths, and weaknesses of cross-sectional study designs. 2. Describe the uses, strengths, and weaknesses of cohort study designs. 3. Apply and manipulate concepts of probability to ascertain prevalence. 4. Differentiate concepts of incidence, prevalence, and estimates of relative risk.
Class Assignment: Read assigned material and be prepared to discuss.
Readings: **1. Designing Clinical Research. Fourth Edition:** **2. Chapter 1, Getting Started: The Anatomy and Physiology of Clinical Research, pp. 2-13** **3. Chapter 7, Designing Cross-Sectional and Cohort Studies, pp. 85-88**

4. Flanders WD, O'Brien TR. Inappropriate comparisons of incidence and prevalence in epidemiologic research. Am J Public Health 1989; 79(9):1301-1303

Week: 4
Date: September 12, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Defining Inclusion and Exclusion Criteria
Instructor(s): Helen Hazuda, PhD
Learning Objectives – participants will be able to: 1. Explain the relationship between the studied target population and the general population 2. Define inclusion and exclusion criteria for their own research projects. 3. Describe how the established inclusion and exclusion criteria effect subject recruitment 4. Describe how the established inclusion and exclusion criteria affect generalizability and validity.
Class Assignment: Read assigned material and be prepared to discuss.
Readings: Designing Clinical Research. Chapter 3, Choosing the Study Subjects: Specification, Sampling, and Recruitment, pp 23-31.

Week: 5
Date: September 19, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Defining a Research Question: Conducting Reviews
Instructor(s): Robert Ferrer, MD, MPH
Learning Objectives – Participants will be able to: 1. Describe the difference between a traditional review and a systematic review 2. Describe the differences between a systematic review and a meta-analysis 3. Describe the process for assuring that all relevant articles have been included in the review. 4. List the steps for assessing quality of articles for inclusion in a systematic review. 5. Interpret meta-analytic charts and graphs that pool data across studies.
Class Assignment: Read assigned material and come to class prepared to discuss.
Readings: Designing Clinical Research, Chapter 2, Conceiving the Research Question, pp. 17-24.

Week: 6
Date: September 26, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Recruitment Strategies for Subject Enrollment
Instructor(s): Helen Hazuda, PhD
Learning Objectives – Participants will be able to: 1. Describe their recruitment methods to the class, discussing process and pitfalls 2. Outline a strategy for improving recruitment of subjects 3. Delineate a process for tracking recruitment and inclusion of subjects in a study.
Class Assignment: Read assigned material and be prepared to discuss.
Readings: Designing Clinical Research. Chapter 3, Choosing the Study Subjects: Specification, Sampling, and Recruitment, pp 23-31.

Week: 7
Date: October 3, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Reading the Literature #1 – Interpretation of Systematic Reviews and Meta-analyses
Instructor(s): Robert Ferrer, MD, MPH
Learning Objectives – Participants will be able to: 1. Analyze and discuss the strengths and weaknesses of published systematic reviews and meta-analyses. 2. Describe the necessary steps for reviewing the quality of a systematic review and meta-analysis.
Class Assignment: Read assigned material and be prepared to discuss.
Readings: Handouts to be distributed prior to class.

Week: 8
Date: October 10, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Analytic Approaches and Interpretation: Stratification, Standardization, and Risk
Instructor(s): Jacqueline Pugh, MD
Learning Objectives – Through homework and class room activities, participants will be able to: 1. Define different epidemiologic estimates of risk. 2. Demonstrate the use of stratification to: A. Determine levels of risk by differing levels of exposure variables B. Standardize population risks estimates to account for differences in variable distributions 3. From a published clinical trial, calculate: A. Absolute risk and absolute risk reduction. B. Relative risk and relative risk reduction C. Number need to treat (NNT) and number needed to harm (NNH) 4. Articulate the means of assessing statistical and clinical significance
Class Assignment: Read assigned material and come to class prepared to discuss.
Readings: To be determined.

Week: 9
Date: October 17, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Diagnostic Test Evaluation
Instructor(s): Byeongyeob Choi, PhD
Learning Objectives – Participants will be able to: 1. Describe evaluation criteria for diagnostic tests.
Class Assignment: Read assigned material and be prepared to discuss
Readings: Vaidya VS et al. Kidney injury molecule-1 outperforms traditional biomarkers of kidney injury in preclinical biomarker qualification studies. Nature Biotechnology 2010;28(5), 478-485.

Week: 10

Date: October 24, 2017 (3:00 - 5:00 pm)

Room: LIB 2.015

Topic: Basic Principles of Survey Instrument Design

Instructor(s): Sara Espinoza, MD

Learning Objectives – Participants will be able to:

1. Describe criteria for choosing established instruments for inclusion in survey work.
2. Defend the inclusion of specific items and scales in their own research projects.
3. Describe define the psychometric properties of measures used in their research work.
4. Design a study to develop and evaluate the validity of a survey item.

Class Assignment: Read assigned material and be prepared to discuss.

Readings and Bibliography:

1. **Designing Clinical Research. Chapter 4, Planning the Measurements: Precision and Accuracy, pp 32-42.**
2. **MacDowell I and Newall C. The theoretical and technical foundations of health measurement, Chapter 2, pp 10-46 in Measuring Health: A Guide to Rating Scales and Questionnaires, 2nd Edition, Oxford University Press, New York 1996.**

Week: 11

Date: October 31, 2017

Room: LIB 2.015

Topic: Case-Control Studies – Uses and Principles

Instructor(s): Byeongyeob Choi, PhD

Learning Objectives- Participants will be able to:

1. Describe the uses of case-control studies
2. Identify the strengths and weaknesses of case-control study designs
3. Define and derive an odds ratio from a 2 X 2 table or a 2 X N table
4. Describe the relationship between odds ratios and direct measures of relative risk

Class Assignment: Read assigned material and be prepared to discuss.

Readings: Designing Clinical Research. Chapter 8, Designing Case-Control Studies, pp 97-116.

Week: 12

Date: November 7, 2017

Room: LIB 2.015

Topic: Case Control Study Design Challenges – Matching and Control Selection

Instructor(s): Byeongyeob Choi, PhD

Learning Objectives – Participants will be able to:

1. Describe the strengths and weaknesses of matched vs. unmatched study designs.
2. Define confounding in the assessment of causal inference in case-control studies
3. Describe the effects of matching on control selection
4. Describe differences in analytic approach for matched vs. unmatched case-control studies
5. Determine the parameters that dictate sample size in case control studies
6. Chart the association between number of controls and study power
7. Utilize published tables and/or software to calculate sample sizes for a case-control study

Class Assignment: Read assigned material and be prepared to discuss
Readings: To be identified

Week: 13
Date: November 14, 2017 (3:00 - 5:00 pm)
Topic: Reading the Literature #2. Minimizing and Detecting Bias in Case-Control Studies
Room: LIB 2.015
Instructor(s): Byeongyeob Choi, PhD
Learning Objectives – Participants will be able to: 1. Read examples evaluating recall bias in case-control studies.
Class Assignment: Read assigned material and be prepared to discuss
Readings: **1. Cockburn M et al. Recall bias in self-reported melanoma risk factors. American Journal of Epidemiology 2001; 15: 1021-6.** **2. Parr CL et al. Recall bias in melanoma risk factors and measurement error effects: a nested case-control study within the Norwegian Women and Cancer Study. American Journal of Epidemiology 2009; 1: 257-66.**

Week: 14
Date: November 21, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Building Clinical Prediction Models
Instructor(s): Byeongyeob Choi, PhD
Learning Objectives – Participants will be able to: 1. Explain challenges related to predicting future events. 2. Describe predictive versus prognostic modeling. 3. What are challenges to high-throughput profiles as predictors? 4. Explain the required steps in building a robust predictive model.
Class Assignment:
Readings: **1. Bouwmeester, Walter, et al. "Reporting and methods in clinical prediction research: a systematic review." *PLoS Med* 9.5 (2012): e1001221.** **2. Lee et al. How to establish clinical prediction models. Endocrinology and Metabolism 2016.** **3. Nashef et al. European system for cardiac operative risk evaluation (EuroScore). European Journal of Cardio-thoracic Surgery 1999; 16: 9-13.**

Week: 15
Date: November 28, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Bias in Evaluation of Diagnostic Tests
Instructor(s): Ismail Jatoi, MD
Learning Objectives – Participants will be able to:

2. Detect bias that may misrepresent test characteristics in a diagnostic test evaluation. 3. Describe strategies for minimizing spectrum bias in the conduct of diagnostic test evaluations. 4. Apply the methodologic principles to the case example of Prostate Cancer and PSA results
Class Assignment: Read assigned material and be prepared to discuss
Readings:

Week: 16
Date: December 5, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Hypothesis Testing and Sample Size
Instructor(s): Byeongyeob Choi, PhD
Learning Objectives – Participants will be able to: 1. Describe concepts of hypotheses, statistical tests and errors. 2. Describe concepts of sample size calculation and determinant factors.
Readings: Designing Clinical Research. Chapter 5, Getting ready to estimate sample size: hypotheses and underlying principles, pp 43-54.

Week: 17
Date: December 12, 2017 (3:00 - 5:00 pm)
Room: LIB 2.015
Topic: Estimating Sample Size and Power
Instructor(s): Byeongyeob Choi, PhD
Learning Objectives – Participants will be able to: 1. Identify appropriate statistical tests for given data and hypotheses. 2. Calculate sample sizes for given hypotheses and statistical tests.
Readings: Designing Clinical Research. Chapter 6, Estimating sample size and power: applications and examples, pp 55-83.