

**TSCI 5071**  
**Patient Oriented Clinical Research Methods – 1**

**Fall 2019**

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**CLASS DAYS and TIME:** Tuesdays (August 20 – December 10, 2019), 3:00 – 5:00 pm

**CLASSROOM:** LIB 2.088

**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](mailto:choib@uthscsa.edu)

**TELEPHONE:** 210-567-0854

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**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](mailto: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 3<sup>rd</sup> 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/eo/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.

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<b>Week</b>	<b>Date</b>	<b>Title/Instructor(s)</b>
1	08/20/2019	Searching the Scientific Literature – Techniques and Databases – Gaspard - LIBRARY
2	08/27/2019	Electronic Reference Management – Software and Methods – Gaspard - LIBRARY
3	09/03/2019	Designing Cross-sectional and Case-control Studies – Choi
4	09/10/2019	Designing a Cohort Study – Choi
5	09/17/2019	Defining Inclusion and Exclusion Criteria – Hazuda
6	09/24/2019	Defining a Research Question – Ferrer
7	10/01/2019	Reading the Literature – Interpretation of Systematic Reviews and Meta-analyses – Ferrer
8	10/08/2019	Case-Control Studies-Design Challenges – Matching and Control Selection – Choi
9	10/15/2019	Basic Principles of Survey Instrument Design - Espinoza
10	10/22/2019	Recruitment Strategies for Subject Enrollment – Hazuda
11	10/29/2019	Designing a Randomized Blinded Trial - Choi
12	11/05/2019	Analytic Approaches and Interpretation - Choi
13	11/12/2019	Diagnostic Test Evaluation – Michalek
14	11/19/2019	Reading the Literature – Minimizing and Detecting Bias in Case-Control Studies – Choi
15	11/26/2019	Enhancing causal inference in observational studies – Choi
16	12/03/2019	Sample size calculation – Choi
17	12/10/2019	Student presentation

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