

**Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)  
Fall 2017**

**CLASS DAYS and TIME:** Mondays 3:00-5:00pm

**CLASSROOM:** MED 3.309L

**COURSE FACULTY:** Kimberly Summers, PharmD and Kay Oyajobi, PhD  
Course Directors

**OFFICE LOCATION and HOURS:** By appointment; Summers (RAB 2.104, Greehey Campus) Oyajobi ( 5.518D MED, Long Campus)

**EMAIL:** [SUMMERS@UTHSCSA.EDU](mailto:SUMMERS@UTHSCSA.EDU) [OYAJOB@UTHSCSA.EDU](mailto:OYAJOB@UTHSCSA.EDU)

**TELEPHONE:** Summers (567-8249) Oyajobi (567-0909)

---

**READ THIS DOCUMENT CAREFULLY --- YOU ARE RESPONSIBLE FOR ITS CONTENTS.**

**COURSE DESCRIPTION AND OBJECTIVES**

**TSCI 5070:** This foundational course introduces students to core ethical content necessary for responsible research conduct. Through interactive seminars, students will learn about (1) scientists as responsible members of society (contemporary ethical issues in biomedical research and environmental/social impacts of research), (2) policies for research with human subjects and vertebrate animals, (3) collaborative research, (4) conflicts of interest (personal, professional, financial), (5) data acquisition and laboratory tools (management, sharing, ownership), (6) responsible authorship and publication, (7) mentor/trainee responsibilities and relationships, (8) peer review, and (9) research misconduct (forms of misconduct and management policies) (10) list the elements of informed consent and describe procedures and precautions for enrolling special populations into clinical investigation.

**Pre-requisites** – none

**Semester credit hours** – TSCI 5070 (2 hrs)

The following lists some of the broad objectives of this course. Specific objectives for each individual lesson can be found at the end of this syllabus.

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

- Associate the responsible conduct of research to the practice of scientific investigation with integrity.
- Be aware of and apply established professional norms and ethical principles for all activities related to scientific research (laboratory, human subjects, and live vertebrate animals).
- Recognize when laboratory practices, publication practices, and other research practices deviate from legal, ethical, or regulatory requirements.
- Describe practices that promote compliance with ethical and legal requirements for the responsible conduct of basic and clinical research.

## **COURSE ORGANIZATION**

**The main teaching modalities used in this course include:**

- 1) Conventional didactic lectures in which information is delivered to the class by speakers, lecturers, or course directors
- 2) Presentations and panel discussions which are highly interactive case-based activities, encouraging two-way communication between the instructor and the class, and requiring student active participation in the learning process

**Materials** – See below

**Computer Access** – Students are required to have a computer that will connect to the UTHSCSA Canvas program.

Computers will not be utilized during the class period. Reading materials and powerpoint presentations will be available for all lectures through Canvas.

Verification of proper operation **prior** to the start of class is highly recommended. Assistance is available through 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 (ALTC 106).

**Reading Assignments** – Required class readings and/or assignments are listed below in the class schedule descriptions for each lecture.

## **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. A student has to arrive no later than 15 minutes after the start of the class to receive credit for attendance for that class. Any student that leaves more than 15 minutes before the end of the class WILL NOT receive credit for attendance for that 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 |
|------------------------------|------------------------------|
| 2.0 (TSCI 5070)              | 2                            |

## TEXTBOOKS

**Required:** None

**Recommended:** None

## GRADING POLICIES AND EXAMINATION PROCEDURES

- 1 Class attendance is essential for anyone who wishes to obtain credit for the course. You must attend >85% in order to obtain credit for the course. **All students must sign in on the attendance sheet for each lecture to be counted present.** You may be able to make up 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 One assignment must be completed during the semester. This assignment will be posted and scored on a 100-point scale. **You must complete and present the assignment on time and receive a minimum score of 70/100 points in order to receive credit for the course.**
- 3 Quizzes will be given at the end of class periods at the discretion of the Course Directors. There will not be advanced notice of the quizzes.
- 4 **You must maintain an overall grade of 70 or above in order to receive credit for the course.**
- 5 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.
- 6 A student who receives an UNSATISFACTORY grade must enroll and retake the course and meet all requirements to receive a grade of satisfactory.

### 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

Every student is issued a University email address and account at the time of enrollment. As a matter of University Policy, communications between students and faculty that occur using the student’s University email address is considered official business. Therefore, students are expected to check their university email inboxes on a regular basis so that any announcements, instructions, or information regarding this course will be received in a timely way. Missed communications due to inadequate monitoring of incoming emails on the University’s email server will not suffice as a valid excuse for unsatisfactory academic progress.

## USE OF RECORDING DEVICES

Recording of lectures and other learning activities in this course by any means (e.g., video, audio, etc.) is only permitted if approved by the instructor or required for compliance with Americans with Disabilities Act (ADA).

## ELECTRONIC DEVICES

Cell phones, tablets, and laptops must be turned off during all class meetings and exams. Texting, tweeting, emailing, web-surfing, gaming, or any use of electronic devices is NOT permitted.

## CLASS SCHEDULE

### Responsible Conduct of Patient Oriented Clinical Research (TSCI 5070)

#### Fall 2017

---

| Wk | Date       | Module | Topic---Instructor  |
|----|------------|--------|---|
| 1  | 08.21.2017 | 5070   | History – Eugenics to the 2018 Common Rule - <b>McGeary</b>                                     |
| 2  | 08.28.2017 | 5070   | Conflicts of Interest – <b>Sertich</b>  |
| 3  | 09.04.2017 |        | <b>LABOR DAY – UT Health Science Center Holiday</b>   |
| 4  | 09.11.2017 | 5070   | Data Ownership, Intellectual Property, and Patents – <b>Fritz (Fox, Feldman, Brenner)</b>       |
| 5  | 09.18.2017 | 5070   | Research Misconduct – Schmelz ( <b>Oyajobi, Sun, Lechleiter, Morilak</b> )                      |
| 6  | 09.25.2017 | 5070   | Ethics and Responsibility in Authorship and Publication - <b>McManus</b>                        |
| 7  | 10.02.2017 | 5070   | Mentoring (Mentor/Mentee Responsibilities and Expectations) - <b>LoVerde</b>                    |
| 8  | 10.09.2017 | 5070   | Peer Review – <b>Ahuja</b>  |
| 9  | 10.16.2017 | 5070   | Data Acquisition, Management, and Sharing – <b>Gelfond / Safe Laboratory Practices – Berton</b> |
| 10 | 10.23.2017 | 5070   | Ethical Use of Animals in Biomedical Research - <b>Kiel</b>                                     |
| 11 | 10.30.2017 | 5070   | Good Clinical Practice (GCP) – <b>Roache</b>  |
| 12 | 11.06.2017 | 5070   | Recruiting Fairly: Inclusion of Special Populations in Research – <b>Hazuda</b>                 |
| 13 | 11.13.2017 | 5070   | Elements of Consent and Protecting Confidentiality – <b>Taranova/James</b>                      |
| 14 | 11.20.2017 | 5070   | Community Based Research and Drafting Consent Documents – <b>Summers</b>                        |
| 15 | 11.27.2017 | 5070   | Class Presentations – Summers/ Oyajobi  |
| 16 | 12.04.2017 | 5070   | Class Presentations – Summers/ Oyajobi  |
| 17 | 12.11.2017 | 5070   | Class Presentations – Summers/ Oyajobi  |

---