TSCI 6102
IRB Procedures Practicum
Fall 2022

CLASS DAYS and TIME: Tuesdays; 1:30 p.m.

CLASSROOM: Online Format

COURSE FACULTY: Krista Kilpadi, MD, PhD, CCRP, Course Instructor

OFFICE LOCATION and HOURS: Research Administration Building, 2.302.4 - Monday – Friday, 8:30 am – 5:30 pm by appointment (*Microsoft Teams may be used in lieu of physical meeting space)

EMAIL: kilpadi@uthscsa.edu

TELEPHONE: 210-450-8365 leave msg for call to be returned, or contact via Microsoft Teams

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

COURSE DESCRIPTION AND OBJECTIVES

This elective course presents an in-depth introduction to the institutional program that provides oversight and regular review of research projects that involve human subjects. This includes consideration of the operational procedures of the multiple Institution Review Boards (IRB) of the UT Health Science Center at San Antonio. Course objectives are achieved through a combination of readings, monthly attendance at selected IRB meetings, and discussions with instructor.

Pre-requisites – None

Semester credit hours – 1 Credit Hour

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

- Discuss the application of the Belmont Principles in the IRB's review and approval of research..
- Describe the role, authority, and composition of the IRB. Compare and contrast the types of IRB review.
- List the main federal regulations applicable to the protection of human research subjects and describe the three basic protections provided by these regulations.
- Describe the required determinations for IRB approval.
- Describe the similarities and differences in the IRB's review of unanticipated problems involving risks to subjects and reports of noncompliance.
- Review one current IRB policy and list any areas for improvement.

COURSE ORGANIZATION

The main teaching modalities used in this course include:

- Meeting personally with the Course Director for the purpose of planning and monitoring of planned activities

Materials – Links to reading material will be provided – See below

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 UT Health SA 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 UT Health SA bookstore with a student ID) and virtualization software.

All laptops will connect to the UT Health SA network via the HSCwave broadcast wireless connection. Authentication for wireless use is based on the UT Health SA 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: 210-567-7777
- E-mail: ims-servicedesk@uthscsa.edu

Assistance is also available at the IMS Student Support Center (ALTC 106).

Reading Assignments – You will be required to read regulations that govern the protection of human subjects.

- 45 CFR Part 46 - https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46
- 21 CFR 50 Protection of Human Subjects - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50
- 21 CFR 56 Institutional Review Boards - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56
- Ethical Principles
    - The Belmont Report - https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
    - The Nuremberg Code - https://history.nih.gov/display/history/Nuremberg+Code
    - Declaration of Helsinki - https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- UTHSCSA – Review of Research Policies
    - 1.6.6 Institutional Review Board - https://uthealthsa.sharepoint.com/RAC/Documents/HOP/Chapter01/1.6.6.pdf
    - 7.2.2 Institutional Review Board (IRB) Responsibilities - https://uthealthsa.sharepoint.com/RAC/Documents/HOP/Chapter07/7.2.2.pdf
    - IRB policies -
        - IRB Approval of Research Policy and Procedure - https://www.uthscsa.edu/sites/default/files/Services/forms/irb_approval_of_research_policy.pdf
        - Initial Review of Research Policy and Procedure - https://www.uthscsa.edu/sites/default/files/Services/forms/initial_review_of_research_policy.pdf
        - Modifications and Amendments Policy and Procedure - https://www.uthscsa.edu/sites/default/files/Services/forms/modifications_amendments_policy.pdf
        - Continuation Review Policy and Procedure -

https://www.uthscsa.edu/sites/default/files/Services/forms/irb_continuation_review_policy.pdf

- Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) And Unanticipated Adverse Device Effects (UADE) Policy and Procedure - https://www.uthscsa.edu/sites/default/files/Services/forms/upirso_uade_policy.pdf
- Noncompliance Policy and Procedure - https://www.uthscsa.edu/sites/default/files/Services/forms/noncompliance_policy.pdf
- Suspension or Termination of Research Policy and Procedure - https://www.uthscsa.edu/sites/default/files/Services/forms/suspensiontermination_irbpolicy.pdf

ATTENDANCE

In order to achieve the expected level of competency, students must be fully engaged. Therefore, attendance for every class session/meeting is expected.

Absence for Religious Observance:

Students requesting an excused absence for religious holidays should follow the guidelines outlined in the UT Health Science Center Catalog.

TEXTBOOKS

Required: There are no textbooks for this course. Links to reading material are listed above in the Reading Assignments section.

GRADING POLICIES AND EXAMINATION PROCEDURES

There will be seven assignments due for this course which will be graded as complete or incomplete. These assignments are posted on CANVAS. You may receive feedback in regarding your assignment. Assignments are due at time points identified in the schedule below. Your final grade will be based on completion of all required assignments.

Grading System

If by the end of the course all critiques have not been submitted, you will receive an (U) Unsatisfactory as a final grade.

(S) Satisfactory = all critiques complete (U) Unsatisfactory = missing critique(s)

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/academicdishonesty/

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 e-mail 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 e-mail 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 never be 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 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, emailing, web-surfing, gaming, or any use of electronic devices that is not directly connected with classroom activities is permitted.