

MEDI 6102
IRB Procedures Practicum
FALL 2017 – August 21, 2017 to December 15, 2017

CLASS DAYS and TIME: Tuesdays; TBD

CLASSROOM: Research Administration Building, Rm 2.104

COURSE FACULTY: Meyad Baghezza, BA CIP, Course Instructor

OFFICE LOCATION and HOURS: Research Administration Building, 2.104 - Monday – Friday (8:00 am – 5:00 pm by appointment)

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TELEPHONE: 210-567-8205

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

- 45 CFR Part 46 - <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-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 - <http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/>
 - The Nuremberg Code - <https://history.nih.gov/research/downloads/nuremberg.pdf>
 - 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 - <http://uthscsa.edu/hop2000/1.6.6.pdf>
 - 7.2.2 Institutional Review Board (IRB) Responsibilities - <http://uthscsa.edu/hop2000/7.2.2.pdf>
 - IRB policies - <http://research.uthscsa.edu/irb/sop.shtml>
 - IRB Approval of Research Policy and Procedure
 - Initial Review of Research Policy and Procedure
 - Modifications and Amendments Policy and Procedure
 - Continuation Review Policy and Procedure
 - Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) And Unanticipated Adverse Device Effects (UADE) Policy and Procedure
 - Noncompliance Policy and Procedure
- Association for Accreditation of Human Research Protection Programs (AAHRPP) Tip Sheets 1-27- As an AAHRPP Accredited institution, these tip sheets offer additional information on how institutions can meet the accreditation standards. <http://www.aahrpp.org/apply/resources/tip-sheets>

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 text books for this course. Links to reading material is listed above in the Reading Assignments section.

GRADING POLICIES AND EXAMINATION PROCEDURES

There will be five 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/eoo/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 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.

CLASS SCHEDULE
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WEEK	DATE	TOPIC	Assignment/Action/Topic	Instructor and Modality
Week 1	August 21, 2017	Introduction	Make appointment with instructor for course introduction	Baghezza (Meeting)
			Sign and submit confidentiality agreement	
Week 2	August 28, 2017	IRB Functions I	CITI Training Assignment 1 Post required IRB Member CITI training completion certificate in CANVAS	CANVAS Post due September 8, 2017
Week 3	September 4, 2017	IRB Functions II	Reading Material: 45 CFR Part 46, 21 CFR 50, and 21 CFR 56 IRB Policy review: IRB Approval of Research Policy and Procedure	Reading Material
Week 4	September 11, 2017	Expedited Review	Schedule meeting with Expedited Reviewer to discuss process. Contact Pam Sabrsula, Clara Vorpahl or me – IRB Expedited Reviewers	Meeting with Expedited Reviewer
Week 5	September 18, 2017	Introduction to Convened IRB Review	Attend IRB 1 - Meeting (1:30– 4PM) room 5.076 5th floor of library IRB meeting scheduled for September 19, 2017	Observation of IRB Meeting
Week 6	September 25, 2017	Determining Difference Between Expedited Review and Full Board Review	Assignment 2 – critique of Expedited Review versus Convened Review	CANVAS Post due September 29, 2017
			Preparation for Assignment 3 – Contact course instructor (on September 27, 2017) to select a New Study to review	
Week 7	October 2, 2017	Initial Review of a New Study Reviewed by a Convened IRB I	Review IRB Policy: Initial Review of Research Policy and Procedure	Observation of IRB Meeting
			Attend IRB 2 - Meeting (1:30– 4PM) room 5.076 5th floor of library IRB meeting scheduled for October 3, 2017	

			Continue preparation for Assignment 3 during this meeting by observing IRB deliberations of the New study	
Week 8	October 9, 2017	Initial Review of a New Study Reviewed by a Convened IRB II	Assignment 3 - Critique of IRB Review of the New Study you chose to analyze	CANVAS Post due October 13, 2017
			Preparation for Assignment 4 – Contact course instructor (on October 11, 2017) to select an Amendment to review	
Week 9	October 16, 2017	Review of a Modification by a Convened IRB I	Review IRB Policy: Modifications and Amendments Policy and Procedure	Observation of IRB Meeting
			Attend IRB 3 - Meeting (1:30– 4PM) room 5.076 5th floor of library IRB meeting scheduled for October 17, 2017	
			Continue preparation for Assignment 4 during this meeting by observing IRB deliberations of the Amendment	
Week 10	October 23, 2017	Review of a Modification by a Convened IRB II	Assignment 4 - Critique of IRB Review of the Amendment you chose to analyze	CANVAS Post due October 27, 2017
			Preparation of Assignment 5 – Contact course instructor (on October 25, 2017) to select an Progress Report	
Week 11	October 30, 2017	Review of Continuing Review by a Convened IRB I	Review IRB Policy: Continuation Review Policy and Procedure	Reading Material & Observation of IRB Meeting
			Attend IRB 1 - Meeting (1:30– 4PM) room 5.076 5th floor of library IRB meeting scheduled for October 31, 2017	
Week 12	November 6, 2017	Review of Continuing Review by a Convened IRB II	Assignment 5 - Critique of IRB Review of the Amendment you chose to analyze	CANVAS Post due November 10, 2017
Week 13	November 13, 2017	Review of Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)	Review IRB Policy: <ul style="list-style-type: none"> Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) And Unanticipated Adverse Device Effects (UADE) Policy and Procedure 	Reading Material

Week 14	November 20, 2017	Review of Noncompliance by Subcommittee	Review IRB Policy: <ul style="list-style-type: none"> • Noncompliance Policy and Procedure 	Reading Material
Week 15	November 27, 2017	Review of UPIRSO and Noncompliance by Subcommittee I	Preparation of Assignment 6 – Contact course instructor (on November 28, 2017) to select an Prompt Report	Reading Material
			Attend UPIRSO/Noncompliance Subcommittee Meeting (10:30 am) room 5.076 5th floor of library IRB meeting scheduled for November 30, 2017	Observation of IRB Subcommittee Meeting
Week 16	December 4, 2017	Review of UPIRSO and Noncompliance Convened IRB	Attend IRB 1- Meeting (1:30– 4PM) room 5.076 5th floor of library IRB meeting scheduled for December 12, 2017	Observation of IRB Meeting
Week 17	December 11, 2017	Assessment of IRB’s review of Unanticipated Events	Assignment 6 – Submit a critique of the IRB’s assessment of a Prompt Report	CANVAS Post due December 15, 2017