

**MEDI 6102**  
**IRB Procedures Practicum**  
**Fall 2019**

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

**CLASSROOM:** Research Administration Building, Rm 2.302.10

**COURSE FACULTY:** Meyad Baghezza, BA CIP, Course Instructor

**OFFICE LOCATION and HOURS:** Research Administration Building, 2.302.10 - Monday – Friday (8:00 am – 5:00 pm by appointment)

**EMAIL:** Baghezza@uthscsa.edu

**TELEPHONE:** 210-567-8205

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**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](mailto: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 - [https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1110](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1110)
- 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/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

## 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/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 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**  
**MEDI 6102**  
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**Fall 2019 – August 19, 2019 to December 13, 2019**

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WEEK	DATE	TOPIC	Assignment/Action/Topic	Instructor and Modality
Week 1	August 20, 2019	Introduction	Make appointment with instructor for course introduction (See contact information on first page)	Baghezza (Meeting)
			Sign and submit confidentiality agreement	
			CITI Training Assignment 1 Post required IRB Member CITI training completion certificate in CANVAS	Assignment 1 CANVAS Post due August 23, 2019
Week 2	August 27, 2019	Non-Research/Non-Human and Exempt Research	Meet with instructor to discuss Non-Research/Non-Human and Exempt Research on <b>August 27, 2019</b> at 1:30 pm in Research Admin Building, Greehey Campus, Rm. 2.302.10	Baghezza (Meeting)
Week 3	September 3, 2019	IRB Functions	Reading Material: <ul style="list-style-type: none"> <li>• 45 CFR Part 46,</li> <li>• 21 CFR 50,</li> <li>• 21 CFR 56</li> </ul> IRB Policy review: <ul style="list-style-type: none"> <li>• IRB Approval of Research Policy and Procedure</li> </ul>	Reading Material
Week 4	September 10, 2019	Expedited Review	Instructor will provide <b>Expedited Research</b> to select on <b>September 4, 2019</b>	Meeting with Expedited Reviewer
			Meet with instructor to discuss an Expedited Submission on September 10, 2019 at 1:30 pm in Research Admin Building, Greehey Campus, Rm. 2.302.10	
Week 5	September 17, 2019	Introduction to Convened IRB Review	Attend <b>IRB 3 - Meeting (1:30 PM – 4:00 PM)</b> room 5.076 5th floor of library IRB meeting scheduled for <b>September 17, 2019</b>	Observation of IRB Meeting
Week 6	September 24, 2019	Determining Difference Between Expedited Review and Full Board Review	Preparation for Assignment 3 – Instructor will provide <b>New Study</b> to select on <b>September 25, 2019</b> .	Reading Material
			Assignment 2 – critique of Expedited Review versus Convened Review	Assignment 2 CANVAS Post due

				September 27, 2019
Week 7	October 1, 2019	Initial Review of a New Study Reviewed by a Convened IRB I	Review IRB Policy: Initial Review of Research Policy and Procedure	Reading Material
			Attend <b>IRB 1</b> - Meeting (1:30 PM – 4:00 PM) room 5.076 5th floor of library IRB meeting scheduled for <b>October 1, 2019</b>	Observation of IRB Meeting
			Assignment 3 – Critique of IRB Review of the New Study you chose to analyze	Assignment 3 CANVAS Post due October 4, 2019
Week 8	October 8, 2019	Review of a Modification by a Convened IRB I	Preparation for Assignment 4 – Instructor will provide <b>Amendment</b> to select on <b>October 9, 2019</b>	Reading Material
Week 9	October 15, 2019	Review of a Modification by a Convened IRB II	Review IRB Policy: Modifications and Amendments Policy and Procedure	Reading Material
			Attend <b>IRB 2</b> - Meeting (1:30 PM – 4:00 PM) room 5.076 5th floor of library IRB meeting scheduled for <b>October 15, 2019</b>	Observation of IRB Meeting
			Continue preparation for Assignment 4 during this meeting by observing IRB deliberations of the Amendment	Assignment 4 CANVAS Post due October 18, 2019
Week 10	October 22, 2019	Review of Continuing Review by a Convened IRB I	Review IRB Policy: Continuation Review Policy and Procedure	Reading Material
			Preparation of Assignment 5 – Instructor will provide <b>Progress Report</b> to select on <b>October 23, 2019</b>	
Week 11	October 29, 2019	Review of Continuing Review by a Convened IRB II	Attend <b>IRB 3</b> - Meeting (1:30 PM – 4:00 PM) room 5.076 5th floor of library IRB meeting scheduled for <b>October 29, 2019</b>	Reading Material
			Assignment 5 - Critique of IRB Review of the Progress Report you chose to analyze	Assignment 5 CANVAS Post due November 1, 2019
Week 12	November 5, 2019	Review of Unanticipated Problems Involving Risks to Subjects or Others	Review IRB Policy: <ul style="list-style-type: none"> <li>Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO)</li> </ul>	Reading Material

		<b>(UPIRSO) &amp; Review of Noncompliance I</b>	And Unanticipated Adverse Device Effects (UADE) Policy and Procedure Review IRB Policy: <ul style="list-style-type: none"> <li>• Noncompliance Policy and Procedure</li> </ul>	
<b>Week 13</b>	<b>November 12, 2019</b>	<b>Review of Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) &amp; Review of Noncompliance II</b>	Preparation of Assignment 6 – Instructor will provide <b>Prompt Report Issue</b> to select on <b>November 12, 2019</b>	
			If possible, attend <b>UPIRSO/Noncompliance Subcommittee</b> meeting to discuss the Prompt Report Issue. Meeting (10:30 AM – 11:30 AM) room 5.076 5th floor of library IRB meeting scheduled <b>November 14, 2019</b>	
<b>Week 14</b>	<b>November 19, 2019</b>	<b>Review of UPIRSO and/or Noncompliance by UPIRSO/Noncompliance Subcommittee III</b>	Review and Consider Subcommittee recommendations	<b>Reading Material</b>
<b>Week 15</b>	<b>November 26, 2019</b>	<b>Review of UPIRSO and/or Noncompliance by UPIRSO/Noncompliance Subcommittee VI</b>	Attend <b>IRB 2-</b> Meeting (1:30 PM – 4:00 PM) room 5.076 5th floor of library IRB meeting scheduled for <b>November 26, 2019</b>	<b>Observation of IRB Meeting</b>
			Assignment 6 – Submit a critique of the IRB’s assessment of a Prompt Report	<b>CANVAS Post due December 2, 2019</b>
<b>Week 16</b>	<b>December 3, 2019</b>	<b>Cooperative research &amp; Single IRB review</b>	Definitions and discussion 45 CFR 46.114	<b>Baghezza (Meeting)</b>
			Meet with instructor to discuss Cooperative Research and Single IRB Review December 3, 2019 at 1:30 pm in Research Admin Building, Greehey Campus, Rm. 2.302.10	
<b>Week 17</b>	<b>December 10, 2019</b>	<b>Course wrap-up</b>	Complete Course Activity documentation	Submit originally signed Course Activity documentation on <b>December 13, 2019</b>