FINAL

Responsible Conduct of Research (TSCI 5070)
Fall 2022

CLASS DAYS and TIME:	Mondays 3:00 - 5:00pm
CLASSROOM:	MED 3.309L
COURSE FACULTY:	**Krista Kilpadi**, MD, PhD, and Kay **Oyajobi**, MBBS, PhD, MBA
	Course Co-Directors
OFFICE LOCATION/HOURS:	By appointment only
	Kilpadi (RAB 2.302, Greehey Campus)
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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) and of commitment

5) Data acquisition and laboratory tools (management, sharing, ownership)

6) Responsible and ethical authorship and publication

7) Mentor/trainee responsibilities and relationships

8) Ethical peer review

9) Research misconduct (forms of misconduct and management policies)

10) Informed consent, privacy regulations, good clinical practice, and special populations in clinical investigations.

Prerequisites – none

Semester Credit Hours – TSCI 5070 (2 hours)

The following lists some of the broad objectives of this course. Specific objectives for each individual lesson can be found in Canvas.

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

o Associate the responsible conduct of research with practice of scientific investigation with integrity.

o 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).

o Recognize when laboratory practices, publication practices, and other research practices deviate from legal, ethical, or regulatory requirements or violate moral standards and societal values.

o Describe practices that promote compliance with ethical and legal requirements for the responsible conduct of basic, translational, 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 instructors/presenters/panelists and the class, and requiring active participation of students in the learning process

Materials – See below

Computer Access – Students are required to have a computer that will connect to the UT Health SA's CANVAS Learning Management System.

Computers are not required 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: 210-567-7777
- E-mail (ims-servicedesk@uthscsa.edu)

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

Reading Assignments – Required class readings and/or assignments for each class schedule will be made available in CANVAS at least one week in advance of the class.

ATTENDANCE

Attendance at scheduled classes and presentations is crucial to meeting course objectives. Therefore, regular attendance in class is expected of each student.

- o 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.
- o Excused absences may be granted by either of the Course Co-Directors in cases such as formal presentations at scientific meetings (with appropriate documentation), illness, or personal emergency.
- o Excused absences will be considered on an individual, case-by-case basis and require electronic communication (email) with one of the Course Co-Directors. Students must request an excused absence in advance of a class (except in an emergency). The e-mail request to the Course Co-Directors for consideration of an excused absence must provide details regarding the circumstances and specific dates. Makeup of excused absences will be allowed only at the **discretion** of one or both Course Co-Directors and only if the above process have been followed. Verbal requests will not be entertained.
- o It is expected that students will provide *advanced notice* of absence for events that are scheduled, e.g., a presentation at a scientific meeting.
- o If a student does not meet the attendance requirements based on absences, they will automatically receive a "U" grade (*Unsatisfactory*).
- o Allowable absences, for which Course Director approval is not required and determined by the credit hours for the course, as follows:

TSCI 5070 Semester Credit Hours	Allowable Absences
2.0	2 classes

TEXTBOOKS

> **Required:** None
>
> **Recommended:** None

GRADING POLICIES AND EXAMINATION PROCEDURES

1. Timely completion of all course requirements is essential for anyone who wishes to obtain credit for the course. **Attendance will not be taken. However, everyone enrolled in the course will be <u>required</u> to complete a quiz, in Canvas, on the material covered in each class period.**

    Each week's quiz will be available immediately after class on Monday and must be completed by 11:59pm the following Sunday. <u>No extensions will be granted.</u> You may be able to make up sessions missed due to extenuating circumstances, provided you contact one of the course co-directors as soon as possible **and an excused absence is approved**. In addition to the allowable excuses, each student is only allowed only two additional *excused* absences. Any student who fails to meet this requirement will receive an UNSATISFACTORY grade for the course.

2. The weekly quizzes will be posted in CANVAS and scored on a 100-point scale. ***You must complete the quizzes on time and receive an average minimum score of 70/100 points overall for the quizzes in order to pass and receive credit for this course***. Quizzes that are not submitted on time will receive a score of zero unless other arrangements have been made with either of the Course Co-Directors.

3. An assignment must also be completed during the semester. The assignment will be posted and scored on a 100-point scale. You must complete and submit the assignment on time and receive a minimum score of 70/100 points for the assignment in order to pass and receive credit for the course.

4. You must receive a passing grade in **<u>both</u>** the quizzes as well as the course assignment to receive a passing grade in this course.

5. A student may receive an INCOMPLETE at the end of the course solely at the discretion of the Course Co-Directors. Any student who receives an INCOMPLETE at the end of the course must develop a plan of action to complete any outstanding work and meet with one of the Course Co-Directors within 4 weeks of the course ending to obtain approval of the plan. Once approved, all outstanding work must be completed within 6 months of the course ending; otherwise, the grade will be changed to UNSATISFACTORY.

6. A student who receives an UNSATISFACTORY grade must enroll and retake the course, within the time period stipulated by the Graduate School of Biomedical Sciences and meet all requirements to receive a grade of Satisfactory.

<u>Grading System</u>
The grading will be conducted on a **Pass / Fail** basis and students must achieve a Satisfactory grade (i.e., ≥70/100) for both the quizzes and the assignment in order to pass the course.

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S = Satisfactory   U = Unsatisfactory

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REQUESTS FOR ACCOMMODATIONS FOR DISABILITIES

In accordance with policy 4.2.3, **Request for Accommodation Under the Americans with Disabilities Act (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, Dr. Bonnie Blankmeyer. 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 UT Health San Antonio

Title IX Defined:
Title IX 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 (UT) Health San Antonio's Commitment:
The University of Texas Health Science Center at San Antonio (UT Health SA) is committed to maintaining a learning environment that is free from discriminatory conduct based on gender. As required by Title IX, UT Health SA 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 the UT Health San Antonio Police Department at 210-567-2800. Additional information may be obtained at
http://students.uthscsa.edu/titleix/

EMAIL POLICY

Every student is issued a university email (Livemail) 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. Course Directors will not respond to emails sent from personal email addresses.

USE OF RECORDING DEVICES

Recording of lectures and other learning activities in this course by any means (e.g., video, audio, etc.) are only permitted if specifically **pre-approved** by the instructor(s) for that class or if required for compliance with an institutionally approved accommodation under the Americans with Disabilities Act (ADA). Requests for recording should be made directly to the specific instructors for that class.

USE OF ELECTRONIC DEVICES IN CLASS

Cell phones and tablets must be turned off during all class times. Use of laptops is allowed as appropriate to follow class presentation. However, texting, emailing, web-surfing, gaming IS NOT permitted. Any use of other electronic devices in class is also NOT permitted.

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CLASS SCHEDULE

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Week	Date	Topic – Instructor
1	22 August	History – Eugenics to the 2018 Common Rule – **McGeary**
2	29 August	Conflicts of Interest / Conflicts of Commitment – **Zuñiga-Rapp**
3	05 September	*No Class* – Labor Day/University Holiday
4	12 September	Data Acquisition, Management and Sharing – **Gelfond** and Data Ownership, Intellectual Property and Patents – **Fritz (and Faculty Panel)**
5	19 September	Research Misconduct – **Oyajobi (and Faculty Panel)**
6	26 September	Ethical Use of Animals in Biomedical Research – **Wiederhold** and Safe and Ethical Laboratory Practices– **Berton**
7	03 October	Mentoring (Mentor - Mentee Responsibilities and Expectations) – **Mustafa**
8	10 October	Good Clinical Practice (GCP) – **Roache**
9	17 October	Ethics and Responsibility in Authorship and Publication – **Oyajobi**
10	24 October	Ethical Peer-Review – **Ahuja**
11	31 October	Trending Ethical Topics in Research – **Quezada / Oyajobi**
12	07 November	Basics of Institutional Review Board (IRB) Review – **Watterson** and Human Subjects Regulatory Oversight – **Quezada**
13	14 November	Recruiting Fairly: Inclusion of Special Populations in Research – **Hazuda**
14	21 November	Elements of Consenting and Protecting Confidentiality – **Kilpadi / Saldivar**
15	28 November	Gene Therapy in Human Research – **Kilpadi**
16	05 December	Safe and Inclusive Training Environment – **Kaulfus**
17	12 December	Class Projects/ In-Person Q&A (Course Directors) – **Kilpadi / Oyajobi**