Keck School of Medicine of USC

INTD 500 – Ethics and Accountability in Biomedical Research

Credit:	1 Unit
Graded:	CR/NC
Term:	Fall 2024
Date/Time:	6 Monday sessions
	10:00 am – 11:50 am
	Sept. 9, 16, 23, 30, Oct. 7, 14
Location:	Lecture: MCA 149
	Discussion: various (TBD)
Instructor:	Axel H. Schönthal, PhD
Office:	HMR 405
Office Hours:	by appointment
Contact Info:	schontha@usc.edu
	(323) 442-1730

First Day of Class:	**September 9, 2024, at 10:00 a.m. in MCA 149**
Last Day of Class:	**October 14, 2024, at 10:00 a.m. in MCA 149**

Course Description

This course satisfies the NIH Responsible Conduct of Research (RCR) training requirements. The course is open to all graduate students, postdoctoral fellows, junior faculty, and staff who are conducting research. Most doctoral students in the biomedical sciences are required to pass INTD 500 prior to advancing to candidacy. Master's students, postdoctoral fellows, and others auditing will receive a certificate of completion of the course.

The Responsible Conduct of Research course includes lecture, video, and discussion topics focused on scientific integrity, misconduct and fraud in science, data acquisition and management, collaborative research, responsible authorship, scientific rigor and reproducibility, conflicts of interest, innovation advancement and patents, animal welfare, human subjects, mentor/mentee responsibilities and professionalism in scientific relationships, and related issues.

The course can be taken for credit (1 unit, Pass/Non-Pass) or can be audited, in which case a certificate of completion will be provided (and no tuition payment is required). In both instances, regular attendance is mandatory (and will be taken), and both modes require 100% participation in all aspects of the course (all lectures and all discussion sessions).

Course Aims

- <u>Knowledge</u>: to increase awareness and understanding of the foundational ethics, including rules, standards, and conventions, which support the planning, conduct, reporting, and management of research activities.
- <u>Attitudes</u>: to promote an appreciation for lifelong learning about research ethics.
- <u>Behaviors</u>: to develop and apply skills that promote reflection and ongoing discussion about responsible and ethical research practices in individuals and their team environments.

Learning Objectives

By the end of the course, students should be able to:

- describe core content areas associated with research ethics;
- identify regulatory and ethical areas most relevant to their discipline;
- find and explain relevant codes, rules, and regulations that guide the conduct of research in their discipline and profession;
- apply a framework to identify and consider the ethical dimensions of an instructional case;
- reflect on how one can influence the "health" of the research ecosystem.

Course Notes

There are two major activities each day:

- ⇒ 10:00 – 10:50 am: lecture in McKibben Annex Auditorium MCA 149.
- ⇒ 11:00 – 11:50 am: small-group discussions with a faculty discussion leaders.

Each day's discussion points are based on one or more videos and case studies. To prepare for discussions, you need to watch/read assigned materials and answer a few simple questions on Brightspace before class each day. Links to video and other reading materials are posted on Brightspace.

Assignments

Review assigned materials and answer questions in Brightspace <u>before each day's class</u>.

Assignment Submission Policy

Unless otherwise specified, all assignments are to be submitted online or presented in class.

Attendance Policy

Attendance of all lectures and all discussion sessions is required.

Course Website

Brightspace

Course Director

Axel H. Schönthal, PhD
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Associate Dean for Biomedical Master's Programs
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Email inquiries should expect to receive a response within 48 hours. If none is received within this time frame, please email again or call and leave a message.

Schedule

Date	Topics	Pre-discussion Assignments
Session 1 09/09	**Mentor and Mentee** • responsibilities and relationships **Conflict of Interest** • personal, professional, and financial • commitment to allocating time, effort, or other research resources **Safe Research Environments** • promote inclusion • free of sexual, racial, ethnic, disability and other forms of discriminatory harassment	Review topics and answer questions in Brightspace before class. 1. Video: Noah's Dilemma 2. Case: Bullied or Mentored

Date	Topics	Pre-discussion Assignments
Session 2 09/16	**Safe Laboratory Practices** **Vertebrate Animal Research** **Human Subjects Research** Lecturer: Julie Slayton Director, Human Research Protection Program (HRPP) Clinical Professor, Rossier School of Education	1. Video: Of Mice and Mendoza 2. Video: The Whole Truth

Date	Topics	Pre-discussion Assignments

Session 3 09/23	**Data Management**
	• acquisition and analysis
	• laboratory tools for analyzing data and creating or working with digital images
	• recordkeeping, including methods such as electronic laboratory notebooks
	• secure and ethical data use
	• data confidentiality
	• management, sharing, and ownership
	    Lecturer: Jennifer E. Dinalo
	               Clinical Services Librarian
	               Norris Medical Library
		1. Video: To Proceed or Not to Proceed Without Raw Data?
		
		2. Video: It's Only a Bridge.
		
		3. Case: Alternative Therapies and Awkward Collaborations

Date	Topics	Pre-discussion Assignments

Session 4 09/30	**Publications**
	• responsible authorship and publication
	    Lecturer: Daniel K. Shapiro
	               Assistant Vice President for Research Compliance
	               Office of Culture, Ethics and Compliance (OCEC)
	Peer Review
	• confidentiality and security in peer review
		1. Video: Where Credit is Due
		
		2. Video: When Authorship Gets Personal
		
		3. Video: I Wrote It, Why Re-write It?

Date	Topics	Pre-discussion Assignments
Session 5 10/07	**Collaborative Research** • with industry • with investigators in other countries **Misconduct** • research misconduct • policies for handling misconduct Lecturer: tbd	1. Video: Crossing the Line into Misconduct 2. Video: You Suspect Research Misconduct. Now What? 3. Case: Career Dreams up in Smoke?

Date	Topics	Pre-discussion Assignments
Session 6 10/14	**"Hard" Data** • Rigor and reproducibility **Society** • the scientist as a responsible member of society • contemporary ethical issues in biomedical research • the environmental and societal impacts of scientific research Lecturer: tbd	1. Video: tbd 2. Case: tbd

Statement on Academic Conduct and Support Systems

Academic Integrity:
The University of Southern California is a learning community committed to developing successful scholars and researchers dedicated to the pursuit of knowledge and the dissemination of ideas. Academic misconduct, which includes any act of dishonesty in the production or submission of academic work, compromises the integrity of the person who commits the act and can impugn the perceived integrity of the entire university community. It stands in opposition to the university's mission to research, educate, and contribute productively to our community and the world.

All students are expected to submit assignments that represent their own original work, and that have been prepared specifically for the course or section for which they have been submitted. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s).

Other violations of academic integrity include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), collusion, knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university. All incidences of academic misconduct will be reported to the Office of Academic Integrity and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see the student handbook or the Office of Academic Integrity's website, and university policies on Research and Scholarship Misconduct.

Please ask your instructor if you are unsure what constitutes unauthorized assistance on an exam or assignment, or what information requires citation and/or attribution.

Students and Disability Accommodations:
USC welcomes students with disabilities into all of the University's educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:
Counseling and Mental Health - *(213) 740-9355 – 24/7 on call*
Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

988 Suicide and Crisis Lifeline - *988 for both calls and text messages – 24/7 on call*
The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

Relationship and Sexual Violence Prevention Services (RSVP) - *(213) 740-9355(WELL) – 24/7 on call*
Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - *(213) 740-5086*
Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

Reporting Incidents of Bias or Harassment - *(213) 740-5086 or (213) 821-8298*
Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

The Office of Student Accessibility Services (OSAS) - *(213) 740-0776*
OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

USC Campus Support and Intervention - *(213) 740-0411*
Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity, Equity and Inclusion - *(213) 740-2101*

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

USC Emergency - *UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call*
Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

USC Department of Public Safety - *UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call*
Non-emergency assistance or information.

Office of the Ombuds - *(213) 821-9556 (UPC) / (323-442-0382 (HSC)*
A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

Occupational Therapy Faculty Practice - *(323) 442-2850 or* otfp@med.usc.edu
Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.