

Overview

It's far too easy to relegate egregious ethical violations to the past. We reassure ourselves these could never happen now. After all, we have Institutional Review Boards (IRBs) and rules and regulations we have to follow when conducting research on humans and animals.

IRBs, and those rules and regulations, like the Belmont Report and the Declaration of Helsinki, are important, helpful, and a good start, but researchers need more. Many of the problems researchers will face during their careers will not be black and white, and it's important to learn to recognize and then navigate through the shades of gray.

This course presents a survey of ethical issues in the conduct of clinical research. Topics include issues related to privacy, confidentiality, protection of human and animal subjects, informed consent, and the role of the IRB in ensuring the responsible conduct of research. We will consider how systemic racism has contributed to research atrocities. We will read important foundational texts, at least one work of fiction, and a set of case studies. You'll interact with fellow course participants on discussion boards, and submit thoughtful written responses to questions taken from the readings.

Objectives

This course aims to enhance your ability to critically think about ethical dimensions of research and the responsible conduct of research. By the end of the course, you should be able to:

- Describe the historical context for today's heightened scrutiny of research ethics.
- Explain current Federal regulations regarding human subject research.
- Analyze norms and violations of research integrity in theoretical and real-life contexts.
- Analyze cases of clinical research and scientific integrity according to ethical criteria.
- Critique cases from the perspective of an Institutional Review Board.

Target Audience

The course is for any student who would like to challenge their assumptions about ethical decision-making. It may be particularly interesting to those students who have limited knowledge of the historical context for ethics and responsible conduct of research.

Books, Videos, and Other Materials

There are two required texts: **An e-version is available to you at no charge.**

You can access the books with your Pitt credentials via the [Health Sciences Library System](#) and PittCat.

1. Integrity: Text and Cases in Responsible Conduct of Research. Francis L. Macrina. Fourth edition. ASM Press; 2005. ISBN-13: 978-1555816612, ISBN-10: 9781555816612.
2. Emanuel EJ, Grady CC, Crouch RA, Lie RK, Miller FG, Wendler DD, editors. The Oxford Textbook of Clinical Research Ethics. Oxford University Press; 2008. ISBN-13: 978-0195168655, ISBN- 10: 0195168658.

Links to other readings and videos are provided in each module. All course information, announcements, and homework assignments are available in Canvas.

Modality

This is a fully online course. You are not required to attend in-person class sessions, which will give you considerable flexibility. But to paraphrase Spidey's Uncle Ben, with great flexibility comes great

responsibility: online courses require time management and self-discipline that traditional courses do not. Without class sessions to organize your academic life, you will need to develop your own schedule for completing module requirements. I will check in with you regularly, participate in online discussions, and provide feedback in a timely manner, but the responsibility will be yours to stay on track and ask for help when you need it.

Course Requirements

As per university credit requirements, each weekly module is designed to require approximately 6 hours of work, including readings, videos, discussion boards, and assignments. This is an average—some may take a little longer, others may take less time. Because there is no in-class component, it is up to you to decide when you complete the coursework, as long as the assignments are submitted by the due date.

Assignments:

Assignments should be turned in by the date and time indicated. Our “class week” begins on a Monday and ends on the following Sunday. Late assignments will receive a 10% deduction per day late. I am a reasonable person and I realize stuff happens. If you let me know an assignment might be late, we can discuss an accommodation, otherwise, late assignments will receive a 10% deduction per day late. You should submit all assignments through the Canvas text entry box for that module unless otherwise instructed.

There are 8 short, required assignments for this course, including both assignments and discussion boards. Each assignment is designed to give you practice with a different research ethics-related topic.

This may sound like a lot of work for a 1-credit course, but remember that there are no class sessions. These readings, videos, and activities serve as the pre-class preparation time, class time, in-class exercises, and homework time that you would expect to encounter in a face-to-face course.

For simplicity, all assignments are weighted equally. All assignments start with a base grade of 95. Discussion boards start with a base grade of 93. Exemplary responses will garner more points.

Discussion Board Participation:

Because this course is online, there is no "attendance requirement" in the traditional sense of the word. That is one reason why your participation in discussion boards is so critical—as a matter of fact, it's required. Active participation by everyone, including me, your instructor, increases the probability that we will achieve the course objectives. To that end, please be prepared for active engagement! Come to the discussion board with a solid understanding of the assigned materials, or whatever resources you will need to participate fully in the discussions. Postings are required by the date and time indicated in this syllabus. Late postings will receive a 10% deduction per day late. Discussion boards will be graded using the following 100-point scale:

- Up to 40 points for original thought/contribution (perspective not previously posted)
- Up to 40 points for development of thought (full explanation, detail, insight; this usually requires a couple of paragraphs or more to accomplish)
- Up to 20 points for responding to posting of others

Your first posting is due by 10 pm on the Thursday of the week in which they occur, with at least one follow-up response to a colleague by Sunday. Read the Summary of Session on the next page for more details.

Office Hours

Online office hours are available by appointment. Email mayowski@pitt.edu and I will happily find a time for a Zoom meeting. I will be available for informal chats about the course, as well as any questions or

concerns you have about the class and the assignments.

Summary of Sessions

Beginning with Module 1, your **initial** discussion board posting is due **by 10 pm on Thursday of each week in which they occur. Your final posting** is due by 10 pm on the following Sunday of the week in which they occur—the same as the assignments.

There has been some confusion in the past, so let me clarify that you need a total of at least two postings to receive a 93. Additional postings will likely glean more points. One posting must happen by Thursday at 10 pm, and at least one subsequent post can happen any time after that but must happen by Sunday at 10 pm.

Beginning with Module 1, each week's assignment(s) must be uploaded to Canvas **by 10 pm on the Sunday of each week.**

So, for example, in Module 1, your initial discussion board posting is due by 10 pm on Thursday, January 12, with the final posting due on Sunday, January 15. For Module 2, your assignment is due on Sunday, January 22.

Module	Focus	Assignments
Module 0 1/8/23	Introduction, Housekeeping	Introduce yourself and familiarize yourself with the syllabus.
Module 1 1/9-1/15/23	The Case for Bioethics: A Selected History of Research Atrocities	Discussion Board M1
Module 2 1/16-1/22/23	Those Who Don't Know History Are Doomed to Repeat It	Assignment M2
Module 3 1/23-1/29/23	Use of Humans in Biomedical Experimentation	Assignment M3
Module 4 1/30-2/5/23	Use of Animals in Biomedical Experimentation	Assignment M4
Module 5 2/6-2/12/23	Navigating Authorship and Peer Review	Assignment M5 – Option 1 OR Assignment M5 – Option 2
Module 6 2/13-2/19/23	Ethics of Team Science	Assignment M6 – Option 1 OR Assignment M6 – Option 2
Module 7 2/20-2/26/23	Risk-Benefit Assessments and Informed Consent	Discussion Board M7

Module 8 2/27-3/5/23	Imagine You're on the Institutional Review Board....	Assignment M8
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Grading

All assignments start with a base grade of 95. Discussion boards start with a base grade of 93. Exemplary responses will garner more points. Your letter grade for this course will be based on:

Discussion Boards (3)	100 points per board (300 total)
Assignments (5)	100 points each (500 total)

Total Possible Points	800

Grading Scale

Numerical Grade Range	Letter Grade
98–100	A+
92–97	A
90–91	A-
86–89	B+
82–85	B
80–81	B-
76–79	C+
70–75	C
60–69	D
<60	F

ICRE's Commitment to Equity and Inclusion

An equitable and inclusive environment strengthens our institution, invigorates our scientific research, and elevates the practice of medicine. Diversity of students, faculty, and staff is critical to the ICRE's educational mission. By cultivating an equitable and inclusive learning environment, the ICRE seeks to train clinical and translational researchers and medical educators who value and respect the unique perspectives, experiences, behaviors, worldviews, and backgrounds of all individuals.

Academic Integrity

As a student in this course, you are expected to comply with the University of Pittsburgh's Policy on Academic Integrity (<http://www.provost.pitt.edu/info/ai1.html>). Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University policy. Furthermore, no student may bring any unauthorized materials to an exam, including dictionaries and programmable calculators.

Use of AI Writing Tools

The use of generative AI writing tools (such as ChatGPT, GrammarlyGO, GPT-3, GPT-4, BERT, or others) is allowed in this class within specific contexts and only if such use is properly acknowledged. As your instructor, I will assume that any use of these tools will be only within the contexts the assignment allows (for instance, you can use ChatGPT for brainstorming). You must acknowledge the use of AI in your assignment in an "Acknowledgement of AI Use" statement that:

- Specifies which technology was used and on what date (ChatGPT, GPT-3, etc.)
- Includes explicit descriptions of how the information was generated
- Identifies the prompts used

- Explains how the output was used in your work

Examples of such Acknowledgments of AI Use can be found on Monash University's website. The use of AI outside of contexts where the instructor specifies its use, or failure to acknowledge any use of AI technologies in your work will be considered an **academic integrity violation** and addressed according to Pitt's Academic Integrity policies noted above. You are the author of your work for the course and authorship means you take responsibility for your words and claims, regardless of which tools you use. Please [email Dr. Mayowski](mailto:Dr.Mayowski) if you have any questions about this policy. This policy is adapted from a [policy provided by the University of Pittsburgh Writing Institute](#).

ICRE Core Competencies Addressed, by Module

Competency	M1	M2	M3	M4	M5	M6	M7	M8
Ethics and Professional Norms: Provide examples of the norms of professional integrity with regard to designing and conducting research including: data collection, sharing and protection; and reporting of findings.	X	X	X	X	X	X	X	X
Multidisciplinary Teamwork: Demonstrate behaviors necessary to be an effective member of a multidisciplinary team including: generating multiple points of view; contributing to the development of new ideas; and demonstrating conflict management skills.	X		X				X	
Written Communication: Prepare written presentations of research at a variety of stages to a range of audiences, technical and non-technical, and respond to constructive criticism and questions.		X		X	X	X		X
Written Communication: Prepare critiques of written presentations following the appropriate guidelines.		X		X	X	X		X