

REG 6190: Research Ethics

Spring 2025

Instructor Information

Course Director

Melissa Byrn, MBE, MS

Class Location & Time

6:00-7:30 pm ET / Thursday
Online

*syllabus is subject to change at professor's discretion

General Information

Description

This course will focus on of the connection between biomedical research ethics and aspects of regulatory affairs. Students will apply frameworks for evaluating research ethics questions through the exploration of modern biomedical research topics. Students will cultivate competency in the application, and limitations, of US human subjects' regulations. This course will prepare students to critically evaluate the ethics of specific research topics and apply ethics-informed decision-making in the regulatory affairs domain.

Contemporary research ethics topics include (but are not limited to) research study recruitment, conflicts of interest, human research protection programs, informed consent, working with vulnerable populations, privacy/confidentiality, and emerging medical technology. The course will implement asynchronous videos and readings and interactive synchronous sessions; assignments include quizzes, discussions (in-class and online), and a generative final project.

Objectives

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

- Summarize and apply the 8-principle framework for evaluating the ethics of research studies.
- Recognize areas of ethical ambiguity in the design of research trials involving human subjects.
- Apply federal regulations and ethical framework governing biomedical research to research ethics topics and cases.
- Identify unique regulatory and ethical issues in modern research topics.

Evaluation and Due Dates

Evaluation Methods:

Students will be graded based on class attendance, active engagement and participation, and assignments.

Assignment	Percent of Grade
Participation	15%
Asynchronous Assignments	35%
Quizzes	20%
Final Project	30%

Program and Course Policies:

Community Standards and Program Expectations

All students taking ITMAT Education online and hybrid courses must ensure that their learning environment for synchronous course meetings is appropriate and free from distractions to themselves, other students, and instructors. Specifically, participate in the session in a physical space and surrounding environment that allows you to devote your full attention to the course meeting. Remain stationary in that location for the duration of class. You are expected to log on using a computer, with working microphone and video capabilities. During class, your video must be operational and be on at all times, with your background blurred and your microphone muted to minimize unexpected distractions to you and your fellow students. If you identify issues that compromise your ability to meet these expectations, contact the course director to seek ways to resolve the situation in a timely manner.

Two general rules of thumb are (i) if you wouldn't expect your instructor to facilitate a class under any condition or set of conditions, it is equally unacceptable for a student to attend class under those same conditions; (ii) if you would not do something in an in-person classroom environment, it should not be done in a synchronous online class. Some examples of unacceptable conduct during synchronous sessions include attending class while driving; attending class while walking; attending class while also working; attending class while being physically located in a busy environment or an environment likely to be disrupted by other people or significant background noise; attending class using your cell phone. Course directors will, at their discretion, include course-specific policies articulated in the course syllabus.

Attendance

- Students are allowed 1 excused absence. Beyond 1 absence, you will receive 1 point off your final, end-of-semester grade per additional absence.

If you will be absent, please contact the course director prior to your absence. If you have other concerns regarding attendance requirements, contact the course coordinator as soon as possible. Beyond the excused absence, grade impacts are at the discretion of the course director.

Students will be on time, keep their video feed on, and remain present engaged in class for the duration of the class. If you will be late to class or need to leave early, please email the course coordinator and instructor prior to class. Any student more than 15 minutes late or who does not keep video on will be considered absent from class. Additionally, any student who leaves early may be marked absent. These guidelines are at the discretion of the instructor and will be outlined in the course syllabus.

Students who are absent from any class are at a minimum always responsible for reviewing the class recording and other materials covered during a synchronous class.

Participation and Active Participation

Participation in class is crucial to students' success. Students will attend and actively engage with the content and participate in discussion all courses.

Examples of active participation in a synchronous session include

- asking or answering questions during class
- posting comments in the chat
- collaborating with other students during group work
- incorporating knowledge or relevant experience to enrich the conversation
- You are expected to speak up and/or include comments or reflections in the chat in the majority of synchronous classes to gain full participation points

Examples of active participation in an asynchronous session include:

- commenting on discussion boards
- completing short reflective assignments

- applying information from asynchronous work to assignments and synchronous sessions
- partnering with other students outside of synchronous class to conduct group assignments
- sharing

This program is committed to creating a supportive, respectful, and productive learning environment for all students. Students will remain professional and respectful of their peers, course instructors, and guest lecturers. An important principal of code of conduct is to behave in the virtual space in the same way you would during an in-person class and/or a work meeting. **If you wouldn't do it in a work meeting or in-person class, don't do it in the virtual space.**

We expect you to:

- Refer to “[Community Standards and Program Expectations](#)” (heading above) for details on creating a quiet, distraction free environment
- Keep your video on
- Be appropriately attired (casual wear is fine)
- Approach debates and disagreements in a thoughtful and respectful manner

If you have questions regarding appropriate behavior in a synchronous class, contact the course coordinator.

Student Disability Services

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of Student Disabilities Services (SDS). Please make an appointment to meet with your instructor and the course coordinator as soon as possible to discuss your accommodations and your needs. To request accommodations or ask questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the [MyWeingartenCenter](#) portal. The office is in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

Learn more about the [types of services and accommodations offered by Weingarten](#).

Grading, Late Work, Extension, and Resubmission

Grading

The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure.

LETTER GRADE	PERCENT SCORE
A	93-100
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72

D+	67-69
D	63-66
D-	60-62
F	0-59

At the graduate level for students enrolled in Regulatory Affairs programs, **the minimum standard for satisfactory work in each course is a B-.**

Course Evaluations

Course evaluations are an opportunity to share feedback on the strengths of the course, and opportunities for improvement. We welcome constructive feedback in the BLUE system. Completing evaluations is a required part of course participation. An email from the BLUE system is sent to students with a link and directions on how to complete the course evaluation(s).

Course Management: Canvas

All course materials and assignments will be managed on [Canvas](#). Log in with Pennkey and password. Additional information on configuring and using Canvas will be provided in the Canvas site.

Student Conduct

ITMAT Ed students must comply with the University's Code of Student Conduct and other University policies related to student conduct that appear in [The PennBook: Resources, Policies and Procedures Handbook](#). These include, but are not limited to, policies on sexual harassment, acquaintance rape and sexual violence, appropriate use of electronic resources, open expression, and drug and alcohol usage.

Additional codes of conduct and expectations students should be familiar with are the [nondiscrimination statement](#), the [sexual misconduct policy and resource offices](#), and [student grievance procedures](#).

Academic Integrity

The fundamental value of our academic community is intellectual honesty; accordingly, our academic community relies upon the integrity of every member. Students are responsible not only for adhering to the highest standards of truth and honesty but also for upholding the principles and spirit of the Academic Code. Violations of the Code include but are not limited to plagiarism, cheating, and fabrication, among others.

If you have questions regarding what is considered a violation of academic integrity, please review The [Code of Academic Integrity](#) in the PennBook.

Alleged violations of the Code of Academic Integrity are reviewed by the Program Director and as necessary referred to the Penn Office of Student Conduct. If a student is unsure whether their action(s) constitute a violation of the Code of Academic Integrity, it is that student's responsibility to consult with the instructor to clarify any ambiguities.

Use of Generative AI

It is plagiarism to submit work produced by a generative artificial intelligence (AI) service as your own without citing the source. Any use of generative AI services must be in alignment with course requirements and restrictions. Course Directors have full discretion to allow or deny use of ChatGPT or similar AI tools in their courses. Ask the course director for permission before using these tools for course assignments.

Religious and Cultural Holidays

Religious and cultural holidays are listed on the [University of Pennsylvania's Chaplain website](#). If a student observes any of the listed holidays and they conflict with a class date, please contact program staff with class date with which the holiday coincides.

If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

Course Schedule

Week	Date	Topic	Assignment	Due
1	1/16	Intro to REG 6190	<ul style="list-style-type: none"> Discussion Assignment: Introductions 	1/16
2	1/23	Research Ethics Framework	<ul style="list-style-type: none"> Readings/ videos IRB Confidentiality Form Quiz: Research Ethics 	1/23
3	1/30	Research Participant Recruitment	<ul style="list-style-type: none"> Readings/ videos Writing Assignment: Research Participant Recruitment 	1/30
4	2/6	The Informed Consent Process	<ul style="list-style-type: none"> Readings Quiz: Informed Consent 	2/6
5	2/13	Therapeutic Misconception and Phase 1 Trials	<ul style="list-style-type: none"> Readings Discussion: Therapeutic Misconception 	2/13
6	2/20	Patient Advocacy in Research and Medical Product Development	<ul style="list-style-type: none"> Readings Discussion: Patient Advocacy Organizations 	2/20
7	2/27	Industry Sponsored Research	<ul style="list-style-type: none"> Readings Presentation Sign-up Quiz: Industry Sponsored Research 	2/27
8	3/06	Artificial Intelligence & Patient Data	<ul style="list-style-type: none"> Readings Discussion: Patient-Generated Data 	3/06
9	3/13	Spring Break	No Class	
10	3/20	Institutional Review Boards: Local vs External Asynchronous Week	<ul style="list-style-type: none"> Readings 	3/20
11	3/27	Reproductive Health Research	<ul style="list-style-type: none"> Readings / Video Writing Assignment: Reproductive Healthcare & Clinical Research 	3/27

12	4/3	Diversity, Equity and Inclusion in Research	<ul style="list-style-type: none"> • Readings/ Videos • Writing Assignment: IRB Reflection • Discussion: Diversity, Equity and Inclusion in Research 	4/3
13	4/10	Genomic Editing	<ul style="list-style-type: none"> • Readings/ videos • Quiz: Genomic Editing 	4/10
14	4/17	Final Project Presentations	<ul style="list-style-type: none"> • Submit: Final Project Presentations • Group 1: Student Presentations 	4/17
15	4/24	Final Project Presentations	<ul style="list-style-type: none"> • Group 2: Student Presentations 	