REG 6190: Research Ethics

# Spring 2023

# Instructor Information

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| Course Director | Email | Class Location & Time |
| **Melissa Byrn** | [mbyrn@bsd.uchicago.edu](mailto:mbyrn@bsd.uchicago.edu) | Mondays, 6 p.m.  Online |
| **Course Coordinator** | **Email** |  |
| **Nik Kroushl** | [nkroushl@upenn.edu](mailto:nkroushl@upenn.edu) |  |

# General Information

## Description

This course will focus on the connection between research ethics and aspects of regulatory affairs. Students will review core methodological aspects of research, trace the history of research ethics, and describe systematic approaches to designing ethical research. Students will cultivate competency in the development, implementation, and limitation of US human subjects regulation. This course will prepare students to critically evaluate the ethics of specific research designs and apply ethics-informed decision-making in the regulatory affairs domain.

The course also includes analysis of regulatory bodies governing biomedical and behavioral research. 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 7-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, participation, and assignments.

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| **Assignment** | **Percent of Grade** |
| Participation | 15 |
| Discussion Boards (4) | 20 |
| Writing Assignments (3) | 15 |
| Quizzes (3) | 15 |
| Final Group Presentation | 20 |
| Individual Project Analysis Paper | 15 |

## Academic Policies:

### Attendance Expectations

Students are allowed 1 excused absence. If you anticipate the need to be absent, please contact the course coordinator prior to your absence. If you have other concerns about your ability to meet the attendance requirements, you must contact the course coordinator prior to your absence.

Students are expected to be on time to all synchronous classes and stay for the duration of the class. If you anticipate being late to class or may need to leave early please email the course coordinator and instructor in a timely manner to let them know of may be late or need to leave early. Any student who is more than 15 minutes late will be considered absent from that class. Additionally, any student who leaves early may be marked absent. Attendance also includes keeping video feed on during synchronous sessions.

### Participation Expectations

Participation in class is crucial to students’ education in this program. Students are expected to attend and actively participate in all courses. Examples of active participation in a synchronous session may include asking or answering questions, posting comments in the chat, or collaborating with other students during group work. Examples of active participation in an asynchronous session may include asking or answering questions via Canvas or email, commenting on discussion boards, or interacting with other students outside of class.

This program is committed to providing a supportive and productive learning environment for all. Active participation requires professionalism and demonstration of respect for peers, course instructors, and guest lecturers.

### Course Evaluations

Course evaluations are completed in the BLUE system. These are a required part of course participation. An email from the BLUE team will be sent to students with a link and directions on how to complete the course evaluation(s).

### Academic Integrity:

As a student at The University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e. do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

### Course Management: Canvas

All course materials and assignments will be managed on [Canvas](https://canvas.upenn.edu). Log in with Pennkey and password.

### Student Disabilities 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 me and the course coordinator as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS, and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the [**MyWeingartenCenter**](https://urldefense.com/v3/__https:/upenn.us10.list-manage.com/track/click?u=6c89def14a1d88f5cb78518e7&id=22bdd97ae3&e=66d3273cbf__;!!IBzWLUs!TPk0vqHbPJWCqAbCO7VesoIOuzTIRx0XQlopbkilPnv5gR0wbSaeTXYnBN_6NAjVSIuRAaKPwFQXf2DnJwtfp5gVDFMNo7LhEQ2R$) portal. The office is located in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

# Course Schedule

| Week | Topic | Facilitator |
| --- | --- | --- |
| 1/23/23 | Research Ethics Framework | Melissa Byrn |
| 1/30/23 | Patient Data | Guest Speaker |
| 2/6/23 | Subject Recruitment and Participation in Clinical Research | Melissa Byrn |
| 2/13/23 | Therapeutic Misconception and Phase 1 Trials | Melissa Byrn |
| 2/20/23 | Randomized Controlled Trials (RCT) and Placebo Controls | Melissa Byrn |
| 2/27/23 | Conflict of Interest | Melissa Byrn |
| 3/6/23 | Spring Break – No Class |  |
| 3/13/23 | Institutional Review Boards: Local vs Central Models | Asynchronous |
| 3/20/23 | Reproductive Health | Panel of Experts |
| 3/27/23 | Real-world Evidence and Patient Generated Data | Melissa Byrn |
| 4/3/23 | Diversity, Equity and Inclusion in Research | Melissa Byrn |
| 4/10/23 | The Informed Consent Process | Melissa Byrn |
| 4/17/23 | Final Project Presentations | Melissa Byrn |
| 4/24/23 | Final Project Presentations | Melissa Byrn |