

# MTR 6040: Scientific & Ethical Conduct

Spring 2023

## Pre-Course Requisites

- Students are required to attend the following sessions in November:
  - Tues, Nov 17<sup>th</sup> at 12:30pm: Course Overview, 8030 Maloney, HUP
  - Tues, Nov 29<sup>th</sup> at 12:30-2pm in 8030 Maloney, HUP:
    - Penn IRB New Members Training (*CHOP will be scheduled separately*)
    - Things I Wish I Knew – Panel (all students)

## Spring 2023 classes will take place in January:

Tuesday's and Thursday's: 8:30-10:00am; 8030 Maloney, HUP (*Except Jan 24<sup>th</sup>*)

Tuesday, January 24: Online modules via Canvas

## Instructor Information

Course Directors:

Emma A. Meagher, MD

Cheilonda Johnson, MD, MHS

Course Coordinator:

Danielle Williams

## General Course Information

### Description

In this course, students will learn the foundational principles of scientific, operational, and ethical conduct of research, complete directed experience in evaluating ethical principles through IRB membership and ultimately be able to apply all principles to their own work. By the end of the foundational class sessions, students will understand scientific conduct, ethical considerations of human subject's research, good clinical practices (GCP), conflict of interest, and budgetary concepts. The directed experience will include becoming a member of an Institutional Review Board (IRB) (Penn or CHOP) and participating as an active member in 6 meetings.

### Course Content & Evaluation

Students will demonstrate their understanding of the course material through:

- 1) IRB Membership - 70%
- 2) Attendance and Participation – 30%

Requirements and Evaluation Methods for IRB Membership (70%):

- All students are expected to:
  - Attend new member training (Penn) or orientation (CHOP)
  - Attend 'Things I Wish I Knew' Panel

- Observe at least 1 IRB meeting by end of December
- Actively participate in 6 meetings between beginning of January and end of August 2023
  - Receive 1 assignment at the first meeting and 2 assignments for the remaining 5 meetings
- At CHOP and Penn, students will be paired with an experienced IRB member who is available for questions and assistance during the review process. The experienced member will have also reviewed the submission and will provide additional comments to the board after the student has presented the study to the committee. Students are encouraged to ask the IRB member they are paired with and the IRB Chairs if they have questions during the meeting(s). If improvement is needed, the IRB Chair(s) or Director(s) will provide feedback to the student.
- Before the meeting:
  - Submit written comments/raise questions for the assigned reviews in a timely manner
    - Penn IRB participants: submit written comments to the regulatory representative and IRB administrator via email *at least 2 days prior* to the meeting if the reviewer is proposing to table the study. If they are not, then at least *one hour* prior to the meeting is fine.
    - CHOP IRB participants: should submit comments through the reviewer portal *at least one hour* prior to the IRB meeting as instructed
- During the meeting:
  - Arrive in a timely manner to the meeting and remain until meeting concludes
  - Participate in discussion of submissions that are not assigned directly to the student
  - Students are encouraged to raise questions to the IRB Chair during and/or after the meeting(s).
  - Present findings to the IRB team as required
- Evaluation will be provided:
  - After the third meeting (35 points) and after the sixth meeting (35 points), students will be awarded their participation grades and will receive formal feedback from the IRB committee.
  - CHOP and Penn IRB Chairs, Leadership, and Staff will provide additional informal feedback throughout the student's participation

**Please note the following:**

- If you have a schedule conflict that will prevent you from completing the 6-meeting requirement by end of August, request an extension immediately so alternative arrangements may be made:
  - Diane Pinder - Penn IRB or
  - Meghan Riley - CHOP IRB
  - CC the course coordinator on all correspondence

**IRB Office Hours**

- Opt-In Sessions: Dr. Johnson will hold optional office hours, on the first and third Tuesday of every month. These meetings are a place for students to ask questions before or after an IRB meeting. Office hours will occur virtually, on Microsoft Teams; students will be invited as optional attendees.
- Mandatory Sessions: Dr. Johnson will schedule two brief, virtual one-on-one sessions with each student to address any questions or concerns about the IRB experience.

### Attendance and Participation (30%)

Attendance and participation will be critical to learn the foundation of scientific and ethical conduct. Students will be evaluated on attendance and participation in all class sessions. Online modules will prepare students to actively engage in case-based discussions. Students are expected to complete quiz assignments within Canvas and KnowledgeLink when applicable.

Attendance, Participation, & Completion of January coursework: 15 points

Assignments are due at least 2 days prior to class to prepare you for case-based discussions:

- Due Jan 3<sup>rd</sup> at 11:59pm: Ethics of Research with Human Subjects (10 pts) and Responsible Conduct of Research (RCR) (2.5pts)
- Due Jan 15<sup>th</sup> at 11:59pm: Good Clinical Practice (GCP) Simulation - (2.5 pts)

### Course Policies and Procedures

#### Attendance

Students are expected to attend *and participate* in all classes. If for any reason a student will not be in class, they should contact the course coordinator prior to class to alert them of the absence and plan to make up course content. One absence is allowed during the course, which will not affect the attendance grade. If a class date conflicts with a holiday or religious observance, please contact the course coordinator in advance. If an assignment is due during this time, please work with the course coordinator to determine an alternative due date.

Attendance will be taken at the beginning of each class, please make sure to be on time to be counted as present. If you anticipate being late to class, then please contact the course coordinator. If you experience technical issues completing online coursework, please let the course coordinator know.

#### Academic Policies:

For information on academic policies, please refer to the [MSTR Student Handbook](#). 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.

#### Canvas:

All course materials (PPT slides, recordings, announcements) and assignments will be posted on Canvas. Contact the Course Coordinator with questions. [Log in](#) with Pennkey.

#### 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).

### 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 SDS 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 through the [MyWeingartenCenter portal](#). The office is located in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260, Philadelphia, PA 19104. All services are confidential.

## Course Schedule

The schedule may change based on instructor scheduling. Protect 8:30-10:00am on all dates/times.

DATE	TOPIC	INSTRUCTOR
Thursday, Nov 17 12:30-12:45pm [8030 Maloney]	Course Overview	Emma Meagher
Tuesday, Nov 29 12:45-2pm [8030 Maloney]	Penn IRB New Members Training <i>(CHOP schedules separately)</i> Things I Wish I Knew Panel (all students)	Diane Pinder  2 <sup>nd</sup> year MSTR Students
<i>Complete online modules &amp; quizzes by Jan 3<sup>rd</sup> at 11:59pm</i>	Ethics of Research with Human Subjects (~4.5 hours) Responsible Conduct of Research (~5 hours)	Zeke Emanuel via Canvas Penn KnowledgeLink
Thursday, Jan 5 8:30-10:00am [8030 Maloney]	Case Studies – Human Subjects Protection	Emma Meagher
Tuesday, Jan 10 [8030 Maloney]	HIPAA Privacy and Human Subjects Research	Laura Fluharty
Thursday, Jan 12 8:30-10:00am [8030 Maloney]	Case Studies – Health Privacy	Maya Nayak Laura Fluharty
<i>Complete online modules &amp; quizzes by Jan 15<sup>th</sup> at 11:59pm</i>	Good Clinical Practice (GCP) - Simulation (~90 mins)	Penn KnowledgeLink
Tuesday, Jan 17 8:30-10:00am [8030 Maloney]	Case Studies - GCP	Stacy Mercado
Thursday, Jan 19 8:30-10:00am [8030 Maloney]	Developing a Study Budget	Jason Molli
<i>Complete online modules by Jan 24<sup>th</sup> at 11:59pm</i>	Conflicts of Interest in Biomedical Research (~75 minutes)	Zeke Emanuel via Medical Ethics Online Education
Thursday, Jan 26 8:30-10:00am [8030 Maloney]	Case Studies - Scientific Conduct	Glen Gaulton