# MTR/REG 5100 – Introduction to Clinical & Translational Research

**Fall 2024** *Working syllabus – last update: 10.10.24*

## Course Contact Information

| | Section 401 | Section 402 | Who to contact for which questions? |
|---|---|---|---|
| **Course Director** | **Emma A. Meagher, MD**<br><br>**Admin: Genevieve Markle** | **Dan Vogl, MD, MSCE**<br><br>**Admin: Julie McDaniel** | - Questions regarding course content<br>*Please add in subject "Reg 5100 Question: …" |
| Teaching Assistant | Shannon Christensen, PhD (formerly) Barbour | Amanda Brock, MSN, MBE, RN | - Excused absences/ Attendance/ Lateness<br>- Clarification on grades<br>- Assignment clarifications<br>  (Please CC Course coordinator and section TA)<br>*Please add in subject "Reg 5100 Question: …" |
| Students | Please make sure to watch the Canvas notifications/ announcements for information from course coordinators. | | |

*Please do not send Canvas Notifications to contact course staff.

**syllabus is subject to change at professor's discretion

# Course Logistical Information

*All times are listed ET.

| | Section 401 | Section 402 | Who to contact for which questions? |
|---|---|---|---|
| **Canvas Link** | | | Note: The content in Canvas will be published in a phased approach for both sections. If you do not see all of the content at once this is normal and you will be able to see it before you need to do anything or submit anything for that unpublished content. |
| **Guest Lecturers** | See "Course Schedule" section below. | | Session specific content questions<br>-  (Please CC Course coordinator and section TA)<br>*Please add in subject "Reg 5100 Question: ..." |
| **Class time(s)** | **M/W 4:00 – 5:30 PM ET;**<br>**DELAYED–** 4:30 – 6 PM on Mon, 9/16<br>*See "Course Schedule" section below for details. | | For questions about scheduling contact your course coordinator. |
| **Online Link(s)** | Please see the Zoom page in your Canvas Course. | Please see the Zoom page in your Canvas Course. | For questions about online links contact course coordinator. |
| **Group Work Sessions** | For "group work only" sessions, schedule with your group. No link will be provided to you. | | Your group members will schedule your session in a platform of your choosing. |

# Description

This introductory course lays the foundation for understanding practical aspects of designing and conducting clinical research in an academic environment. The course is divided into two modules: Module 1: Trial Design and Execution and Module 2: Regulatory Environment for clinical research inclusive of clinical trials. The first module introduces clinical research, clinical protocols, study design and execution and the drug development process. The second module covers ethical considerations in clinical research, study oversight, and the regulatory environment for clinical trials. Upon completion, students should have a strong foundation in the fundamentals of clinical research.

## Objectives

By the end of the course, students will:
- Describe the concepts of clinical and translational research.

- Explain the methodical approach to designing a research protocol.
- Evaluate numerous study designs and best practices for their use.
- Identify sources of bias and confounding in studies.
    - Recall the fundamental principles of pharmacology.
- Distinguish between Phase I-III trials in the drug development process.
- Recognize ethical principles for research and regulatory framework as they relate to research and protocol privacy and confidentiality.
- Assess basic clinical study oversight.
- Describe the regulatory environment for conducting clinical studies.
- Apply principles of budget development for clinical research studies.
- Describe concepts of intellectual property in drug development.

# Assessment Overview

- 10% - Participation
- 10%
    - Knowledge Checks – Multiple choice
    - Discussion Board(s)
        - Intellectual property discussion board (async; individual)
- 70% - Case Studies/ Activities – These activities are generally short, in-class presentations and analyses that will be graded by the facilitator with a rubric.
    - Human subjects case studies group assignment (synchronous)
    - Trial execution case studies group assignment (synchronous)
    - GCP/ALCOA-C case studies group assignment (synchronous)
    - Product finalization mini presentation (synchronous)
    - Budget group activity (async)
- 10% - Final assessment

*Assessments/ discussion boards/ activities may be added to this category during the running of course.

## Assignment Descriptions
### Quizzes/ Knowledge Checks (Asynchronous)
All quizzes/ knowledge checks are multiple-choice and immediately graded.

### Activities (Trial Execution, Human Subjects Protections, GCP/ALCOA-C, Product finalization)
Students review recorded lecture materials to provide context for the case studies. Then, using a set of case studies and prompt questions provided by the facilitator, students will be divided into groups, each reviewing 1-2 cases in depth (depending on total number of cases).

Students will meet as a group to discuss the cases/scenarios, during designated "Group Coworking" sessions that take place at the same time as a synchronous session would. Groups should take notes on their discussion and answer prompt questions posed by the facilitator. They will prepare a short presentation (under 8 minutes) to be given in synchronous class.

Groups will post their slides prior to class. During synchronous class, each group will present their findings followed by questions & comments from peers and the instructor. Time should also be reserved for students to ask general questions of the instructor related to content, clarifying cases, etc.

Finally, students will have the option to respond with written comments to other groups' presentations in a discussion board. The written comments will provide opportunity for any comments/questions that we ran out of time for in class and also make space for students less able to speak up in synchronous classes.

### Intellectual Property Discussion (Asynchronous)
After reviewing an asynchronous lecture on IP, students will respond individually to a discussion board prompt.

### Group Activity: Budget Development (Asynchronous)
Students review asynchronous videos for context. In groups (either independently or during Group Coworking time), they complete a spreadsheet budget activity related to a case study.  Groups will summarize their findings as a group, then select 1 person to post your Excel sheet and a brief summary on behalf of the group to the discussion.

### Final Assessment: Reflection (Asynchronous)
An open-book, written reflection on course topics.

## 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. However, students are required to make up the content from the missed class.

Beyond 1 excused absence, for every unexcused absence you will receive 2 points off your final, end-of-semester grade per additional absence.

If you will be absent, please contact the course coordinator prior to your absence. If you have other concerns regarding attendance requirements, contact the course coordinator as soon as possible.

Students need to be on time, in a location with guaranteed connectivity, keep their camera on, and remain engaged in class for the duration of the class. In the event of unavoidable circumstances that lead you to be late for class or need to leave early, please contact course coordinator and course director prior to class at least one hour prior to. 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.

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.

## 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. There are ten synchronous sessions for this course. To understand how to earn the full credit for participation below, please see the examples and expectations below. For special circumstances, please email your course coordinator.

**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" 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

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 |

Students enrolled in the Masters in the Regulatory Affairs are required to maintain **minimum standard for satisfactory work in each course which is a B-.**

## Miscellaneous

### 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). The program will release the grades once students submit their course evaluations.

### 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

## Module 1: Trial Design and Execution

*Async/ Group Meetings Only Note: Students should review content asynchronously prior to the group meeting during the time provided. If the students in the group agree, you may reschedule this time to another time provided you give yourselves enough time to collaborate on the assignment which will be due for the next class. Students should make their own virtual space to meet with their group.

**Schedule may change as needed.

| Date *4:00 PM ET | Topic | Modality | Lecturer(s) | To Do | Due *3:59 PM ET unless noted |
|---|---|---|---|---|---|
| Mon, Sept 9 | Introduction to Clinical Research & Overview of Clinical Research Methods | Sync | Meagher/ Vogl | | |
| Wed, Sept 11 | Protocol Development I | Sync | Meagher/ Vogl | | |
| Mon, Sept 16 | Protocol Development II 4:30 pm Delayed | Sync | Meagher/ Vogl | Knowledge Check: Research Methods & Protocol Dev | 09/18 |
| Wed, Sept 18 | Drug Development Designs | Sync | Meagher/ Vogl | | |
| Mon, Sept 23 | Drug Development Process | Async | Meagher/ Vogl | Knowledge Check: Drug Development & Trial Design | 09/25 |
| Wed, Sept 25 | Basic Pharmacology I & II | Async | Meagher/ Vogl | Knowledge Check: Pharmacology I & II | 09/30 |
| Mon, Sept 30 | Basic Pharmacology III | Async | Meagher/ Vogl | Knowledge Check: Pharmacology III | 10/2 |
| Wed, Oct 2 | Basic Pharmacology IV | Async | Meagher/ Vogl | Knowledge Check: Pharmacology IV | 10/07 |
| Mon, Oct 7 | FDA Regulation in Academic Studies | Sync | Meagher/ Vogl | Knowledge Check: FDA Regulation in Academic Studies | * 10/16- Holiday exception |
| Wed, Oct 9 | Roadmap to Product Development | Sync | Meagher/ Vogl | | |
| Mon, Oct 14 | NO CLASS – COLUMBUS DAY | | | | |
| Wed, Oct 16 | Introduction to Human Subjects Protections | Async/ Group Meeting only | | Human Subjects Case studies | 10/20 @11:59 p.m. |
| Mon, Oct 21 | Case Studies in Human Subjects Protections | Sync | Meagher/ Vogl | Mini Presentation | Class time |

## Module 2: Regulatory and Funding Environment for Clinical Trials

*Async/ Group Meetings Only Note: Students should review content asynchronously prior to the group meeting during the time provided. If the students in the group agree, you may reschedule this time to another time provided you give yourselves enough time to collaborate on the assignment which will be due for the next class. Students should make their own virtual space to meet with their group.

**Schedule may change as needed.

| Date *4:00 PM ET | Topic | Modality | Lecturer | To Do | Due *3:59 PM ET |
|---|---|---|---|---|---|
| **Wed, Oct 23** | Mobile App Technology | Sync | Gooneratne | | |
| **Mon, Oct 28** | Trial Execution: Study Start-Up, Enrollment, Study Close-Out I | Async/ Group Meeting only | | Case studies: Trial Execution Prep | 10/29 @11:59 p.m. |
| **Wed, Oct 30** | Case Studies in Trial Execution | Sync | Fluharty | Mini Presentation | Class time |
| **Mon, Nov 4** | Role of Investigational Pharmacy in Clinical Trials | Sync | Capozzi | | |
| **Wed, Nov 6** | Good Clinical Practices I | Async/ Group Meeting Only | | Case studies: ALCOA-C | 11/10 @11:59 p.m. |
| **Mon, Nov 11** | Case Studies in Good Clinical Practice  *Section 402 Note: This guest lecture session will not combine the section. Section 402 will use the link for their sections. | Sync | Mercado-Section 401  MacDonald-Section 402 | Mini Presentation | Class time |
| **Wed, Nov 13** | Intellectual Property | Async/ Group Meeting | Brougher | Discussion board | **Post 1:** 11/16 **Post 2:** 11/20 |
| **Mon, Nov 18** | Part 1: Roadmap to Product Finalization | Async/ Group Meeting Only | | Product Finalization Mini Presentation Prep | 11/20 |
| **Wed, Nov 20** | Part 2: Product Finalization Presentation | Sync | Gooneratne | Mini Presentation | Class time |
| **Mon, Nov 25** | Funding Clinical Research: Grants & Contracts | Async | Schieri | Knowledge Check: Funding Clinical Research: Grants & Contracts | 12/02 |
| **Wed, Nov 27** | Holiday, NO CLASS | | | | |
| **Mon, Dec 2** | Clinical Trial Budgets | Async/ Group Meeting only | Molli | Group Activity: Budget development | **Post 1:** 12/6 **Post 2:** 12/09 |
| **Mon,** Dec 2 | End of Term Assessment Assigned | Async | | Final assessment: Written reflection | 12/12 |