REG 611 Clinical Trial Management

Summer 2023

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| Course Directors | Contact | Class Time & Format |
| **Amy Marshall, MPH**  **Megan Singleton, JD, MBE, CIP** | [**amy.marshall@pennmedicine.upenn.edu**](mailto:amy.marshall@pennmedicine.upenn.edu)  [**msingl16@jhmi.edu**](mailto:msingl16@jhmi.edu) | **Mon/Wed**  **4:00-5:30PM, Online** |

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| Course Coordinator | Contact | Office Location |
| **Nik Kroushl** | [nkroushl@upenn.edu](mailto:nkroushl@upenn.edu) | **8-Maloney** |

## Description

This course will focus on the practical aspects of executing clinical trials in an academic environment in a GCP compliant fashion. Upon course completion students will understand the requirements to effectively implement and manage both investigator-initiated and industry-sponsored clinical research studies. This course is divided into three segments. In the first segment, students will be guided through the operational aspects and regulatory processes of clinical trial management across the clinical trial life cycle from pre-study activities through study start-up and implementation, and ongoing compliance through study close out. Students will learn strategies for navigating the complex regulatory/operational clinical research environment and for successful protocol development and approval, subject recruitment, data management and IRB/FDA interactions. In the second segment of the course, students will learn about specific trial management challenges that may arise based on study type and will learn skills for navigating these challenges for investigator-initiated studies, federally-funded and commercially-sponsored research and research with unique trial management concerns such as conflicts of interest and the use of new technologies. Finally students will have the opportunity to apply the skills they have learned through a final course project which includes identification of a trial management challenge and a proposal for solutions to address that challenge. Protection of human research subjects and adherence to good clinical practices guiding research in humans is a critical concept that will be integrated throughout each of the lectures and course assignments.

## Learning Objectives

At the conclusion of the course, learners will be able to:

1. Explain the requirements for implementing and managing investigator-initiated and industry-sponsored clinical research studies
2. Describe the operational aspects and regulatory processes of clinical trial management, from pre-study activities through study start-up, implementation, and close-out
3. Explain best practices for managing ongoing compliance throughout study life cycles
4. Differentiate strategies for navigating the challenges of (1) investigator-initiated, (2) federally funded, and (3) commercially sponsored research
5. Define the requirements related to conflicts of interest and strategies for managing conflicts in the context of clinical trials
6. Recognize new technologies in clinical trial management
7. Develop comprehensive proposals to address unique challenges in trial management
8. Comply with human subjects research protections and good clinical practices

## Activities and Assessment

Students will engage with the course material in a variety of ways and demonstrate that they understand the key elements and considerations of clinical study management through virtual class attendance, class participation (including online quizzes/assignments and readings), a paper, and a presentation.

**Grading:**

35% - Class Participation [Includes 4 online activities related to Asynchronous sessions and 3 Pre-Class Activities for Synchronous Sessions]

5% - Attendance & Synchronous Class Participation

20% - Paper

40% - Presentation (10% Presentation Proposal; 30% Presentation/Deliverable)

**Class Participation & Attendance**  (40%; 15% pre-class assignments (3 assignments, each at 5% per assignment); 20 % online quizzes/assignments related to Asynchronous sessions, 5% attendance and synchronous class participation)

**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.

**Presentation** (40%; 10% proposal, 30% presentation) \*Additional assignment description will be presented in class and posted on Canvas.

A critical aspect of effective clinical study management is the ability to adapt to and address challenging issues that arise in the course of study management. Issues related to study design, study communications, and management of unexpected events pose unique challenges to research teams. To prepare this presentation, students are asked to identify and research a challenging issue in clinical study management and develop practical solutions as to how a research team might address the issue. Students may draw upon their own experiences, a current topic in the literature or an issue raised through class discussion to select a presentation topic.

June 28th: Presentation Proposal Due

July 26th, July 31st, August 2nd: Class Presentations (All students must submit presentation materials by 12pm on July 26th)

*Please note: On the scheduled presentation dates, each class will be scheduled for at least 2 hours.*

**Paper** (20%) \*Additional assignment description will be presented in class and posted on Canvas.

The course paper is comprised of a case analysis and is designed to enable students to demonstrate the knowledge acquired through the first two course segments to a specific clinical trial case example. Students will select one of two cases and write a 3-4 page analysis of the case. As part of the assignment students are asked to identify one operational issue and one ethical or regulatory issue raised by the case and for each describe how the issue might be addressed by the study team.

July 19, 2023: Paper Due

## Course Policies & Procedures

**Attendance:**  
Students are expected to attend and participate in all synchronous sessions. If for any reason a student will not be in class, they should contact the Course Coordinator and instructors prior to class to alert them of the absence. One absence is allowed during the course which will not affect the attendance grade, regardless of the reason. All absences require students to make up content which would include watching the recording for the missed session or an alternate assignment as assigned by the instructor.

Throughout the course there are three synchronous sessions which include a pre-assignment to prepare for the session. These will be held on May 31, June 7, and June 21. These sessions are designed as discussion/activity based and are intended to provide an opportunity to work with your peers to engage in activities and discussion of the course content. If you have a conflict for any of these sessions, please contact the Course Directors to discuss asap. If you must miss one of synchronous sessions, an alternate assignment will be required to be eligible for your full participation grade for that session.

To facilitate both discussion and student engagement, we are requiring all students have their video enabled during all virtual classes.

**Academic Integrity:**

As a student at The University of Pennsylvania, you are required to uphold the [Code of Academic Integrity](https://provost.upenn.edu/policies/pennbook/2013/02/13/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 directors or coordinator if you are not clear on potential violations.

**Canvas:**

All course materials (ppts, announcements, lecture recordings) and assignments will be posted on Canvas. Contact the course coordinator with questions. [Log in](https://canvas.upenn.edu) with Pennkey: [**https://canvas.upenn.edu/**](https://canvas.upenn.edu/)

**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 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.

**Online Office Hours:**

One or both of the course instructors will be available after synchronous sessions for pre-scheduled virtual office hours. Students may join office hours via Zoom during the pre-scheduled sessions or arrange a separate time to speak with the course instructors individually to pose any questions about assignments, etc.

# Course Schedule

***I. Clinical Trial Management Across the Trial Life Cycle [Weeks 1-6]***

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| --- | --- | --- | --- | --- |
| Date | Topic | Modality | Lecturer | Asynchronous Assessments/  Learning Activities/Assignments |
| Mon May 22 | **Course Introduction and Course Roadmap** | Synchronous | Singleton | Pre-Class Assignment: Respond to the Discussion thread in Canvas to introduce yourself |
| Wed May 24 | **Feasibility and Study Planning** | Asynchronous | Marshall | ***Associated Assignment:***  ***Online Quiz [Due 5/24/2023; 11:59pm]*** |
| Mon May 29 | **No Class/Holiday** | | | |
| Wed May 31 | **Other Regulatory Approvals/Mock IRB**  ***In Class Exercise*** | Synchronous | Singleton/Marshall | ***Pre-Class Assignment [Due 5/31/2023; 3:59pm]:***   * ***Asynchronous Lectures: Protocol Review & Approval Process (Singleton) (3 videos)*** * ***Mock IRB Review assignment (includes reviewer form and pre-class questions in Canvas)*** |
| Mon June 5 | **Recruitment/Retention** | Asynchronous | Fluharty | ***Associated Assignments:***  **Online Quiz [Due 6/5/2023; 11:59pm]**  **Asynchronous Materials:**   * **ACRP Training Module “Informed Consent Simulation” (Optional)**   **Online Readings:**   * Nipp RD, Hong K, Paskett ED. Overcoming Barriers to Clinical Trial Enrollment. Am Soc Clin Oncol Educ Book. 2019 Jan;39:105-114. Doi: 10.1200/EDBK\_243729. Epub 2019 May 17. PMID: 31099636. * Lacey Andrews, Todd H. Davies. Participant recruitment and retention from vulnerable populations in clinical trials is a matter of trust, Contemporary Clinical Trials, Volume 123, 2022, 106969, ISSN 1551-7144. * Zimmermann BM, Willem T, Bredthauer CJ, Buyx A. Ethical Issues in Social Media Recruitment for Clinical Studies: Ethical Analysis and Framework. J Med Internet Res. 2022 May 3;24(5):e31231. doi: 10.2196/31231. Erratum in: J Med Internet Res. 2022 Sep 7;24(9):e40848. |
| Wed June 7 | **Engaging with Participants**  ***In Class Exercise/Debate*** | Synchronous | Singleton | **Pre-Class Assignment [Due 6/7/2023; 3:59pm]:**   * **Prepare 3 arguments for assigned debate position and post in Canvas** |
| Mon June 12 | ***Data Collection, Management, and Integrity*** | Asynchronous | Marshall | ***Associated Assignment:***  ***Online Assignment [Due 6/12/2023; 11:59pm]*** |
| Wed June 14 | **IP Management** | Synchronous | Guest Lecturer: Asamoah | ***Pre-Class Assignment [Due 6/14/2023; 3:59pm]:***   * ***Asynchronous Lecture: Investigational Product Management: An Academic Cell Therapy Lab Perspective (Fesnak)*** * ***Online Readings: To Be Specified*** |
| Mon June 19 | **No Class- Holiday** | | |  |
| Wed June 21 | **Reportable Events, Root Cause Analyses, Corrective and Preventative Action Plans**  ***In Class Exercise*** | Synchronous | Singleton/Marshall | ***Pre-Class Assignment: [Due 6/21/2023 3:59pm]*** |
| Mon June 26 | **Operational Aspects of Study Close-Out; Authorship Considerations** | Asynchronous | Marshall | ***Associated Assignment:***  ***Online Quiz [Due 6/26/2023; 11:59pm]*** |
| Wed June 28 | **End of Study Activities:**  **Results Reporting, FDA Reporting Considerations; Investigator Perspectives** | Synchronous | Guest Panelists:  Hexner; Keyes; Emanuel | ***Pre-Class Assignment [Due 6/28/2023; 3:59pm]:***   * ***Asynchronous Lecture: Statistical Considerations in Clinical Trial Management (Hwang)***   ***Presentation Proposal [Due 6/28/2023; 11:59pm]*** |

**II. Trial Management Challenges for Various Study Types**

| Date | Topic | Modality | Lecturer | Asynchronous Assessments/  Learning Activities/Assignments |
| --- | --- | --- | --- | --- |
| Mon July 3 | **Considerations for Commercially-Funded Trials: Contracting, Intellectual Property, COI** | Asynchronous | Guest Lecturer: Chen | ***Online Readings: To Be Specified*** |
| Wed July 5 | **Considerations for Federally-Funded Research: CoC, GWAS, Data Sharing, sIRB review** | Asynchronous | Singleton | ***Online Readings: To Be Specified*** |
| Mon July 10 | **Intellectual Property/COI** | Synchronous | Guest Lecturer: Chen |  |
| Wed July 12 | **Considerations for Investigator-Initiated Trials: Sponsor-Investigator Responsibilities, DSMBs, Sponsor TMF, DSMPs/DMP, etc.** | Asynchronous | Marshall | ***Online Readings: To Be Specified*** |
| Mon July 17 | **New Technologies in Clinical Research Management** | Synchronous | Guest Panelists: Levin, Balachandran, Steigerwalt |  |
| Wed July 19 | **Course Directors Office Hours/Presentation Consults** | Synchronous | Singleton/Marshall | ***Trial Management Paper [Due 7/19/2023; 11:59pm]*** |

**III. Preparing for a Future in Clinical Trial Management [4 synchronous]**

| Date | Topic | Modality | Lecturer | Asynchronous Assessments/  Learning Activities/Assignments |
| --- | --- | --- | --- | --- |
| Mon July 24 | **Careers in Clinical Trial Management** | Synchronous | Singleton/Marshall,  Guest Panel | ***Online Readings: To Be Specified*** |
| Wed July 26 | **Student Presentations** | Synchronous | Students;  Singleton/Marshall | ***All presentation materials due regardless of presentation date; Must be submitted by 12pm on 7/26/2023.*** |
| Mon July 31 | **Student Presentations** | Synchronous | Students;  Singleton/Marshall |  |
| Wed August 2 | **Student Presentations** | Synchronous | Students;  Singleton/Marshall |  |

# Virtual Office Hours

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| Date | Time |
| Mon, May 22, 2023 | 5:30-6:00pm |
| Wed, May 31, 2023 | 5:30-6:00pm |
| Wed, June 7, 2023 | 5:30-6:00pm |
| Wed, June 14, 2023 | 5:30-6:00pm |
| Wed, June 21, 2023 | 5:30-6:00pm |
| Wed, June 28, 2023 | 5:30-6:00pm |
| Mon, July 10, 2023 | 5:30-6:00pm |
| Wed, July 19, 2023 | 4:00-5:00pm |
| Mon, July 24, 2023 | 5:30-6:00pm |