REG 6110 Clinical Trial Management

Summer 2024

Course Directors	Class Time & Format
Amy Marshall, MPH **Megan Singleton, JD, MBE, CIP**	**Mon/Wed** **4:00-5:30PM, Online**

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. Understand 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. Understand 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

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 & Participation:

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 excused 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. Beyond the excused absence, you must contact the course director for a makeup assignment. Missing 4 or more synchronous classes will result in a maximum final grade of C+.

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. Beyond the excused absence, grade impacts are at the discretion of the course director.

Students are expected to 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.

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.

Throughout the course there are three synchronous sessions which include a pre-assignment to prepare for the session. These will be held on June 5, June 12, and June 26. 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.

Participation and Active Participation

Participation in class is crucial to students' success. Students are expected to 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
- sharing relevant expertise with other students and the instructor

Examples of active participation in an asynchronous session include:

- asking or answering questions after class via Canvas or email
- interacting with other students outside of synchronous class

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.

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 & Online Assignments [Includes 4 online activities related to Asynchronous sessions and 3 Online 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% Online pre-class assignments (3 assignments, each at 5% per assignment); 20 % online quizzes/assignments related to Asynchronous sessions, 5% attendance and synchronous class participation)

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 26th: Presentation Proposal Due
July 29th, July 31st, August 5th: Class Presentations (All students must submit presentation materials by 12pm on July 29th)

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 22, 2024: Paper Due

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.

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

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

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

Date	Topic	Modality	Lecturer	Asynchronous Assessments/ Learning Activities/Assignments
Wednesday May 29th	**Course Introduction and Course Roadmap**	Synchronous	Singleton	**Pre-Class Assignment:** ***Respond to the Discussion thread in Canvas to introduce yourself***
Monday June 3	**Feasibility and Study Planning**	Asynchronous	Marshall	**Associated Assignment:** ***Online Quiz [Due 06/03/2024; 11:59pm]***
Wednesday June 5th	**Other Regulatory Approvals/Mock IRB** ***In Class Exercise***	Synchronous	Singleton/Marshall	**Pre-Class Assignment: [Due 06/05/2024; 3:59pm]:** • ***Asynchronous Lectures: Protocol Review & Approval Process (Singleton) (3 videos)*** • ***Mock IRB Review assignment (includes reviewer form and pre-class questions in Canvas)*** ***Online Reading:*** • Bagley, S.J., Binder, Z.A., Lamrani, L. et al. Repeated peripheral infusions of anti-EGFRvIII CAR T cells in combination with pembrolizumab show no efficacy in glioblastoma: a phase 1 trial. Nat Cancer 5, 517–531 (2024). https://doi.org/10.1038/s43018-023-00709-6.
Monday June 10th	**Recruitment/Retention**	Asynchronous	Fluharty	**Associated Assignments:** ***Online Quiz [Due 6/10/2024; 11:59pm]*** ***Asynchronous Materials:*** • ***ACRP Training Module "Informed Consent Simulation" (Optional)*** ***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.
Wednesday June 12th	**Engaging with Participants** ***In Class Exercise/Debate***	Synchronous	Singleton	**Pre-Class Assignment [Due 6/12/2024; 3:59pm]:** • ***Prepare 3 arguments for assigned debate position and post in Canvas***
Monday June 17th	***Data Collection, Management, and Integrity***	Asynchronous	Marshall	**Associated Assignment:** ***Online Assignment [Due 6/17/2024; 11:59pm]***
Wednesday June 19th	**Holiday- No Class**			
Monday June 24th	**IP Management**	Asynchronous	Guest Lecturers: Asamoah, Fesnak	***Optional Online Reading:*** • Finnes et al. Adapting investigational drug services during a pandemic: Recommendations for future preparedness from the Hematology/Oncology Pharmacy Association Investigational Drug Services Special Interest Group, American Journal of Health-System Pharmacy, Volume 80, Issue 1, 1 January 2023, Pages e67–e73, https://doi.org/10.1093/ajhp/zxac267.
Wednesday June 26th	**Reportable Events, Root Cause Analyses, Corrective and Preventative Action Plans** ***In Class Exercise***	Synchronous	Singleton/Marshall	**Pre-Class Assignment: [Due 6/26/2024 3:59pm]** ***Presentation Proposal [Due 06/26/2024; 11:59pm]***
Monday July 1	**Operational Aspects of Study Close-Out; Authorship Considerations**	Asynchronous	Marshall	**Associated Assignment:** ***Online Quiz [Due 6/26/2024; 11:59pm]***
Wednesday July 3	**Holiday- No Class**			
Monday July 8	**End of Study Activities: Results Reporting, FDA Reporting Considerations; Investigator Perspectives**	Synchronous	Guest Panelists: Hexner; Keyes; Emanuel	**Pre-Class Assignment:** • ***Asynchronous Lecture: Statistical Considerations in Clinical Trial Management (Hwang)***

II. Trial Management Challenges for Various Study Types [Weeks 7-9]

Date	Topic	Modality	Lecturer	Asynchronous Assessments/ Learning Activities/Assignments
Wednesday July 10	**Considerations for Commercially-Funded Trials: Contracting, Intellectual Property, COI**	Asynchronous	Guest Lecturer: Chen	
Monday July 15	**Considerations for Federally-Funded Research: CoC, GWAS, Data Sharing, sIRB review**	Asynchronous	Singleton	
Wednesday July 17	**Intellectual Property/COI**	Synchronous	Guest Lecturer: Biron	***Online Readings:*** • Wayant C, Turner E, Meyer C, Sinnett P, Vassar M. Financial Conflicts of Interest Among Oncologist Authors of Reports of Clinical Drug Trials. JAMA Oncol. 2018;4(10):1426–1428. doi:10.1001/jamaoncol.2018.3738 • Harmonization of Financial Disclosure Reporting in Biomedical Journals Recommendations from the Working Groups on Harmonization [Month] 2020 (aamc.org)
Monday July 22	**Considerations for Investigator-Initiated Trials: Sponsor-Investigator Responsibilities, DSMBs, Sponsor TMF, DSMPs/DMP, etc.**	Asynchronous	Marshall	***Trial Management Paper [Due 7/22/2024; 11:59pm]***
Wednesday Jul 24	**New Technologies in Clinical Research Management**	Synchronous	Guest Panelists: Hinson, Balachandran, Zimmerman	

III. Preparing for a Future in Clinical Trial Management [Weeks 10 and 11]

Date	Topic	Modality	Lecturer	Asynchronous Assessments/ Learning Activities/Assignments
Monday July 29	**Student Presentations**	Synchronous	Students; Singleton/Marshall	***All presentation materials due regardless of presentation date; Must be submitted by 12pm on 7/29/2024.***
Wednesday July 31	**Student Presentations**	Synchronous	Students; Singleton/Marshall	
Monday Aug 5	**Student Presentations**	Synchronous	Students; Singleton/Marshall	

Virtual Office Hours

Date	Time
May 29, 2024	5:30-6:00pm
June 5, 2024	5:30-6:00pm
June 12, 2024	5:30-6:00pm
June 26, 2024	5:30-6:00pm
July 8, 2024	5:30-6:00pm
July 17, 2024	5:30-6:00pm
July 24, 2024	5:30-6:00pm