REG 6320: Implementation of the Clinical & Translational Research Protocol

FALL 2025

Course Director	Class Time & Format
Amanda Brock	Online; Tuesdays, 5:00PM – 6:00PM ET **(5 synchronous sessions)**

Course Coordinator
Layah Bogen

Course Description

This course prepares Clinical Research Nurses (CRNs) to implement clinical and translational research protocols with precision, professionalism, and strategic insight. Through a two-part structure, students will gain hands-on experience and foundational knowledge in protocol execution and career development.

Part One focuses on the operational aspects of protocol implementation. Students will explore the CRN's role in investigational and cell product administration, clinical monitoring, patient observation, and alignment between standard care and research practices. Topics include biospecimen sampling, pharmacokinetics, long-term follow-up, and collaboration with key stakeholders such as Investigational Drug Services, Radiology, and Principal Investigators. Ethical considerations and Good Clinical Practice are integrated throughout.

Part Two emphasizes professional growth and leadership in clinical research nursing. Students will engage in negotiation simulations, team science discussions, and career planning activities. Assignments include portfolio development, abstract writing, and reflections on the evolving field of clinical research nursing. By the end of the course, students will be equipped to navigate complex research environments, foster interdisciplinary partnerships, and advance their careers as CRNs.

Learning Objectives

By the end of the course, students will be able to:

1. Describe the role of the Clinical Research Nurse (CRN) in investigational product administration, biospecimen sampling, and post-administration monitoring across diverse clinical settings.
2. Explain the principles of pharmacokinetics and the CRN's responsibilities in maintaining data integrity during sample collection and analysis.
3. Apply protocol-specific procedures to develop treatment plans, order sets, and documentation strategies within electronic medical records and electronic data capture systems.
4. Analyze the alignment and differences between standard clinical care and research protocol requirements, particularly in patient observation and monitoring.
5. Evaluate strategies for stakeholder collaboration and ethical decision-making in protocol implementation, including interactions with industry sponsors, ancillary staff, and regulatory bodies.
6. Create a professional development portfolio and articulate a personalized career advancement plan that reflects leadership, negotiation skills, and engagement in team science.

Evaluation Methods

Students will be graded based on class attendance, participation, and assignments.
Grading = 65% assignments, 35% participation and engagement on Harmonize Discussion Boards

Percent of Grade	Assignment
5%	Protocol Analysis Worksheet
5%	Pharmacy Manual Analysis
5%	Beacon Treatment Plan Request Form
5%	Committee Meeting Reflection
15%	Negotiation Skills Reflection
10%	Professional Portfolio and CV
10%	Abstract Submission
5%	Professional Development Plan
5%	State of the Field Reflection
35%	Harmonize Discussion Boards

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 ITMAT Ed programs, the minimum standard for satisfactory work in each course is a B-.

Class Participation:
Participation is a crucial component in 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.

Attendance Expectations:
Students are allowed 1 excused absence. If you anticipate the need to be absent, late, or leave early, please contact the course director prior to your absence. If you have other concerns about your ability to meet the attendance requirements, you must contact the course director to discuss. All absences require students to

make up content which may include watching a recording or completing an assignment or a quiz, as provided by the instructor.

Students are expected to be on time to all classes and stay for the duration of the class. 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.**

Assignments (65%)

Protocol Analysis Worksheet for Mock Protocol:

The Protocol Analysis Worksheet is designed to guide students through a structured evaluation of clinical trial protocols. By completing this worksheet, students will demonstrate their deeper understanding of the mock protocol, study design, and outcome measures.

Pharmacy Manual Analysis Worksheet:

Students will critically evaluate a poorly written IV investigational product pharmacy manual to identify safety risks and compliance gaps. This exercise emphasizes the importance of clear documentation in protecting patient welfare and ensuring protocol fidelity.

Committee Meeting Reflection:

Students will attend and observe a clinical research protocol review meeting involving investigators, medical directors, nurses, and finance personnel. This assignment encourages students to reflect on the interdisciplinary collaboration, decision-making processes, and ethical considerations involved in clinical research planning and approval. Use of a simple reflection structure is encouraged, including description of observations → analysis → personal insight, → future implications.

Negotiation Skills Reflection:

Students will engage in an AI-driven negotiation simulation focused on clinical research operations. This reflection assignment encourages students to analyze negotiation strategies, stakeholder priorities, and the role of technology in facilitating complex decision-making in clinical trials.

Professional Portfolio and Resume:

Students will develop a professional portfolio and resume aligned with the Clinical Research Nurse Certification Council (CRNCC) standards. This portfolio will serve as a preparatory exercise for board certification and will showcase the student's expertise, growth, and contributions in clinical research nursing.

Abstract Submission:

Students will identify a current call for abstracts from a clinical research-related conference and prepare a draft abstract suitable for submission. This assignment helps students practice scientific writing, align their work with professional standards, and engage with current topics in clinical research.

Professional Development Plan:

Students will create a personalized Professional Development Plan (PDP) tailored to clinical research roles. This assignment emphasizes strategic career planning, skill development, and professional growth within the field of clinical research.

State of the Field Reflection:

In this final reflection, students will assess the current state of clinical research nursing, drawing on course content, personal experiences, and professional trends. This assignment encourages critical thinking about the evolution, challenges, and future directions of the field.

Participation/Harmonize Discussion Boards (35%):
Students are expected to contribute to harmonize boards by posting thoughtful, well-organized responses that

demonstrate engagement with course content and critical thinking. Each post should be:
- Original and substantive (minimum 200–300 words)
- Connected to course materials, readings, or current issues in clinical research
- Respectful and professional in tone
- Submitted by the deadline

Program and Course Policies:

ITMAT Education Learner's Guide

This guide aims to prepare you to engage meaningfully in ITMAT Ed courses. As an ITMAT Ed student, you may engage in both in-person and remote delivery methods. Remote course delivery can add flexibility for instructors and students by allowing for both synchronous interactions (live remote sessions) and asynchronous learning (out-of-class learning time used for studying resources, completing assignments, etc.).

If you have questions, feel free to reach out to your course coordinator, course director, and/or program director. If you have a circumstance or disability for which particular accommodations might be helpful, please check the Weingarten Center Resources for Students in Online Programs and contact program staff.

Community Standards and Program Expectations

Students must comply with the University's Code of Student Conduct, Code of Academic Integrity, and other University policies related to student conduct that appear in the PennBook. 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. Students must comply with all PSOM research policies, including but not limited to, policies on authorship. Additional codes of conduct and expectations students should be familiar with are the equal opportunity and nondiscrimination statement, the sexual misconduct policy and resource offices, and student grievance procedures.

Online and Hybrid Courses

All students engaging in a virtual classroom must ensure that their learning environment 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 a 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, and attending class using your cell phone. **Understanding that schedules can be demanding, in special circumstances, accommodations may be made for those unable to attend via computer.**

If you have concerns about your learning environment, contact the course director and coordinator at the time of registration to get clarity on what is acceptable.

Synchronous Session Guidelines

- **Arrive Early.** Be on time; if online, make sure to log in to the virtual session a few minutes early to double-check your audio and video.

- **Be Respectful.** Be considerate and professional to the instructor and your peers. Avoid any behaviors that might be distracting to others.
- **Be an Active Participant.** Bring questions for instructors and classmates. During student presentations, actively engage with the content being presented by other students in the same way you would with an instructor.
- **Review Resources Ahead of Time.** Ensure you have a firm grasp on any content provided in advance of class and that you have followed instructions related to that content.
- **If online: Limit Noise.** Be in a quiet place, free of distractions or background noise. Keep yourself muted to reduce background noise, and then un-mute to ask questions or engage in discussion.
- **If online: Be Visible.** Have your video on during class. Be appropriately attired (casual wear is fine). It is important to the instructor and other students to feel engaged and attentive. If you need to step away to deal with a time-sensitive issue, you should turn off your video, send a message in the Zoom chat about needing to step away, and return as promptly as possible.
- **If online: Enable Live Transcription.** If captions would help you better understand or retain the conversation, enable live transcription in Zoom. (This is enabled on an individual basis)

Asynchronous Learning

- **Complete Assignments On Time.** Identify an effective method to keep track of assignments and due dates.
- **Engage with Peers**. Participate actively in discussion boards, group work, and other forums for peer communication.
- **Ask for Insight on Feedback.** If you have questions about feedback you received on an assignment, reach out to your course director.
- **Ask Questions as You Have Them.** Stay connected. Email your course director or program staff, ask for a phone call or meeting. Both program staff and course directors are happy to assist.

Canvas Best Practices

- **Turn on Notifications.** You can find your notification settings under "Account" on the top left menu. Please also ensure you've included your preferred email indicated through Account Settings and updated under "Ways to Contact" on the far right. Settings that will be most helpful to you are:
  - Announcement – Notify immediately (bell icon)
  - Grading – Notify immediately (bell icon)
- **Fill in Your Canvas Profile.** Adding a profile photo and your pronouns to your Canvas page lets your instructor and classmates get to know you better.
- **Use the course calendar and To-Dos**. The "Calendar" can help you keep track of due dates. Review the syllabus for important dates and transfer them into your personal calendar.
- **Check your browser compatibility.** Refer to the "**Policies, Procedures, and Technology**" page in your Canvas course to learn more about the browser and other technical information you need for Canvas. We recommend Chrome and Firefox's most up-to-date versions. (Safari has caused problems in the past.)

ITMAT Ed 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. We expect students to approach debates and disagreements in a thoughtful and respectful manner.

Academic Policies:

General Attendance Guidelines

Attendance policies vary from course to course. Please see the course-specific policies regarding the number of acceptable excused absences and how to log absence excuses. Please note that the course director is not required to excuse multiple absences from students. If you are aware that you will not be able to attend multiple course sessions, you may be encouraged to seek a different course that is more suited to your schedule.

Incompletes

The mark of I is used to designate "incomplete". A student who fails to complete a course and does not withdraw or change their status to auditor within the prescribed period shall receive, at the instructor's discretion, either a grade of I (incomplete) or F (failure). When assigning an incomplete, the instructor may permit an extension of time up to one year for the completion of the course. Any course that is still incomplete after one calendar year from its official ending must remain as "incomplete" on the student's record and shall not be credited toward a degree. If a student has 2 or more incompletes on their academic transcript, the student is ineligible to register for future courses and must meet with program leadership to develop a plan for how the incompletes will be resolved.

Code of 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 & 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 the 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 Management: Canvas

All course materials and assignments will be managed on Canvas. Log in with Pennkey and password at 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 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

Part 1: Successful Protocol Implementation

This module will review empowering Clinical Research Nurses (CRNs) to **design, implement, and continuously refine** a **comprehensive protocol monitoring system** that ensures **maximum adherence, safety, and data integrity** in the administration of Investigational Products across diverse clinical settings.

Session	Topic	To Do
Week 1, Sept 2nd	Course Introduction	**Watch:** Course Introduction Video **Assignment Preparation:** - Protocol Analysis Worksheet - Pharmacy Manual Analysis **Submit:** Harmonize Post - Introduction
Week 2, Sept 9th	CRN Role in Investigational & Cell Product Administration	**Watch**: Guest lecturer – Lester Lledo, DNP, RN, CRNP **Assignment Preparation:** - ASHP Guidelines for the Management of Investigational Products - CHPS Equipment List **Submit**: - Protocol Analysis worksheet for mock protocol (9/8) - Knowledge Check - CAR T-Cell Therapy & CRN Responsibilities (9/8) **Attend Sync Session:** Discuss Pharmacy Manual
Week 3, Sept 16th	Clinical Monitoring Patient Observation Finding Alignment Between Standard of Care & Clinical Research Skillsets	**Watch**: - Lee Ann Lawson Lecture - Ellen Napier- Pathology Reports and Immunotherapy **Read:** - Emergency Management Email - ONS Voice: Master Hypersensitivity Reactions with these Strategies for Prevention and Management **Submit:** - Respond to comments on Pharmacy Manual on Harmonize (9/15) - Pharmacy Manual Analysis (9/15) - Knowledge Check - Emergency Management (9/15)
Week 4, Sept 23rd	Bio sampling, Pharmacokinetics, and the Role of the CRN CRN Role in Investigational Product Administration Committee Meeting Observation	**Review**: Observation of CHPS Protocol Review Meeting/Budget Feasibility meeting – submit date (9/22) **Watch**: - Investigational Product Preparation – Amanda - Guest Lecturer- Yael Malul/Amanda **Read**: Understanding PK Sampling: What is a PK Sample. **Submit**: - Committee Meeting Reflection (1 week after committee observation)

Session	Topic	To Do
		- Knowledge Check - PK Sampling (9/29) - Harmonize Reflection (9/29) - Email meeting observation date (9/29)
Week 5, Sept 30th	Impact of CRN: Teamwork and Communication Importance of Long Term Follow up	**Watch**: - Rianne Cueto- LTFU Guest lecturer - Quality and Safety in Research – Amanda - Teamwork and Communication- Amanda **Submit**: - Harmonize Discussion Board - Reflection of Long Term Follow up (10/6) - Knowledge Check - Safety (10/6)

Part 2: Professional Development of the CRN

This module will review cultivating a professionally empowered CRN workforce capable of leading, mentoring, and advancing the field of clinical research nursing through strategic implementation, lifelong learning, and professional engagement.

Session	Topic	To Do
Week 6, Oct. 7th	Effective Negotiation & Hands on Practice with AI Simulation	**Watch**: Negotiation Videos **Read**: Negotiation reading **Submit**: - Harmonize Discussion board- submit AI negotiation thread (10/13) - Negotiation Skills Reflection (10/13) **Attend Sync Session:**
Week 7, Oct. 14th	Team Science	**Watch**: Candy Capilli Lecture **Submit**: Harmonize Discussion board - Team Science CRN Nurse Scientist (10/21)
Week 8, Oct. 21st		**Watch:** Phaedra **Submit:** Harmonize Discussion Board - Industry Perspectives
Week 9, Oct. 28th	Career Growth as a CRN	**Watch**: Lecture – Maria Hendricks **Review**: CRN-BC Certification Website **Submit**: Harmonize Discussion board **Attend Sync Session:** Prep for Prof. Portfolio CRN-BC Submission
Week 10, Nov. 4th	Professional Development for the CRN	**Watch**: Carolynn Jones Lecture **Submit**: Professional Portfolio and CV (11/3)
Week 11, Nov. 11th		**Watch**: Abstract Presentation - Amanda **Submit**: Abstract Assignment (11/16) **Attend Sync Session:**

Week 12, Nov. 18th		**Submit**: Professional Development Plan (11/24)
Week 13, Nov. 25th	State of the Field, Considerations for Future Practice	**Attend Sync Session**
Week 14, Dec. 2nd		**Submit**: State of the Field Reflection (12/1)