The Role of the Clinical Research Nurse: Principles, Procedures, and Purpose (REG 6310)

Term: Spring 2025

Synchronous Class Session Meeting Day/Time: Wednesdays, 5:30pm-7pm ET (via Zoom)

Location: Course Canvas Site

Instructor/Course Director: Amanda Brock MSN, MBE, RN, CRN-BC

*syllabus is subject to change at professor's discretion

Description:
This 1.0 c.u. course provides a framework for the Clinical Research Nurse (CRN) to effectively incorporate the standards and competencies of the specialty of Clinical Research Nursing into their practice. Through focused discussions (both written and verbal), the course aims to sharpen a student's critical thinking skills and facilitate the clear expression of the student's ideas and knowledge of the course material. By the end of the course, the student will be able to synthesize the concepts presented and the feedback given by the Instructor to outline both the effective strategies for implementation of a clinical research protocol and the role of the CRN in relationship to the other stakeholders involved with a focus on communication and teamwork. The student will be able to demonstrate a clear understanding of and appreciation for the CRN's responsibility to uphold both fidelity to the protocol and the highest standard of patient care in an effective, ethical, and professional manner.

Learning Objectives:

At the conclusion of this course, learners will be able to:
1. Explain the unique professional identity of the CRN and the importance of lifelong learning, networking, and continuous improvement as a CRN.
2. Describe the roles and responsibilities of each of the members of the clinical research team, including that of the CRN, and how the CRN relates to each member of the team.
3. Discuss how to apply the *Clinical Research Nursing: Scope and Standards of Practice* and *Clinical Research Nursing Core Curriculum* to one's practice as a CRN.
4. Evaluate and critique a clinical research protocol with a focus on patient safety and patient experience.
5. Describe the practical nursing implications of clinical research protocol execution in various practice environments and describe strategies for effective implementation of a protocol from start to finish.
6. Discuss strategies for a CRN to facilitate effective communication amongst all stakeholders involved in a clinical research study.
7. Explain the dual responsibility of the CRN to maintain fidelity to a protocol and uphold the highest standards of patient care as it relates to the provisions of the *Code of Ethics for Nurses* and the clinical research ethical framework, particularly regarding the conduct of clinical trials as part of the healthcare provider team.
8. Explain how CRNs can engage with the community to improve trust, especially with those from under-represented populations.

9. Discuss strategies for facilitating Decentralized Clinical Trials (DCTs) with consideration for the regulatory, ethical, and logistical issues involved.

Required Texts:
This course utilizes the following texts. Students will be expected to access and refer to the texts throughout the course in order to successfully participate in discussions and complete assignments. Students should let the Instructor know as soon as possible if they encounter any difficulties obtaining the required texts.

1. *Clinical Research Nursing: Scope and Standards of Practice* 2nd ed. eBook. American Nurses Association, Inc.; 2024.
   - Available to purchase through ANA website; $36.95 USD/$29.00 members
2. McCabe M, Ness E, ed. *Clinical Research Nursing Core Curriculum*. eBook [Kindle edition]. International Association of Clinical Research Nurses (IACRN); 2021.
   - Available to purchase through Amazon website [Kindle]; $9.99 USD
3. *Code of Ethics for Nurses with Interpretive Statements* 2nd ed. eBook. American Nurses Association, Inc.; 2015.
   - Available through Penn Libraries website
   - Also available to view on the ANA website

Course Assessment and Grading

Students will engage with the course material in a variety of ways and demonstrate that they understand the key elements and considerations of the role of the CRN through a combination of synchronous online class session attendance and participation and asynchronous online activities and assignments.

Grading:

Discussion Board Participation Assignments	30%
Synchronous Class Session Attendance and Participation	28%
The Concept Map Assignment (Final)	15%
The Process Map Assignment (Final)	15%
The Stakeholders Identification Worksheet Assignment (Final)	10%
Knowledge Check Quizzes	2%

Assessments/Assignments:

Discussion Board Participation Assignments (30%)
For each Week/Module in the course, there are 3 distinct types of Discussion Board Participation Assignments due: Part A, Part B, and Part C.
- Completion of Part A will make up 15% of your grade in the course.
- Completion of Part B will make up 10% of your grade in the course.
- Completion of Part C will make up 5% of your grade in the course.
- Thus, the Discussion Board Participation Assignments make up a combined 30% of a student's final grade in the course.
    - *Part A*. In general, Part A is centered upon the student being presented with an example of a real-world scenario a CRN may encounter in their role. Often, the student will be asked to refer to the mock Protocol and related documents for the course in order to answer the prompt. Students are encouraged to take a natural approach to the prompt, answering as completely and appropriately as possible with the understanding that, as long as they meet all the requirements for the assignment, they will get full credit.
        - Requirements for successfully completing Part A are that the student must: compose an appropriate response to the writing prompt, meeting the minimum word count requirement (typically 300 words), citing sources properly, and posting it by the due date/deadline.
            - Please note that minimum word counts to receive credit for Part A do NOT include the text of the prompts or bibliography/reference lists/citations. No partial credit will be given for Part A.
            - Failure to answer the prompt appropriately and completely, meet the minimum word count, follow citation/reference guidelines, and submit by the due date can result in an "Incomplete" on Part A and subsequent loss of credit towards the 15% component of the student's final course grade.
    - *Part B*. In general, Part B is centered upon the student being asked to reflect on the course material and describe how the content is influencing their thinking, often as it relates to some of the other major assignments in the course (specifically, The Process Map, The Concept Map, and The Stakeholders Identification Worksheet). Again, students are encouraged to take a natural approach to the prompt, answering as completely and appropriately as possible with the understanding that, as long as they meet all the requirements for the assignment, they will get full credit.

- Requirements for successfully completing Part B are that the student must: compose an appropriate response to the writing prompt, meeting the minimum word count requirement, (typically 200 words) citing sources properly, attaching a draft or final version of another assignment (such as The Process Map, The Concept Map, and The Stakeholders Identification Worksheet) and posting it by the due date/deadline.
    - Please note that minimum word counts to receive credit for Part B of the writing assignments do NOT include the text of the writing prompts or bibliography reference lists. No partial credit will be given for Part B.
    - Failure to answer the prompt completely, meet the minimum word count, submit by the due date, upload a required attachment (if applicable), and follow citation/reference guidelines can result in an "Incomplete" on Part B and subsequent loss of credit towards the 10% component of your final grade.
    - Again, students will be asked periodically to include an attachment in Part B as part of the assignment. Failure to include an attachment that is due in Part B will result in an "Incomplete" on Part B AND <u>a missing submission for the attachment that is due</u>.
  - *Part C*. In Part C, the student must post at least 1 additional meaningful contribution (according to the prompt) to the Discussion Board by the deadline. Please note that Part C is separate from the Part A and Part B Discussion Board Participation Assignments; that is, <u>you cannot get credit for completing Part C by making an additional post on either Part A or Part B</u>. However, your Part C contribution can reference another student's post(s) from Parts A, B, or C.
    - Please note that the same citation guidelines that apply to Parts A and B apply to Part C as well. There is no minimum word count requirement for Part C. No partial credit will be given for Part C.
    - Failure to meet any of the discussion contribution requirements in Part C can result in an "Incomplete" on Part C and subsequent loss of credit towards the 5% component of your final grade.
- Parts A, B, and C of these Discussion Board Participation Assignments are not graded on a numerical scale; instead they will be marked as either "Complete" or "Incomplete."
- Important: Text responses to the prompts should be posted directly to the Discussion Board (the student should not upload an attachment containing the text of their response to a writing prompt).
  - <u>However, on certain occasions when a student is prompted to attach either a draft or final version of another assignment (such as The Process Map, The Concept Map, or the Stakeholders Identification Worksheet) in Part B, the student must do so in order to get credit for that Discussion Board Participation Assignment AND in order to successfully submit the assignment due to be attached</u>.
- Please use the American Medical Association (AMA) citation style: https://guides.library.upenn.edu/citationpractices/citationstyles

<u>Synchronous Online Class Session Attendance and Participation (28%)</u>
Attendance and participation in synchronous online class sessions via Zoom will make up 28% of a student's final grade in the course.

Students are expected to attend and participate in all synchronous class sessions. If, for any reason, a student will not be in class, they should contact the Instructor <u>prior</u> to class to alert them of the absence and make arrangements to make up course content.

Students are allowed 1 excused absence. However, students are required to make up the content from the missed class. Beyond 1 excused absence, students will receive 2 points off their final course grade per each additional absence.

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 a student to be late for class or need to leave early, the student should contact the Instructor at least one hour prior to class. Any student more than 15 minutes late or who does not keep their 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 always, at a minimum, responsible for reviewing any class recording and any other materials covered during a synchronous class as soon as possible once they become available.

If you have other concerns regarding attendance requirements, contact the Instructor as soon as possible.

Participation in class is crucial to students' education in this program. Students are expected to attend and actively participate. 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.

This program is committed to providing a supportive and productive learning environment for all. Active participation requires professionalism and demonstration of respect for peers, Instructors, and Guest Speakers/Lecturers/Panelists.

The Process Map (15%)
Students will review the course's mock Protocol and design a detailed Process Map to explain the step-by-step logistics of how to implement the Protocol from screening to end of study for a participant, including locations for each visit and the staff required to implement the visits.

The Concept Map (15%)
A critical aspect of successful protocol implementation is teamwork and communication. Role delineation in clinical research can be nuanced. Students will create a Concept Map including all of the roles of the clinical research team and identify ways by which the CRN will communicate and collaborate with each team member.

The Stakeholders Identification Worksheet (10%)
The CRN plays a large role in facilitating communication and collaboration amongst all stakeholders on a study. For this assignment, students will work to identify all internal and external stakeholders, the level of influence each has on the project, and their goals and values as they relate to the project.

Knowledge Check Quizzes (2%)
Knowledge Check Quizzes, formative assessments to check for understanding of the material, are given during the course. These are brief, multiple-choice, single-best-answer quizzes. The student gets an unlimited number of attempts to answer all questions correctly before being able to progress to the next item/activity in the course. There are deadlines for completing the Knowledge Check Quizzes successfully. Two percent (2%) of a student's final grade in the course will be calculated based on the successful and timely completion of the Knowledge Check Quizzes.

Course-Specific Policies and Procedures

Course Management:
The course Canvas site is where the interactions and instruction in this course will take place. Only students registered for this course will have access to the Canvas site. Students must refer to the REG6310 Canvas course site for all course information, announcements, materials, and assignments. Contact the Instructor with questions. Log in with Pennkey.

Communication:
Students must pay attention to all communications (including Announcements, Conversations in Canvas Inbox, emails, etc.) from the Instructor (and/or staff) via the Canvas course site. Students should ensure that the email address listed on Path@Penn is the one they look at regularly or that it is forwarded to their preferred email address. If a student has no email address listed on Path@Penn, they will not receive course emails. Students are urged to make sure that their email notifications for "Conversations" are set to "Immediately."

The best way to reach the Instructor is directly via email (please see Page 1 of this document) for contact information.

Feedback:
Students can view their progress and feedback in the Grades area and should email the Instructor with any questions regarding individual feedback.

Deadlines/Due Dates:
There are deadlines/due dates throughout the term. Students can view the due dates for completing assignments by checking out the Course Summary on the Syllabus page, the Modules area, and in their Canvas calendar.

If there are extenuating circumstances that prevent a student from completing an assignment on time, the student must alert the Instructor via email prior to when the assignment is due in order to request that a deadline extension be considered. A student may not be able to receive credit for the assignment if the assignment is late and the students has not been granted an extension prior to the deadline.

Attendance and Participation:
See above regarding Synchronous Online Class Session Attendance and Participation.

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 observation of the holiday conflicts with a synchronous class session date and/or assignment deadline, the student must contact the Instructor within the first two (2) weeks of the term in order to address the conflict and make arrangements.

ADA Accommodations:
The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and whose accommodations have been approved by Penn's Disability Services. Students should reach out to make an appointment to meet with the Instructor and Course Coordinator as soon as possible in order to discuss accommodations needs. If a student has not yet contacted Disability Services, and would like to request accommodations or have questions, they can make an appointment by calling Penn Disability Services at (215) 573-9235 or by 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. Please contact the Instructor with any questions or concerns regarding any accommodations approved by Penn Disability Services during the course.

Course Evaluations:
Student feedback is important. Please note that students must complete evaluations of the course at the end of the term. 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 will be 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.

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 Policies:
For information on academic policies, please refer to the Program 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 Instructor/Program Director if you are not clear on what potential violations are.

Use of Generative AI:
In this course (REG6310), the use of AI LLMs (i.e. ChatGPT, etc.) is not allowed; all work submitted must be the original work of the student.

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 Center for Community Standards and Accountability. 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.

Copyright:
Materials posted in Canvas are intended to be used for private study, scholarship, and research and should not be used for any other purpose. Redistribution of these materials without authority is in violation of Penn's Code of Student Conduct and may constitute an infringement of copyright law.

Course Schedule

[Note: No synchronous class session (SYNC) will be held on the first day of term or during Spring Break; students must pay close attention to all information posted on the course's Canvas site regarding SYNC sessions, assignments, and all due dates/deadlines.]

Week/Module	Learning Objective(s)	Assessment(s)/Assignment(s)
1. Course Overview; Introduction to Clinical Research for the CRN; 5 Domains of Clinical Research Nursing	• Describe the specialty of clinical research nursing. • Classify the 5 Domains of Practice for the CRN. • Define key terminology associated with Clinical Research Nursing • Explain how a CRN can apply the *Clinical Research Nursing Scope and Standards* to one's understanding of a clinical research protocol.	• Introduce Yourself on Discussion Board • Knowledge Checks 1.1 and 1.2 due by 11:59pm on Sunday. • Discussion Board Participation Assignments (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 1 (begins at 5:30pm ET on Wednesday)
2. IACRN Core Competencies	• Discuss the Clinical Research Nursing Standards of Practice and Professional Performance and Core Competencies. • Discuss the *Code of Ethics for Nurses* in the context of clinical research nursing. • Discuss how the CRN can view implementation of a research protocol through the lens of the Joint Task Force for Clinical Trial Competency (JTF) Framework.	• Knowledge Checks 2.1 and 2.2 due by 11:59pm on Sunday. • Discussion Board Participation Assignments (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 2 w/Guest Speaker, Meg McCabe (begins at 5:30pm ET on Wednesday)
3. Informed Consent and the Role of the CRN in the Care of Research Participants	• Discuss best practices for providing Informed Consent. • Discuss how to identify educational resources available to the CRN and research participants. • Demonstrate the ability to accurately apply the key concepts of the teach-back method to the informed consent process and describe this to peers.	• Knowledge Checks 3.1 and 3.2 due by 11:59pm on Sunday. • Discussion Board Participation Assignments (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 3 (begins at 5:30pm ET on Wednesday)

Week/Module	Learning Objective(s)	Assessment(s)/Assignment(s)
4. Professional Identity of the CRN; Roles and Responsibilities of the Research Team	• Describe the professional identity of the CRN. • Discuss differentiations amongst the roles of the clinical research team, including areas where nursing licensure is required, and how to assess a protocol for these delineations. • Identify communication strategies for advocating for nursing expertise. • Describe the roles and responsibilities of the clinical research team.	• Discussion Board Participation Assignments (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 4 (begins at 5:30pm ET on Wednesday)
5. The Importance of Communication on a Research Team	• Discuss one's own communication style and its significance in one's role as a CRN. • Explain the potential for different communication styles amongst other members of the research team. • Describe strategies a CRN can utilize to facilitate more effective collaboration amongst the research team through an understanding of different communication styles. • Identify areas where a research team could be at risk for communication breakdowns.	• Discussion Board Participation Assignments & Draft of Concept Map Due (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 5 (begins at 5:30pm ET on Wednesday)
6. Adverse Events (AEs)	• Discuss how to properly communicate AEs to the patient and the research team. • Identify areas of a protocol that address AEs and describe the steps necessary to ensure patient safety and protocol adherence, including where AEs need to be documented. • Utilize the CTCAE for AE assessment.	• Discussion Board Participation Assignments & 1st Draft of Process Map Due (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 6 (begins at 5:30pm ET on Wednesday)
7. How to Identify and Map Stakeholders	• Discuss how to conduct a stakeholder analysis for a clinical research protocol. • Identify relevant stakeholders, including for each their level of influence, values/goals, and concerns as it relates to a clinical research protocol.	• Discussion Board Participation Assignments & Draft of Stakeholders Identification Worksheet Due (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 7 (begins at 5:30pm ET on Wednesday)

Week/Module	Learning Objective(s)	Assessment(s)/Assignment(s)
8. Strategies for Successful Engagement with Stakeholders	• Discuss the strategies necessary for optimal engagement of stakeholders in the execution of a complex clinical research protocol. • Identify the skills necessary for excellent relationship-building. • Identify challenges when protocol execution intersects with clinical workflows.	• Discussion Board Participation Assignments & Final Stakeholders Identification Worksheet Due (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 8 (begins at 5:30pm ET on Wednesday)
9. Dealing with Difficult Stakeholders	• Discuss strategies for a CRN to effectively implement a clinical research protocol amid challenges with other stakeholders • Explain the importance of a CRN's ability to understand stakeholder concerns, align goals with stakeholders, and manage expectations of the entire research team, including the PI.	• Discussion Board Participation Assignments (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 9 (begins at 5:30pm ET on Wednesday)
10. Community Engagement and Collaborative Research Design	• Define community engagement and explain its importance in clinical research. • Discuss how to develop strategies to build trust with community members. • Explain the role of cultural competence in fostering strong community relationships. • Discuss strategies to involve community members in the design and implementation of research studies.	• Discussion Board Participation Assignments (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 10 w/Guest Speaker, Deb Dunbar (begins at 5:30pm ET on Wednesday)
11. Ethical Concerns in Research; Case Example	• Review a protocol and identify potential areas of ethical concern. • Describe the responsibilities and unique perspective of each role on the research team as it pertains to ethical issues related to a clinical research protocol.	• Discussion Board Participation Assignments & Final Concept Map Due (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 11 (begins at 5:30pm ET on Wednesday)

Week/Module	Learning Objective(s)	Assessment(s)/Assignment(s)
12. Nursing Code of Ethics Open for Public Comment	• Explain the provisions of the *ANA Code of Ethics for Nurses* as a framework for clinical research nursing practice. • Discuss strategies for resolving ethical conflicts when caring for research patients.	• Discussion Board Participation Assignments & 2nd Draft of Process Map Due (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 12 (begins at 5:30pm ET on Wednesday)
13. Decentralized Clinical Trials (DCTs)	• Discuss the role of technology in facilitating DCTs. • Describe mechanisms to leverage local healthcare providers/agencies for trial-related procedures and patient support in DCTs. • Explain how to identify relevant regulatory guidelines and ethical considerations for patient safety and data integrity in DCTs. • Discuss how to identify potential risks specific to DCTs and develop mitigation strategies.	• Discussion Board Participation Assignments (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 13 (begins at 5:30pm ET on Wednesday)
14. Understanding Nursing Roles in Research	• Discuss the intersections and practical application of clinical nursing skills and clinical research skills. • Identify practice environments and nursing roles in which CRNs are critical to the successful and safe implementation of clinical research and production of reliable and valid data. • Explain the differences between the role of the CRN and the role of a Nurse Scientist and identify areas of harmony. • List examples of the various roles and career pathways of nurses in clinical research.	• Discussion Board Participation Assignments & Final Process Map Due (Parts "A" and "B" due by 11:59pm on Sunday; Part "C" due by 11:59pm on Tuesday) • SYNC Session 14 (begins at 5:30pm ET on Wednesday)