**** Syllabus is only relevant for the CTCR Scholars enrolled in GSK****

Course Title: Clinical Research Study Management and Compliance
Course Number: M410
Credits: 1
Course Directors: Gregory J. Riely, MD, PhD, Christopher A. Barker, MD, Michael J. Morris, MD
Grading Policy: Pass/Fail

Course Description:
One of the main goals of the Master's in Clinical and Translational Cancer Research is to train researchers to apply their understanding of biomedical science and analytical and critical thinking skills to solve challenging clinical problems. However, these skills are not sufficient to conduct successful clinical cancer research. Clinical scientists must also possess thorough knowledge of the management, regulatory, and compliance practices necessary to implement clinical research projects. This course aims to fulfill these training needs by focusing on the practical aspects of executing clinical trials in a Good Clinical Practice (GCP) and Human Subject Research (HSR) regulatory compliant fashion. Topics include conducting clinical trials in accordance with GCP; regulations established by state, federal, and international regulatory bodies; managing relationships with external academic and industry partners, and the roles and responsibilities of investigators, sponsors, monitors, and auditors. The course will also provide an overview of regulatory affairs in relation to three key areas of therapeutic development: drugs, biologics, and medical devices. Throughout the course, practical issues facing researchers as they work with the FDA and other international regulatory bodies to secure and keep product approval will be addressed. Through expert advice and groups discussions, this course will enhance the foundational knowledge that students gain during the CITI online modules and allow them to provide these lessons to their own research.

Course Learning Outcomes
Upon course completion students should understand and incorporate the following concepts and skills into their own research:

- Apply Good Clinical Practice (GCP) standards to research;
- Ensure Human Subject Research Protection standards are followed;
- Follow regulatory standards for new drugs and devices;
- Identify Principal Investigator's and Sponsor's responsibilities in clinical trials;
- Collect and maintain clinical data using basic medical informatic tools and strategies;
- Identify common problems that occur in clinical research and how to addresses these challenges should they occur;
- Estimate the resources needed to implement a research strategy and predict the limitations that could slow research progress;
- Establish project management strategies that adhere to deliverables outlined in the research protocols;
- Incorporate safety best practices including documenting and reporting adverse events;
- Ensure research project financial accountability including budgeting, funding resources, and federal compliance standards; and
- Working knowledge of clinical trial ethics and informed consent.

Course Schedule
This course will meet once a week for 15 weeks (excluding the Thanksgiving holiday).
Classes meet for 60 minutes per session for a total 15 hours of in-class instruction.

Course Topics
Week 1: Introduction to Clinical Research Implementation and Management
Date: Thursday, September 4, 2025 | 8:00 am- 9:00 am
Instructor(s): Paul J. Sabbatini, MD

- Standard of Care vs Clinical Research
- Administrative Oversight at MSK and beyond
- The Responsibilities of the Principal Investigator in Clinical Research

Week 2: Human Subjects Protection
Date: Thursday, September 11, 2025 | 8:00 am- 9:00 am
Instructor(s): Eileen M. O'Reilly, MD and R. Michael Tuttle, MD

- The roles and responsibilities of the IRB
- Vulnerable populations
- Research Regulatory Bodies in the US that govern human protection
    - FDA, OHRP

Week 3: The Scientific Protocol Review Process at MSK and other NCI Designated Cancer Centers
Date: Thursday, September 18, 2025 | 8:00 am- 9:00 am
Instructor(s): Alexia Iasonos, PhD, Dana E. Rathkopf, MD and Mark A. Dickson, MD

- Research Council
- Other Committees

Week 4: Investigational New Drug and Data & Safety Monitoring Committees
Date: Thursday, September 25, 2025 | 8:00 am- 9:00 am
Instructor(s): Alan L. Ho, MD, PhD and Susan F. Slovin, MD, PhD

- INDC
- IDE
- Data Safety Monitoring Committee (DSMC)

Week 5: Logistics of Enrolling Patients – Reducing Barriers to Clinical Trials
Date: Thursday, October 2, 2025 | 8:00 am- 9:00 am
Instructor(s): Lisa Diamond, MD, MHS, MPH

- Discuss common barriers to accruing patients to clinical trials that represent the general population
- Outline best practices in ensuring accessibility of participation in clinical research to all

Week 6: Subject Safety
Date: Thursday, October 9, 2025 | 8:00 am- 9:00 am
Instructor(s): James J. Harding, MD

- Common Terminology Criteria for Adverse Events (CTCAE)
- Reporting serious adverse events (SAEs)
- Documenting adverse events

Week 7: Sponsor – Investigator Relationships and Responsibilities
Date: Thursday, October 16, 2025 | 8:00 am- 9:00 am
Instructor(s): Gregory J. Riely, MD, PhD and Erika McCarthy

- Agreements and contracts
- Investigator responsibilities including review of the 1572
- Sponsor responsibilities including auditing and monitoring
- Research Privacy
- Conflict of Interest

Week 8: The Patient's Perspective - ***Required attendance***
Date: Thursday, October 23, 2025 | 8:00 am- 9:00 am
Moderator: Annie Ellis

- Patient Advocacy
- Patient Experience

Week 9: Securing Multidisciplinary Support and Multimodality Studies
Date: Thursday, October 30, 2025 | 8:00 am- 9:00 am
Instructor(s): Michael Offin, MD, Himanshu Nagar, MD, Edmund Bartlett, MD and Yingbei Chen, MD, PhD
Moderator: Carly Ryan

- Conducting Collaborative Studies
    - Tips for working with physicians outside of your field
    - Effective communication and collaboration
    - Getting buy in from co-investigators
    - Avoiding and dealing with conflict
- Securing Support for Multimodal studies
    - Pharmacy
    - Radiology
    - Lab Medicine
    - Other

Week 10: Conduct of the Trial Part I
Date: Thursday, November 6, 2025 | 8:00 am- 9:00 am
Instructor(s): Gregory J. Riely, MD, PhD and Ruth Ann Gordon, MSN, FNP-BC, OCN®

- The roles of the investigator
- Plans for research rigor and integrity
- Eligibility
- Creating attainable and reasonable deliverables when writing the protocol

Week 11: Conduct of the Trial Part 2
Date: Thursday, November 13, 2025 | 8:00 am- 9:00 am
Instructor(s): Gregory J. Riely, MD, PhD and Marlon S. Lasa-Blandon

- Training and best practices (regular meetings with staff and sponsor(s)
- Project management and delegation
- Meeting deliverables in the protocol
- Amendments

Week 12: Multicenter Trials
Date: Thursday, November 20, 2025 | 8:00 am- 9:00 am
Instructor(s): Michael J. Morris, MD and Mary Warren

Week 13: Effective Documentation and Corrective and Preventive Action Plan Reviews
Date: Thursday, December 4, 2025 | 8:00 am- 9:00 am
Instructor(s): Karima Yataghene, MD

- Real-time documentation
- Consent and reconsent
- Electronic Documentation and 21 CFR Part 11 Compliance
- Reporting deviations
- Tools
- Regulatory Binders

Week 14: Financial Accountability
Date: Thursday, December 11, 2025 | 8:00 am- 9:00 am
Instructor(s): Kevin Frodell, Elena Lascu and Barry Zakrzewski

- Budgeting
- Medicare and research
- Funding resources
- Research billing
- Reviewing Corrective and Preventive Action response to audits

Week 15: FDA Regulations
Date: Thursday, December 18, 2025 | 8:00 am- 9:00 am
Instructor(s): Richard Ellis

Course Assignments
Session Question Submissions
Before each class you will submit a question relevant to the upcoming session's topic. Submitted questions will be asked during the Q&A section of each session. Questions are due by 10:00 AM the day before the next lecture. All questions should be submitted through the course site on Moodle.

Grading
This course will be graded as pass/fail. Students will pass the class if they receive a passing score on 12 of 15 of their submitted questions. Students must participate in 80% of the class to pass the class (12 sessions).

Attendance Policy
All lectures will be recorded. However, due to the highly interactive nature of this course, attendance for all classes is mandatory. We recognize that students may miss class for personal or clinical emergencies. If students miss a class, they must watch the recorded lectured of the class that was missed prior to the next session.

Course Resources
FDA: Good Clinical Practice
https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090259.htm

NIH: Office of Clinical Research
https://ocr.od.nih.gov/

NCI Coordinating Center for Clinical Trials
https://www.cancer.gov/about-nci/organization/ccct

Other supplemental CITI Courses (optional)

- Conflict of Interest
- CT billing and compliance
- Research Study Design

Course Evaluations
Students will evaluate this course by completing an optional survey after the last class. Student feedback will help us improve the course.