

Course Title: Protocol Review and Monitoring Observerships

Course Number: M420

Credits: 1 Credit

Course Directors: Michael Tuttle, MD, Eileen M. O'Reilly, MD, and Dana Rathkopf, MD

Course Organizers: Roy Cambria, Director, Human Research Protection Program, Research and Technology Mgmt and Sara Hanley, Associate Director, Protocol Review and Monitoring, Research and Technology Mgmt

Course Prerequisites: N/A

Grading Policy: Pass/Fail

Course Description

In order to ensure that clinical protocols are meeting appropriate compliance and safety standards, Memorial Sloan Kettering has established a rigorous internal review process for investigator initiated and external clinical trials. During these observerships, students will learn how the institution evaluates research protocols (therapeutic and non-therapeutic) by observing the MSK Research Council and the Institutional Review Board (IRB). After observing IRB and Research Council, scholars will serve as junior reviewers for assigned protocols and identify and present the strengths and weaknesses of these protocols during committee meetings. For those who are already active members of IRB or Research Council, they may participate in the Investigational New Drug committee (INDC) instead. Scholars should use lessons learned during these observerships to improve their own clinical protocols.

Learning Objectives

By the end of this observership, scholars should:

- Understand the institutional review process for therapeutic and non-therapeutic trials
- Appreciate how protocols are evaluated from the perspectives of scientific design, patient safety and human subjects research and compliance standards
- Understand decisions and recommendations prepared by each review committee and understand the rationale for these decisions
- Use the learnings of how these committees deliberate to inform the development of protocols

Observership Schedule

Scholars will receive a customized schedule that assigns them to designated Research Council and IRB meetings.

Orientation and Committee Overviews

During this orientation, the course and organizers will review the purpose, structure, and decision-making authority of each protocol review committee. Scholars will also be provided with insight on how to review their assigned protocols and effectively observe the committee discussions.

Observership Sessions

Scholars are expected to observe at least one session of IRB and Research Council prior to serving as a junior reviewer for an assigned session. For those who are already active members of IRB or Research Council, they may participate in the Investigational New Drug committee (INDC) instead.

Assigned Review Sessions

Scholars will be assigned a protocol to be reviewed at IRB and Research Council as junior reviewers. Scholars will be paired with Senior members of the Clinical Research Administration. At these meetings, scholars must present the strengths and weaknesses of their assigned protocols.

Methods for Assessing Student Achievement

Written Judgment and Presentation (Due by Assigned Review Session)

Scholars will prepare a one-page analysis of their assigned protocol from the perspective of IRB or Research Council. The assessment will describe the strengths and weaknesses of the protocols according to the standards addressed during each specific committee. This assessment will be presented during committee in collaboration with a senior reviewer.

Attendance

Attendance at all group sessions and review committee meetings for their designated protocols will be mandatory. Scholars who miss a committee meeting for personal or clinical emergencies must make-up an equivalent session.

Basis for Grade Determination

Successful completion of the course assignments stated above will be assessed by the Course Organizer. Scholars will receive a passing grade if they attended all sessions, submit a written judgement that accounts for all compliance standards, and present this judgement at a committee meeting in collaboration with a senior reviewer.

Course Evaluation

Scholars will be asked to complete an optional survey to assess the effectiveness of this experience. Students will provide feedback on the observership's structure, scope, and time commitment.