M306: Clinical Trial Design and Protocol Writing

February 24, 2026 – June 9, 2026

Course Director
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Class Times: Tuesday: 9:00am-11:30am.
Thursday (4/23): 8:00am-10:30am – class does not meet Tuesday this week (4/21)
No class on 6/2.
Location: ZRC-104, Thursday class on Teams
Credits: 4 credits
Grading: Letter grade

Course Description
This course aims to teach the fundamentals of clinical trial design through lectures, discussions, and development of clinical trial protocols. Classroom lectures will cover clinical trial phases, choosing appropriate endpoints, commonly used clinical trial designs in oncology, randomization, interim analyses, and novel trial methods, such as basket trials and master protocols. We will also cover patient reported outcomes, integrative medicine, and imaging studies. Scholars will also learn about using real world data, barriers to accrual, and what is expected to get a protocol ready and approved by IRB. Discussions will incorporate lecture themes. The scholars will choose a clinical trial to develop and then methodically develop their own protocol during the protocol development segment of the course. Protocols will be presented to the class.

Learning Objectives
By the end of the course, students should be able to:

(1) Understand the principles of clinical trial design and be able to translate a research question into a study objective with an appropriate primary endpoint for a clinical trial;

(2) Describe the study designs commonly used for phase I-III trials;

(3) Develop an IRB-ready clinical trial.

Responsibilities and Grading
Scholars' performance will be evaluated based on their finished protocol and class participation. Each assignment will be weighted according to the following ratios when determining the final grade:

Assignment	% of grade
Protocol Development	50%
Class Participation	30%
Protocol Critiques	20%
Total	**100%**

Protocols

Each scholar will identify a protocol development idea and a mentor from his or her own field and build an IRB-ready protocol expected after completion of protocol writing course in the spring.

Scholars will be required to submit draft portions of their protocols during the course of the semester. Scholars will be required to critique and give feedback to other protocols during the course of the semester.

Due Dates for Protocol Assignments

Portion of Protocol	**Due Date**	**Percentage**
Protocol Synopsis, Objectives, Endpoints, Background, Design,	Sunday, April 12th	15%
Protocol Synopsis, Objectives, Endpoints, Background, Design, Eligibility Criteria, and Calendar of Events	Sunday, May 17th	15%
Final Completed Protocol	Sunday, June 7th	20%

Students will receive a deduction of 1 point for every two days an assignment is late

Class Participation

Full credit for class participation will be awarded to students who regularly engage meaningfully in discussions.

After three missed sessions (not including medical or parental leave), each additional missed session will result in 50% off the student's class participation grade, or 15% off their total grade (i.e. a student with 4 missed sessions can receive a maximum of 15% class participation, a maximum of 85% in the class).

Class participation and attendance is mandatory on April 14th, May 19th and June 9th. Scholars will present their protocols and critiques to other protocols during these dates in class.

Grading

At the end of the class, scholars will receive a final letter grade based on their performance on the above assignments. The final letter grade will be determined using the following grading scale:

Letter Grade	**Range**
A	93-100
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
F	<70

Attendance Policy
Full attendance is expected in this course. There are no texts or notes than can substitute for the discussion and interaction that will take place.

Please be on time for class. You are responsible for turning in assignments when they are due and for knowing information announced in class, whether or not you were in class on any particular day. It is your responsibility to obtain handouts, assignments, and information you missed when absent.

All scholars who will miss class must notify the course director and TA, as well as the GSK Dean's office (Assistant Dean Julie Nadel at nadelj1@mskcc.org and Stacy De La Cruz at delacrs1@mskcc.org).

While each lecture will be recorded, attendance at all lectures and active participation in class discussions are mandatory. There are no texts or notes than can substitute for the discussion and interaction that will take place. Students who must miss a lecture need prior approval from the instructor and are required to watch the recorded lecture before the next session. Regardless of attendance, students are still expected to complete all any assignments on time.

Class participation and attendance is mandatory on April 14th, May 19th and June 9th.

Academic Integrity Policy
Each scholar in this course is expected to abide by the Gerstner Sloan Kettering Policy of Academic Integrity and Plagiarism.

Scholars are expected to understand all standard rules associated with plagiarism. Resources available to further inform the scholar of what constitutes plagiarism can be found in the MSK Code of Conduct, the content of the Responsible Conduct of Research course as well as in many guides offered to explain the seriousness of any breach of not submitting one's own work for credit. A guidebook "Writing with Sources – a Guide for Scholars", is offered to each scholar upon matriculation; an additional copy is available in the scholar library.

Any instance of suspected plagiarism by a scholar will be brought to the attention of the Dean for further inquiry and action. Penalty for violation of this Code can also be extended to include failure of the course and Graduate School disciplinary action.

Course Evaluation
In order to evaluate the effectiveness of the class, students will be asked to complete an anonymous survey. This optional survey will ask students to provide feedback on the course structure, time commitment, and effectiveness, as well as the performance of the course instructors.

Schedule and Assignments

Date	Topic	Speakers
Tuesday, 2/24	Introduction to Protocol Development	Alexia Iasonos Paul Chapman
Tuesday, 3/3	Phase I Trials	Yonina Murciano-Goroff Alexia Iasonos
Tuesday, 3/10	Phase II Trials	Audrey Mauguen David Aggen
Tuesday, 3/17	Phase III Trials	Marinela Capanu Geoffrey Ku
Tuesday, 3/24	Basket Trials	Andrea Arfe Robert Maki
Tuesday, 3/31	Roundtable Discussion – Clinician Feedback Lecture: Pediatric Trials	Alexia Iasonos Julia Glade Bender
Tuesday, 4/7	Randomization	Elyn Riedel, Jessica Lavery Colin Begg
Tuesday, 4/14 **Mandatory attendance**	Review of proposals – Clinician Feedback Lecture: Trials with multiple modalities Draft proposal due from scholars April 12th.	Kay See Tan Greg Riely
Thursday, 4/23 (*note Thursday*)	Patient Report Outcomes Radiology Trials (Imaging) Virtual Lecture only	Ray Baser Chaya Moskowitz
Tuesday, 4/28	Roundtable Discussion – Clinician Feedback Lecture: Time to event endpoints in single arm trials	Zhigang Zhang Gopakumar Iyer
Tuesday, 5/5	Pragmatic Trials	Andrew Vickers Fiyinfolu Balogun
Tuesday, 5/12	Behavioral Science Trials	Yuelin Li Chris Nelson
Tuesday, 5/19 **Mandatory attendance**	Review of proposals roundtable – Lecture: Early drug development - sponsored trials Draft proposal due from scholars May 17th	Irina Ostrovnaya James Harding
Tuesday, 5/26	Committee Review Process/IRB – from design to activation	Alexia Iasonos Mark Dickson
Tuesday, 6/9 **Mandatory attendance**	Final Presentations Final proposals due from scholars June 7th	Li-Xuan Qin Alexander Shoushtari