Course Syllabus – TRBIO 430

Course Information

Course Number: TRBIO 430 FA25
Course Name: Clinical Investigation
Term: Fall 2025
Start Date: 09/03/2025
End Date: 12/05/2025
Credits: 3.0

Meeting Days / Times

Tuesdays and Thursdays, 8:00-9:30am PT / 11:00am-12:30pm ET
(See Calendar in Canvas for the most up-to-date schedule.)

Locations

CA: Graduate Office Large Conference Room (Hazen Theory Building)
FL: B387

Course Managers

Role	Last Name	First Name	Email Address
Course Director	Nicholson	Laura	lnicho@scripps.edu
Course Director	Jaiswal	Stuti	stuti@scripps.edu
Administrative TA	Hill	Theresa	gthill@scripps.edu
TA	Abad-Yang	Nereida	nabad@scripps.edu
TA	Ortiz	Valery	vortiz@scripps.edu

Course Description

This course introduces the design and conduct of clinical research. Students will become familiar with the essential components of clinical studies. Topics will include research design, introductory biostatistics, methodology and bias risk, human subjects' protection, drug discovery overview, partnering with industry, and the communication of research to peers and with the community. Ultimately, the course will enable students to effectively design clinical investigation involving human subjects and human biologic materials. This course originates as an education and training translational science offering of the Scripps Research Translational Institute (SRTI), which is dedicated to improving medicine and human health via biomedical discoveries. SRTI is a member of the NIH-funded Clinical and Translational Science Award (CTSA) Consortium.

Background Preparation & Expectations

There are no prerequisites for this course. It is intended to be an introduction to clinical investigation for students not previously exposed to clinical research or clinical trials. Students are not expected to become experts in any of the topics covered; rather, they are expected to think critically about the

fundamentals of clinical investigation in order to pursue clinical and translational research as practicing scientists or to collaborate effectively with clinical researchers.

Course Objectives

1. Describe various clinical research study designs and the advantages and disadvantages of each approach.
2. Identify basic characteristics of a randomized clinical trial and differentiate clinical trials from other types of clinical investigations and epidemiologic studies.
3. Apply basic principles to design a clinical study that answers a specific clinical research question.
4. Estimate statistical power and sample size for clinical investigations, considering real-world determinants such as the magnitude of the expected effect and available resources and subjects.
5. Identify basic statistical techniques for the analysis of data from clinical investigations.
6. Understand the discrepancy between efficacy and effectiveness and describe some reasons why clinical research may fail to change care standards.
7. Identify and apply the basic ethical principles that should guide the design of clinical investigations.
8. Demonstrate knowledge of the role of Institutional Review Boards and related regulation in the context of clinical investigations involving human subjects.
9. Demonstrate the ability to communicate research ideas.
10. Consider special topics in clinical investigation, including use of digital health devices, commercialization of research, communication between scientists and the community, and strategies to improve generalizability of clinical research.

Course Format

This course is offered in a traditional classroom setting. Most class sessions will involve a lecture on the topic listed with explicit opportunities for class discussion and/or group participation. Please remember to turn off cell phones during class and turn on your camera if you are attending by Zoom.

Text and Readings

Optional Textbook: *Designing Clinical Research*, 5th Ed., Browner WS et al.

Additional Readings: Additional required and optional readings specific to the topics presented may be assigned by individual speakers. These additional readings will be distributed on Canvas or by email.

Course Requirements

Attendance

Students are expected to attend all classes. Students who are unable to attend class must seek permission for an excused absence from a Course Director. Unapproved absences or late attendance may result in a lower grade or an "incomplete" for the course. If a student must miss a class, he or she should arrange to review the recorded lecture through the graduate office.

In-Class Assignments

During many class sessions, students will be asked to complete a short exercise and possibly turn it in. This may involve working in pairs or larger groups.

Study Proposal

Proposing a clinical or translational study will help you understand and implement the material learned in class. Formulating questions, study aims, data collection plans, and power calculations to detect significant effect(s) will help develop skills for clinical research implementation. This assignment will occur in steps, so that you receive feedback during the process. We will discuss this project in class, and your unique research proposals will be regarded as private information. All class members and course faculty will be asked to respect the confidentiality of your ideas and of any preliminary discoveries described in your presentation. The components of the proposal and their respective due dates are listed below, as well as on the Course Schedule. **Late assignments will be docked 10% per day late.**

1. 9/9 (Tues) List of three potential clinical research questions
2. 9/18 (Thurs) Draft of specific aims for chosen question
3. 9/30 (Tues) Power calculations to answer primary question
4. 10/9 (Thurs) Take-home Midterm due at midnight
5. 10/14, 10/16 Oral presentation – pitch of research idea (5 slides 5 minutes)
6. 11/11 (Tues) Full proposal due
7. 12/2 (Tues) Take-home Final due at midnight

Exams

Mid-term and end-of-term exams will each consist of short answer and essay questions, and will cover material from lectures, class discussion, and assigned readings; thus attendance and thoughtful consideration of class discussions will be of benefit. While entirely open book, all students should take the exams on their own and contact only course directors or TAs for any questions or assistance.

Grading

Grading will be based on attendance, study proposal elements, mid-term exam, oral presentation, and final exam. The breakdown of course grading is as follows:

Attendance	20 (points)
Oral Presentation	15
Study Proposal	25
Mid-Term Quiz	20
Final Exam	20
Total	**100**

Participation

There will be opportunities for class discussion, and students should come to class prepared to participate. In general, students may feel free to interrupt the lecturer with questions, unless the

lecturer explicitly states a preference for holding questions until the end. Students may also email the Course Directors and TAs with questions or arrange for a 1:1 meeting.

Scientific and Professional Ethics

The work you do in this course must be your own. You must be aware when you are building on the ideas of others – classmates, professors, authors you read – and explicitly acknowledge their contribution. If you ever have questions about the delineation between others' work and your own, ask the Course Directors, who will give you guidance. **We ask that you not use artificial intelligence (AI) tools (e.g. ChatGPT) for writing the proposal, and course directors and teaching assistants will check for this in your text. Using AI for searching reference information is fine, and please confirm the veracity of your search results for AI "hallucination" or "confabulation."**

Technology Requirements and Support

For issues related to Canvas, please contact the Graduate Office by email at: gradprgm@scripps.edu or by phone at: 858-784-8469.

Course Grading
Grading is in accordance with the academic policies of the Skaggs Graduate School.

Grade Point	Letter Grade	
4.00	A	Outstanding achievement. Student performance demonstrates full command of the course subject matter and evinces a high level of originality and/or creativity that far surpasses course expectations.
3.67	A-	Excellent achievement. Student performance demonstrates thorough knowledge of the course subject matter and exceeds course expectations by completing all requirements in a superior manner.
3.33	B+	Very good work. Student performance demonstrates above-average comprehension of the course subject matter and exceeds course expectations on all tasks as defined in the course syllabus. There is notable insight and originality.
3.00	B	Satisfactory work. Student performance meets designated course expectations and demonstrates understanding of the course subject matter at an acceptable level.
2.67	B-	Marginal work. Student performance demonstrates incomplete understanding of course subject matter. There is limited perception and originality.
2.33	C+	Unsatisfactory work. Student performance demonstrates incomplete and inadequate understanding of course subject matter. There is severely limited or no perception or originality. Course will not count toward degree.
2.00	C	Unsatisfactory work. Student performance demonstrates incomplete and inadequate understanding of course subject matter. There is severely limited or no perception or originality. Course will not count toward degree.
0.00	I	Incomplete is assigned when work is of passing quality but is incomplete for a pre-approved reason. Once an incomplete grade is assigned, it remains on student's permanent record until a grade is awarded.

0.00	P	Satisfactory work. Student performance demonstrated complete and adequate understanding of course subject matter. Course will count toward degree.
0.00	F	Unacceptable work/Failure. Student performance is unacceptably low level of knowledge and understanding of course subject matter. Course will not count toward degree. Student may continue in program only with permission of the Dean.
0.00	W	Withdrew from the course with Dean's permission beyond the second week of the term.

- All courses will be recorded and maintained in the student's permanent academic record; only courses that apply towards the degree will appear on the academic transcript. Non-credit or audited courses will not appear on the transcript.
- 4 core courses taken for a letter grade (pass = B- or higher for a core course)
- 2 elective courses taken pass/fail (pass = A, B, C for an elective)

Because students are encouraged to take electives outside their area of expertise, a "C" letter grade is passing.

Summary of Topics: Please refer to the Calendar in Canvas for the most updated list of topics and associated dates

DAY	**DATE**		**TOPIC**	**SPEAKER**
Tues	*9/2*	*No Class*	*No Class*	*N/A*
Thurs	9/4		Class Overview, Anatomy of a Research Question	Laura Nicholson, MD PhD
Tues	9/9	Research Questions, Study Designs, & Data Planning	Clinical Research Questions – PICO	Stuti Jaiswal, MD PhD
Thurs	9/11		Investigating Treatments – Randomized Clinical Trial	Stuti Jaiswal, MD PhD
Tues	9/16		Investigating Exposures – Observational Studies	Stuti Jaiswal, MD PhD
Thurs	9/18		Investigating Prognosis & Diagnostic Tests	Laura Nicholson, MD PhD
Tues	9/23		Statistical Power	Nate Wineinger, PhD*
Thurs	9/25		Statistical Considerations in Study Design	Samantha Spierling, PhD*
Tues	9/30		Efficacy, Effectiveness and Pragmatic Trials	Evan Muse, MD, PhD
Thurs	10/2		Tips for Written Proposals I – Aims/background	Natalie D'Silva, PhD
Tues	10/7	Communicating your Research Plan – Funders, Regulators, & the Community	Pitching your Research	Greg Botta, MD PhD*
Thurs	10/9		Human Subjects Protection / IRB	Jennifer Holmes, CIP*
Tues	10/14		5 Slides in 5 Minutes	Students
Thurs	10/16		5 Slides in 5 Minutes	Students

Tues	10/21		Community Engaged Research	Athena Philis-Tsimikas
Thurs	10/23		Tips for Written Proposals II – approach/pitfalls	Mike Williams, PhD
Tues	10/28		Commercialization of Research and Public-Private Partnerships	Ashley Van Zeeland, PhD MBA*
Thurs	10/30		Early Drug Discovery and Development	Mihee Kim, PhD*
Tues	11/4	Special Topics	Setting Up Your Data Collection	Samantha Spierling, PhD*
Thurs	11/6		Survey Studies	Emily San Diego, PhD*
Tues	11/11		AI in Clinical Studies	Sanjeev Thohan, PhD*
Thurs	11/13		Digital Health Studies	Jay Pandit, MD
Tues	11/18	Proposal Feedback	Mock Study Section	Faculty Group
Thurs	11/20		Mock Study Section	Faculty Group