Course Syllabus – TRBIO 430

Course Information

Course Number: TRBIO 430 FA21
Course Name: Clinical Investigation
Term: Fall 2021
Start Date: 09/09/2021
End Date: 12/10/2021
Credits: 3.0

Meeting Days / Times

Tuesdays and Thursdays, 8:30-10:00am PT / 11:30am-1:00pm ET
(See Calendar in Canvas for the most up-to-date schedule.)

Locations

Graduate Office Large Conference Room (CA) / C304 (FL) / Zoom

Course Managers

Role	Last Name	First Name	Email Address
Course Director	Nicholson	Laura	lnicho@scripps.edu
TA	Lazar	Daniel	dlazar@scripps.edu
TA	Onubogu	Ugoma	uonubogu@scripps.edu

Course Description

This course introduces the design and conduct of clinical research. Students will become familiar with the essential components necessary to conduct clinical studies. Topics will include research design, basic trial biostatistics, ethics and regulatory considerations, grant applications, social science research, research in industry, and the communication of scientific information to peers and to 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 course offered through 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.

Program Learning Outcomes

By the end of the program, students will have accomplished these objectives:
PLO1: Original Research – graduate students are expected to develop the skills critical for generating high-quality research output. This would include absorbing, recalling, and contextualizing scientific knowledge, evaluating scientific information and data, creating testable hypotheses and investigating hypotheses, mastering scientific tools and techniques, displaying ethical behavior, and receiving and giving feedback.
PLO2: Communication – graduate students are expected to demonstrate the oral, written, and media skills to effectively communicate the impact of a study or a body of work to the greater scientific community and to the public at large using a number of methods.
PLO3: Critical Thinking – graduate students are expected to develop a self-directed process to analyze information, form opinions or judgments, and use this process to improve the quality of their scientific thoughts, navigate problems, and make informed decisions.
PLO4: Intellectual Curiosity – graduate students are expected to acquire the capacity to build their intellectual curiosity and demonstrate problem solving approaches that serve their professional growth and ability to impact a field.
PLO5: Career and Professional Development – graduate students are expected to develop a variety of transferable skillsets throughout their graduate experience, including management and leadership, inclusiveness, resilience, scientific rigor, collaboration, accountability, time management, teamwork, networking, and career planning.

Course Learning Outcomes

By the end of this course, students will be able to:
CLO1: Describe various clinical investigation study designs and the advantages and disadvantages of each approach.
CLO2: Identify basic characteristics of a randomized clinical trial and differentiate randomized clinical trials from other types of clinical investigations and epidemiologic studies.
CLO3: Apply basic principles to design a clinical investigation that answers a specific clinical research question.
CLO4: Estimate statistical power and sample size for clinical investigations, taking into account real-world determinants such as the magnitude of the expected effect and available resources and patients.
CLO5: Identify basic statistical techniques for the analysis of data from clinical investigations.
CLO6: Understand the discrepancy between efficacy and effectiveness and describe some reasons why clinical research may fail to change care standards.
CLO7: Identify and apply the basic ethical principles that should guide the design of clinical investigations.
CLO8: Demonstrate knowledge of the role of Institutional Review Boards and related procedures in the context of clinical investigations involving human subjects.
CLO9: Demonstrate grant-writing skills and the ability to communicate your research ideas.
CLO10: Consider special topics in clinical investigations, including use of medical and wireless

devices, commercialization of research, communication between scientists and the community, and considerations for inclusiveness among culturally diverse subjects.

Background Preparation (Prerequisites)

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-translational research as practicing scientists or to collaborate effectively with clinical researchers.

Course Materials

Required: Hulley et al. (2013). Designing clinical research (4th edition). ISBN: 9781608318049.
Recommended: Friedman, Furberg, DeMets, Reboussin & Granger (2015). *Fundamentals of clinical trials* (5th edition). ISBN: 978-3319307732.
Recommended for those who want additional information: Gallin, Ognibene & Johnson (2017). Principles and practice of clinical research (4th edition). ISBN: 9780128499054.
Additional required and optional readings specific to the topics presented may be assigned by individual lecturers. These additional readings will be distributed in class or made available in Canvas.

Expectations and Logistics

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. Please remember to turn off cell phones during class and avoid bringing food that may be disruptive.

In-Class Assignments: During many class sessions, students will be asked to complete a short handout and possibly turn it in. This may involve working in pairs or larger groups.

Grant Proposal: The grant proposal assignment is the most important requirement for this course. The assignment is designed to be completed in stages, so that you will receive feedback during the process. It will help you formulate your ideas and possibly set the stage for you to obtain funding for your proposed project(s) going forward. We will discuss the specific requirements for this project in class, and students will also be provided with examples. The work you turn in will be evaluated by your classmates, the Course Director, and other SRTI/Scripps Research faculty members. Your unique research proposals will be regarded as private information, and all class members and faculty reviewers will be asked to respect the confidentiality of your work and of any preliminary discoveries described in your grant exercise. The components of the project and their respective due dates are listed on the Course Calendar. Late assignments will be docked 10% per day late.

Exam: A take-home exam will consist of short answer and essay questions, and will cover material from lectures, class discussion, and the assigned reading; thus attendance and thoughtful consideration of class discussions will likely be of benefit when taking exams. While it is entirely open-book, each student should take the exam on his/her own and contact only course directors or TAs for any assistance.

Course Extra Credit Option: You will have the option of earning 10 points of extra credit that will count toward your final course grade by identifying an actual grant application solicitation in your area of research and submitting your grant assignment as an application, as the primary investigator (PI) or co-PI. The Course Director must receive confirmation of your submission in order for you to receive extra course credit. For most of you, the mechanisms that will be appropriate are training grants, e.g., predoctoral fellowships, NIH K-Awards, STSI Pilot Awards, SCMG Research and Education Awards.

Participation: There will be a number of opportunities for class discussion, and students should come to class prepared to participate. Along these lines, if something is not clear, please ask. 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 Director and TAs with questions, or arrange for an in-person meeting.

Course Requirements

Grades will be based on the following:

- 10% attendance
- 10% oral presentation
- 50% grant proposal
- 30% exam

Attendance Statement

Students are expected to attend all classes. Students who are unable to attend class must seek permission for an excused absence from the course director or teaching assistant. Unapproved absences or late attendance for three or more classes may result in a lower grade or an "incomplete" for the course. If a student has to miss a class, he or she should view the video for the missed session, through the graduate office.

Scientific and Professional Ethics

The work you do in this course must be your own. Feel free to build on, react to, criticize, and analyze the ideas of others but, when you do, make it known whose ideas you are working with. You must explicitly acknowledge when your work builds on someone else's ideas, including ideas of classmates, professors, and authors you read. If you ever have questions about drawing the line between others' work and your own, ask the course professor who will

give you clear guidance. Exams must be completed independently. Any collaboration on answers to exams, unless expressly permitted, may result in an automatic failing grade and possible expulsion from the Graduate Program.

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. The breakdown of grading is as follows:
Attendance 10%
Oral Presentation 10%
Grant Proposal 50%
Exam 30%

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.

Course Schedule:

Date	Details
Mon Sep 6, 2021	Labor Day (No Class)
Tue Sep 7, 2021	No Class
Thu Sep 9, 2021	Overview of Class, Anatomy of Clinical Research (Nicholson)
Fri Sep 10, 2021	Graduate Student Symposium (No Classes)
Tue Sep 14, 2021	Clinical Research Questions – PICO (Nicholson)
Thu Sep 16, 2021	Investigating Treatments – Randomized Clinical Trial (Nicholson)
	List of 3 Potential Research Questions for Grant Proposal
Tue Sep 21, 2021	Investigating Exposures – Observational Studies (Nicholson)
Thu Sep 23, 2021	Investigating Prognosis & Diagnostic Tests (Nicholson)
Tue Sep 28, 2021	Statistical Considerations in Study Design (Spierling-Bagsic)
	Draft of Specific Aims for Chosen Question
Thu Sep 30, 2021	Statistical Power (Wineinger)
Tue Oct 5, 2021	Planning for your Data Collection (Spierling-Bagsic)
Thu Oct 7, 2021	Efficacy versus Effectiveness (Muse)
	Power Calculations
Tue Oct 12, 2021	Pitching your Research (Botta)
Thu Oct 14, 2021	Community Engaged Research (Philis-Tsimikas)
Tue Oct 19, 2021	Large Scale RCTs: The GUSTO Trial (Topol)
Thu Oct 21, 2021	Science Communication & Social Media (Duglan)
	Quiz Due
Mon Oct 25, 2021	5 Slides for Oral Presentation of Interim Grant Proposal Due
Tue Oct 26, 2021	5 Slides in 5 Minutes (Group #1)
Wed Oct 27, 2021	5 Slides for Oral Presentation of Interim Grant Proposal Due
Thu Oct 28, 2021	5 Slides in 5 Minutes (Group #2)
Tue Nov 2, 2021	Human Subjects Protection/International Studies (Nicholson)
Thu Nov 4, 2021	Privacy Risk (Ramos & Torkamani)
Tue Nov 9, 2021	Mock IRB (Muse)
Thu Nov 11, 2021	Large Data Sets for Population-Based Research (Radin)
Tue Nov 16, 2021	Commercialization of Research and Public-Private Partnerships (Van Zeeland)
Thu Nov 18, 2021	Early Drug Discovery and Development (Kim)
Tue Nov 23, 2021	Thanksgiving Holiday (No Class)
Thu Nov 25, 2021	Thanksgiving Holiday (No Class)
Tue Nov 30, 2021	Digital Health Studies (Bhavnani)
Thu Dec 2, 2021	Social Sciences/Survey Research (Bloss)