Course Syllabus – TRBIO 430

Course Information

Course Number: TRBIO 430 FA19
Course Name: Clinical Investigation
Term: Fall 2019
Start Date: 09/10/2019
End Date: 12/13/2019
Credits: 3.0

Meeting Days / Times

Tuesdays and Fridays, 8:30-10:00am PT / 11:00am-12:30pm ET
(See Calendar in Canvas for the most up-to-date schedule.)

Locations

CA Campus: Graduate Dining Room (Hazen Theory Building)
FL Campus: B214

Course Managers

Role	Last Name	First Name	Email Address
Course Director	Nicholson	Laura	nicholson.laura@scrippshealth.org
Course Co-Director	Muse	Evan	emuse@scripps.edu
Academic TA	Daniel	Lazar	dlazar@scripps.edu
Academic TA	Shepard	Alyssa	ashepard@scripps.edu
Administrative TA	Hill	Theresa	gthill@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: Published research story.
PLO2: Generate creative approaches and methodologies for complex scientific questions.
PLO3: Master a potent set of technical research skills.
PLO4: Possess strong communication skills.

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: 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, all students should take the exam on their 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 arrange to get notes from a fellow student and is strongly encouraged to meet with the teaching assistant to obtain the missed material.

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.

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
Tue Sep 10, 2019	Overview of Clinical Research & Building a Study Protocol (Nicholson)
Fri Sep 13, 2019	The Randomized Clinical Trial & Trial Phases (Nicholson)
Tue Sep 17, 2019	Observational Studies & Retrospective Analyses (Nicholson)
Fri Sep 20, 2019	Efficacy versus Effectiveness (Muse)
	List of 3 Potential Research Questions for Grant Proposal
Tue Sep 24, 2019	Human Research: Rules, Regulations and Ethics (Holmes)
Fri Sep 27, 2019	Human Research: Case Study Analysis (Holmes)
Tue Oct 1, 2019	Statistical Considerations in Study Design (Wineinger)
Fri Oct 4, 2019	Statistical Power (Wineinger)
	Draft of Specific Aims for Chosen Question
Tue Oct 8, 2019	Meta-Analysis (Waalen)
Fri Oct 11, 2019	Multi-Site/International Trials (AuYoung)
Tue Oct 15, 2019	Managing Your Data for Efficient Interpretation (Waalen)
Fri Oct 18, 2019	Commercialization of Research and Public-Private Partnerships (Ashley Van Zeeland)
Tue Oct 22, 2019	Large Scale RCTs: The GUSTO Trial (Topol)
Fri Oct 25, 2019	Scientific Communication, Beyond Your Comfort Zone (Quigley)
Tue Oct 29, 2019	Student Grant Proposal Interim Presentation
	Quick Pitch (https://members.sdvg.org/event-3395732)
	5 Slides for Oral Presentation of Interim Grant Proposal Due
Fri Nov 1, 2019	Student Grant Proposal Interim Presentation
	5 Slides for Oral Presentation of Interim Grant Proposal Due
Tue Nov 5, 2019	Research Using Existing Data (Quer)
Fri Nov 8, 2019	Early Discovery and Development: how target selection and biomarkers can influence clinical trial design (Mihee Kim)
Tue Nov 12, 2019	Applying for Funding/Grant Writing (Teyton)
	Draft of Study Proposal, including Preliminary Data (if any)
Fri Nov 15, 2019	Community Engaged Research (Philis-Tsimikas)
Tue Nov 19, 2019	Remote Monitoring & Clinical Research (Muse)
Fri Nov 22, 2019	Graduate Student Symposium (No Class)
	Social Sciences/Survey Research (Bloss)
Tue Nov 26, 2019	Final Grant Proposal
Fri Nov 29, 2019	Thanksgiving Holiday (No Class)
Tue Dec 3, 2019	Student Grant Proposals & Mock Study Section