PUBH 6303, SECTION 001

Clinical Research Project Seminar
Spring 2019

COURSE & CONTACT INFORMATION
Credits: 2
Meeting Day(s): Mondays
Meeting Time: 2:30pm – 4:25pm
Meeting Place: MoosT 1-317

Instructor: Russell V. Luepker, MD, MS
Email: luepk001@umn.edu
Office Phone: 612-624-6362
Fax: 612-624-0315
Office Hours: By appointment
Office Location: MoosT and WBOB

COURSE DESCRIPTION
This seminar is designed for clinical research students. It allows them to present their thesis work. This constitutes approximately 50% of the class time.

The other 50% of the class time is spent reviewing NIH grant applications in a NIH study section format.

COURSE PREREQUISITES
Clinical Research MS or Certificate students: other students with appropriate academic/professional background may be admitted with permission of instructor. Prerequisites are Fundamentals of Clinical Research, Biostatistics and Epidemiology.

COURSE GOALS & OBJECTIVES
The Clinical Research Seminar has five major objectives:
1. To learn to present and critique NIH research protocols.
2. To learn more about issues facing an investigators interaction with the IRB and NIH.
3. To better understand NIH review processes.
4. To present student research in a supportive environment.
5. To become certified in the Responsible Conduct of Research (RCR).

METHODS OF INSTRUCTION AND WORK EXPECTATIONS
Lectures and student presentations

Objective 1: Protocol review will give students an opportunity to review and critique applications to the NIH. These will include R01, R21, T32 and other NIH categories. Student will be expected to write NIH-type reviews and lead discussions in a NIH study section format.

Objective 2: Invited experts will present on research record keeping and FDA.

Objective 3: The seminar will give students the opportunity to present their thesis project in clinical research. Lecturers will focus on topics relevant to these projects.

Objective 4: As part of the course, it is mandatory that each student complete the Universities web-based program in RCR: https://research.umn.edu/units/rco/training-education/responsible-conduct-research-rcr-core-curriculum

Like other work in the course, all student to student communication is covered by the Student Conduct Code (https://z.umn.edu/studentconduct).

COURSE TEXT & READINGS
None

COURSE OUTLINE/WEEKLY SCHEDULE

Week	Topic	Speaker(s)
Week 1: January 28, 2019	• **Introduction** • **Reviewing an NIH Grant**	• **Russell Luepker**
Week 2: February 4, 2019	• **How to prepare for an FDA inspection** • **Footprinting research activity in the medical chart**	• **Harvey Arbit & Wrenda Teeple** • **Jo-Anne Young**
Week 3: February 11, 2019	• **Grant Review**	• **Russell Luepker**
Week 4: February 18, 2019	• **Grant Review**	• **Russell Luepker**
Week 5: February 25, 2019	• **Grant Review**	• **Russell Luepker**
Week 6: March 4, 2019	• **Grant Review**	• **Russell Luepker**
Week 7: March 11, 2019	• **Grant Review**	• **Russell Luepker**
Week 8: March 25, 2019	• **NO CLASS - RCR Training**	
Week 9: April 1, 2019	• **Grant Review**	• **Russell Luepker**
Week 10: April 8, 2019	• **Thesis Presentations**	• **Russell Luepker**
Week 11: April 15, 2019	• **Thesis Presentations**	• **Russell Luepker**
Week 12: April 22, 2019	• **Thesis Presentations**	• **Russell Luepker**
Week 13: April 29, 2019	• **Thesis Presentations**	• **Russell Luepker**
Week 14: May 6, 2019	• **Thesis Presentations**	• **Russell Luepker**
Week 15: May 13, 2019	• **Thesis Presentations**	• **Russell Luepker**

SPH AND UNIVERSITY POLICIES & RESOURCES

The School of Public Health maintains up-to-date information about resources available to students, as well as formal course policies, on our website at www.sph.umn.edu/student-policies/. Students are expected to read and understand all policy information available at this link and are encouraged to make use of the resources available.

The University of Minnesota has official policies, including but not limited to the following:
- Grade definitions
- Scholastic dishonesty
- Makeup work for legitimate absences
- Student conduct code
- Sexual harassment, sexual assault, stalking and relationship violence
- Equity, diversity, equal employment opportunity, and affirmative action
- Disability services
- Academic freedom and responsibility

Resources available for students include:
- Confidential mental health services
- Disability accommodations
- Housing and financial instability resources
- Technology help
- Academic support

EVALUATION & GRADING

Evaluation

Students will be evaluated based on their preparation of their thesis project and quality of participation in all aspects of the seminar. The web-based program in RCR and attendance are required (prior approval required for absenteeism).

- Class participation in the discussion process and written reports (70%)
- Oral presentations (30%)

Grading Criteria

The grading for this course is S/N.

N - Represents failure (or no credit) and signifies that the work was either (1) completed but at a level of achievement that is not worthy of credit or (2) was not completed and there was no agreement between the instructor and the student that the student would be awarded an I.

S - Achievement that is satisfactory will be expected to complete all assignments and receive a minimum of 70% to receive a passing score (achievement required for a S is at the discretion of the instructor but may be no lower than 70%).

Evaluation/Grading Policy	Evaluation/Grading Policy Description
Scholastic Dishonesty, Plagiarism, Cheating, etc.	You are expected to do your own academic work and cite sources as necessary. Failing to do so is scholastic dishonesty. Scholastic dishonesty means plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; altering, forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis (As defined in the Student Conduct Code). For additional information, please see https://z.umn.edu/dishonesty The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: https://z.umn.edu/integrity. If you have additional questions, please clarify with your instructor. Your instructor can respond to your specific questions regarding what would constitute scholastic dishonesty in the context of a particular class-e.g., whether collaboration on assignments is permitted, requirements and methods for citing sources, if electronic aids are permitted or prohibited during an exam. Indiana University offers a clear description of plagiarism and an online quiz to check your understanding (http://z.umn.edu/iuplagiarism).

Late Assignments	If late, permission must be requested.
Attendance Requirements	No more than 1 unexcused absence.
Extra Credit	N/A