

PubH 6303 - Section 001
Clinical Research Project Seminar
Spring 2009

Credits:	2	
Meeting Days:	Mondays	
Meeting Time:	2:30pm - 4:25pm	
Meeting Place:	Mayo D327	
Instructors:	Russell V. Luepker, MD, MS	William Thomas, PhD
Office Address:	300 WBOB or 1-321 Moost	A460 Mayo
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Office Hours:	By Appointment	2:30–3:30 Wednesdays or by appointment

I. Course Description

This seminar is designed for clinical research MS students. It allows them to present their thesis work in a preliminary form. This constitutes 50% of the class.

The other 50% of the class is spent reviewing study proposals for the General Clinical Research Center (GCRC). Students critique these proposals for scientific integrity and ethical considerations.

II. Course Prerequisites

Clinical Research MS students; other students with appropriate academic/professional background may be admitted with permission of instructor. Prerequisites are Fundamentals of Clinical Research and Epidemiology I.

III. Course Goals and Objectives

The principle objective of the Clinical Research Seminar has four major purposes:

1. To learn to present and critique clinical research protocols.
2. To learn more about issues facing an investigators interaction with the IRB, FDA, and NIH.
3. To provide a venue for discussion of contemporary topics in clinical research.
4. To become certified in the Responsible Conduct of Research (RCR).

IV. Methods of Instruction and Work Expectations

Lecture and student presentations

Aim 1: The GCRC Scientific Advisory Committee (SAC) meets the first and third Monday at 4:00pm in Conference Room 245, Office of Clinical Research (OCR), 717 Delaware St SE. During the week before this meeting, protocols to be reviewed will be posted as PDF documents on the GCRC website and email notices will be sent to students. Each student will write a summary and critique of these protocols. From

2:30 until 3:45, students will review the protocols and discuss their criticisms. Then the students walk to the OCR to attend and participate in the SAC meeting.

Aim 2: The seminar will give students the opportunity to present their thesis project in clinical research. Lecturers will focus on topics relevant to these projects.

As part of the course, it is mandatory that each student complete the Universities web-based program in RCR <http://www.research.umn.edu/first/>

V. Course Text and Readings

None

VI. Course Outline/Weekly Schedule

Class	Date	Topic	Speaker(s)
Class 1	January 26	Introduction IND Process I	Russell Luepker Will Thomas Harvey Arbit
Class 2	February 2	How to Prepare for an FDA Inspection	Harvey Arbit
Class 3	February 9	GCRC SAC Meeting	Will Thomas
Class 4	February 16	No Class - work on presentations	
Class 5	February 23	GCRC SAC Meeting	Will Thomas
Class 6	March 2	Thesis Presentation	Russell Luepker
Class 7	March 9	GCRC SAC Meeting	Will Thomas
	March 16	Spring break, no class	
Class 8	March 23	GCRC SAC Meeting	Will Thomas
Class 9	March 30	Thesis Presentation	Russell Luepker
Class 10	April 6	GCRC SAC Meeting	Will Thomas
Class 11	April 13	Thesis Presentation	Russell Luepker
Class 12	April 20	GCRC SAC Meeting	Will Thomas
Class 13	April 27	Thesis Presentation	Russell Luepker
Class 14	May 4	GCRC SAC Meeting	Will Thomas
Class 15	May 11	Thesis Presentation	Russell Luepker

VII. Evaluation and 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 option for this course is A-F or S/N. Grades will be assigned on the basis of total number of grade points earned as listed below.

Final grades will be assigned as follows:

100 - 95	A	(4.0) Represents achievement that is outstanding relative to the level necessary to meet course requirements
90 - 94	A-	
87 - 89	B+	
83 - 86	B	(3.0) Represents achievement that is significantly above the level necessary to meet course requirements
80 - 82	B-	
77 - 79	C+	
73 - 76	C	(2.0) Represents achievement that meets the minimum course requirement
70 - 72	C-	

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%).

Course Evaluation

Beginning in fall 2008 the SPH will collect student course evaluations electronically using a software system called CoursEval. The system will send email notifications to students when they can access and complete their course evaluations. Students who complete their course evaluations promptly will be able to access their final grades just as soon as the faculty member renders the grade. All students will have access to their final grades two weeks after the last day of the semester regardless of whether they completed their course evaluation or not. Student feedback on course content and faculty teaching skills are important means for improving our work. Please take the time to complete a course evaluation for each of the courses for which you are registered.

Incomplete Contracts

A grade of incomplete "I" shall be assigned at the discretion of the instructor when, due to extraordinary circumstances (e.g., documented illness or hospitalization, death in family, etc.), the student was prevented from completing the work of the course on time. The assignment of an "I" requires that a contract be initiated and completed by the student before the last day of class, and signed by both the student and instructor. If an incomplete is deemed appropriate by the instructor, the student in consultation with the instructor, will specify the time and manner in which the student will complete course requirements. Extension for completion of the work will not exceed one year (or earlier if designated by the student's college). For more information and to initiate an incomplete contract, students should go to:

www.sph.umn.edu/grades.

University of Minnesota Uniform Grading and Transcript Policy

A link to the policy can be found at onestop.umn.edu.

VIII. Other Course Information and Policies

Grade Option Change (if applicable)

For full-semester courses, students may change their grade option, if applicable, through the second week of the semester. Grade option change deadlines for other terms (i.e. summer and half-semester courses) can be found at onestop.umn.edu.

Course Withdrawal

Students should refer to the Refund and Drop/Add Deadlines for the particular term at onestop.umn.edu for information and deadlines for withdrawing from a course. As a courtesy, students should notify their instructor and, if applicable, advisor of their intent to withdraw.

Students wishing to withdraw from a course after the noted final deadline for a particular term must contact the School of Public Health Student Services Center at sph-ssc@umn.edu for further information.

Student Conduct, Scholastic Dishonesty and Sexual Harassment Policies

Students are responsible for knowing the University of Minnesota, Board of Regents' policy on Student Conduct and Sexual Harassment found at www.umn.edu/regents/polindex.html.

Students are responsible for maintaining scholastic honesty in their work at all times. Students engaged in scholastic dishonesty will be penalized, and offenses will be reported to the Office of Student Academic Integrity (OSAI, www.osai.umn.edu).

The University's Student Conduct Code defines scholastic dishonesty as "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; or altering, forging, or misusing a University academic record; or fabricating or falsifying of data, research procedures, or data analysis."

Plagiarism is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: <http://writing.umn.edu/tww/plagiarism/>.

Students are urged to be careful that they properly attribute and cite others' work in their own writing. For guidelines for correctly citing sources, go to <http://tutorial.lib.umn.edu/> and click on "Citing Sources".

In addition, original work is expected in this course. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable.

Disability Statement

It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have a documented disability (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services to have a confidential discussion of their individual needs for accommodations. Disability Services is located in Suite 180 McNamara Alumni Center, 200 Oak Street. Staff can be reached by calling 612/626-1333 (voice or TTY).