

PubH 6305-Section 001**Introduction to Clinical Research for Health Professionals
Spring 2009**

Credits:	2
Meeting Days:	Mondays
Meeting Time:	11:15am - 1:10pm
Meeting Place:	1-430 MoosT
Instructor:	Russell V. Luepker, MD, MS
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Office Hours:	By Appointment

I. Course Description

This course will provide learning opportunities on the design and implementation of clinical research protocols. It is an introductory course intended for nurses and other health professional staff working in or preparing to work in a clinical research setting. It aims to enhance the knowledge and skills of research staff working in medical research in humans.

This course is being taught in response to a request from the AHC Administration and is part of the effort to provide skills in research and clinical disciplines by the Office of Clinical Research to AHC units, a high priority in the strategic planning process of the AHC. It will be taught by the Clinical Research graduate faculty and guest lecturers in that program although it is not part of the formal requirements for the MS program.

II. Course Prerequisites

Bachelors degree and/or RN degree or student in AHC graduate program (Dentistry, Medicine, Nursing, Pharmacy, Public Health, Vet Medicine) or permission from instructor.

III. Course Goals and Objectives

Students will understand:

- A. Types and characteristics of clinical research study designs;
- B. ethical issues;
- C. functions and requirements of the Institutional Review Board (IRB);
- D. role of industry, the FDA and the PHS in clinical research;
- E. roles and responsibilities of clinical research staff;
- F. organization, budgeting and implementation of clinical research;
- G. presentation of clinical research protocols.

IV. Methods of Instruction and Work Expectations

Lectures - Principal Method

Readings

Student Discussion/Exercises/Group Presentations

V. Course Text and Readings

Friedman LM, Furberg CD, Demets DL (eds). Fundamentals of Clinical Trials, 3rd edition. New York, NY, Springer-Verlag New York Inc., 1998.

Available at the Coffman Union Bookstore

VI. Course Outline/Weekly Schedule

<i>Date</i>	<i>Topic</i>	<i>Readings</i>	<i>Assignment</i>	<i>Assignment Due Date</i>	<i>Instructor</i>
January 26	Introduction	Chapter 1 Readings 1-10 Lecture Notes			Russell Luepker
February 2	Study Designs	Chapters 3, 4, 6 Lecture Notes	Assignment 1		Russell Luepker
February 9	Ethics in Clinical Research TBA	Lecture Notes		Assignment 1 - DUE	Mary Faith Marshall TBA
February 16	Study Management • Roles & Responsibilities • Budgeting	Reading 14 Lecture Notes Handouts	Assignment 2		Debbie Dykhuis
February 23	Recruitment and Retention	Chapters 9, 13 Readings 11-13 Lecture Notes		Assignment 2 - DUE	Russell Luepker
	Measurement Issues	Lecture Notes			
March 2	Conflict of Interest	Lecture Notes			Robert Cipolle
	Informed Consent	Lecture Notes			Patrice Webster
March 9	Data Collection and Recording • Forms Design	Chapter 10 Lecture Notes Handout	Assignment 3		Eileen Harwood
	IND Process	Lecture Notes			Harvey Arbit
March 16	SPRING BREAK				
March 23	TBA Work on Assignment 5 with Group in Class			Assignment 3 - DUE	Hanna Bloomfield Russell Luepker
March 30	MIDTERM EXAM				
April 6	Confidentiality	Lecture Notes			Russell Luepker
April 13	NIH, Industry and FDA	Lecture Notes			Alan Berger
April 20	Reporting Adverse Events	Chapter 11 Lecture Notes	Assignment 4 Assignment 5		Alan Berger
April 27	Group Presentations			Assignment 4 - DUE	Russell Luepker
May 4	Group Presentations			Assignment 5 - DUE	Russell Luepker
May 11	FINAL EXAM				Russell Luepker

VII. Evaluation and Grading

Midterm Exam	25%
Exercises	30% (5 exercises)
Group Presentation	10%
Final Exam	35%

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).