



PubH 6301-001 Fundamentals of Clinical Research Fall 2016

Credits:	3
Meeting Days:	Thursdays
Meeting Time:	11:15am – 1:10pm
Meeting Place:	Mayo D325
Instructor:	Russell V. Luepker, MD, MS and Kamakshi Lakshminarayan, MD, PhD, MS
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Office Hours:	By appointment

I. Course Description

This course is intended to provide a foundation for the more advanced study that is necessary to become an accomplished clinical research investigator. This course will review the concepts that underlie successful clinical research design, implementation, and reporting. This course will also introduce students to the resources and opportunities available to support clinical research at the academic health center.

II. Course Prerequisites

This course is a core requirement for Clinical Research MS students and Clinical Research Certificate students. Other students with appropriate academic/professional backgrounds (e.g., any post-bachelor health degree) may be admitted with the permission of the instructor.

III. Course Goals and Objectives

On completing this course, the student should be able to:

- Utilize a practical knowledge base that can be applied to the variety of approaches to clinical research;
- Understand the stages involved in clinical research, components of design, and types of trials;
- Understand the roles of the FDA, industry sponsors, and the NIH in the clinical research enterprise;
- Understand the study and challenges of research in different populations;
- Understand the ethical issues associated with research in humans; and
- Be familiar with the resources that are available for clinical research within the Academic Health Center.

IV. Methods of Instruction and Work Expectations

This course is largely delivered via the web. It is required to participate in web-based discussions. Participation in web classes and discussion is required. Attendance will be taken and more than **two** unexcused absences will result in loss of final grade points (Section VII).

Students are required to submit at least one question for discussion on the Monday prior to class.

V. Course Text and Readings

Textbook:

Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing Clinical Research. Fourth Edition. Lippincott Williams & Wilkins, 2013.

Additional Readings:

Readings will be posted on the Moodle as required for each lecture.

VI. Course Outline/Weekly Schedule:

CLASS	DATES	TOPIC	LEADER	READINGS	ASSIGNMENT AND DUE DATES
1a	9/8/16	Course Overview	Russell Luepker	Lecture Notes	
1b		Context for Clinical Research: Definitions, Terminology and History of Clinical Research		Chapters 1, 2 Readings 1-10	
2a	9/15/16	Study Designs	Russell Luepker	Lecture Notes Chapters 7, 8	
2b		Recruitment and Retention	Russell Luepker	Lecture Notes Readings 11-14	Assignment 1
3a	9/22/16	Clinical Trials I & Clinical Trials II: Precision and Accuracy	Russell Luepker	Lecture Notes Chapters 4, 10-12 Reading 15	Assignment 1: Due Assignment 2
3b		IND Application, Process, and Responsibility	Harvey Arbit	Lecture Notes	
4a	9/29/16	Ethics of Clinical Research	Debra DeBruin	Lecture Notes Readings 16-18 Chapter 14	Assignment 3
4b		Meta-analysis	Sue Duval	Lecture Notes	
5a	10/6/16	Working with Affiliated Institutions	George Tadros	Lecture Notes	Assignment 2: Due
5b		Working with the Elderly in Clinical Research	Bob Kane	Lecture Notes	
6a	10/13/16	Management of the Clinical Research Team	James Begun	Lecture Notes	Assignment 3: Due
6b		Challenges in Emergency and Acute Care Research	Michelle Biros	Lecture Notes	
7a	10/20/16	Developing and Testing Medical Devices	Bob Wilson	Lecture Notes	
7b		Clinical Research in Mental Health Patients	Chuck Schulz	Lecture Notes	
8a	10/27/16	Clinical Research with Pharmaceutical Companies: Practical Issues	Russell Luepker for Mohamed Eid	Lecture Notes Readings 19-23	Assignment 4
8b		Mid-Term Exam			
9a	11/3/16	Clinical Research in the International Setting	Alan Lifson	Lecture Notes	
9b		Conducting Outcomes Research	Kamakshi Lakshminarayan	Lecture Notes Readings 24-28	
10a	11/10/16	Using Laboratory Testing in Clinical Research	Bharat Thyagarajan	Lecture Notes	Assignment 4: Due
10b		Working with Minorities and the Disadvantaged in CR	Russell Luepker for Tracie Collins	Lecture Notes	
10c		Clinical Research in the Surgical Setting	Russell Luepker for Todd Tuttle	Lecture Notes	

CLASS	DATES	TOPIC	LEADER	READINGS	ASSIGNMENT AND DUE DATES
11a	11/17/16	Adverse Events and Reporting / DSMB	Kamakshi Lakshminarayan	Lecture Notes Readings 29-31 Readings 32-33	Assignment 5
11b		Practice-Based Research: A Dental Example	Don Nixdorf	Lecture Notes Readings 34-35	
	11/24/16	THANKSGIVING (NO CLASS)			
12a	12/1/16	Clinical Research in Children	Julia Steinberger	Lecture Notes	Assignment 5: Due
12b		Role of the NIH in Clinical Research	Kamakshi Lakshminarayan	Lecture Notes Readings 36-37	
13a	12/8/16	Conflict of Interest	Michael Oakes	Lecture Notes	
13b		Comparative Effectiveness	Alan Hirsch	Lecture Notes Readings 38-43	
14a & 14b	12/15/16	STUDY DAY			
15a & 15b	12/22/16	FINAL EXAM emphasizes last half [classes 8-13] but includes materials from the entire course	Russell Luepker		

VII. Evaluation and Grading

Point values for determining the final course grade are assigned as follows:

Midterm exam	20 points
Final exam	20 points
Homework Assignment 1	10 points
Homework Assignment 2	10 points
Homework Assignment 3	10 points
Homework Assignment 4	10 points
Homework Assignment 5	10 points
Discussion, Attendance & Participation in Group Presentation	10 points (missing >5 - loss of 10 points; missing >3 - loss of 5 points)

Final grades will be assigned as follows:

100-94	A	(4.0) Represents achievement that is outstanding relative to the level necessary to meet course requirements
90-93	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%).

For additional information, please refer to:

<http://policy.umn.edu/Policies/Education/Education/GRADINGTRANSCRIPTS.html>.

Course Evaluation

The SPH will collect student course evaluations electronically using a software system called CourseEval: www.sph.umn.edu/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 in SPHGrades: www.sph.umn.edu/grades. All students will have access to their final grades through OneStop 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 an 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 official 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 SPHGrades at: 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 Office of Admissions and Student Resources at sph-ssc@umn.edu for further information.

Student Conduct Code:

The University seeks an environment that promotes academic achievement and integrity, that is protective of free inquiry, and that serves the educational mission of the University. Similarly, the University seeks a community that is free from violence, threats, and intimidation; that is respectful of the rights, opportunities, and welfare of students, faculty, staff, and guests of the University; and that does not threaten the physical or mental health or safety of members of the University community.

As a student at the University you are expected adhere to Board of Regents Policy: *Student Conduct Code*. To review the Student Conduct Code, please see:

http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf.

Note that the conduct code specifically addresses disruptive classroom conduct, which means "engaging in behavior that substantially or repeatedly interrupts either the instructor's ability to teach or student learning. The classroom extends to any setting where a student is engaged in work toward academic credit or satisfaction of program-based requirements or related activities."

Use of Personal Electronic Devices in the Classroom:

Using personal electronic devices in the classroom setting can hinder instruction and learning, not only for the student using the device but also for other students in the class. To this end, the University establishes the right of each faculty member to determine if and how personal electronic devices are allowed to be used in the classroom. For complete information, please reference:

<http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Scholastic Dishonesty:

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. (Student Conduct Code:

http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf) If it is determined that a student has cheated, he or she may be given an "F" or an "N" for the course, and may face additional sanctions from the University. For additional information, please see:

<http://policy.umn.edu/Policies/Education/Education/INSTRUCTORRESP.html>.

The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: <http://www1.umn.edu/oscai/integrity/student/index.html>. If you have additional questions, please clarify with your instructor for the course. 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.

Makeup Work for Legitimate Absences:

Students will not be penalized for absence during the semester due to unavoidable or legitimate circumstances. Such circumstances include verified illness, participation in intercollegiate athletic events, subpoenas, jury duty, military service, bereavement, and religious observances. Such circumstances do not include voting in local, state, or national elections. For complete information, please see:

<http://policy.umn.edu/Policies/Education/Education/MAKEUPWORK.html>.

Appropriate Student Use of Class Notes and Course Materials:

Taking notes is a means of recording information but more importantly of personally absorbing and integrating the educational experience. However, broadly disseminating class notes beyond the classroom community or accepting compensation for taking and distributing classroom notes undermines instructor interests in their intellectual work product while not substantially furthering instructor and student interests in effective learning. Such actions violate shared norms and standards of the academic community. For additional information, please see:

<http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>.

Sexual Harassment:

"Sexual harassment" means unwelcome sexual advances, requests for sexual favors, and/or other verbal or physical conduct of a sexual nature. Such conduct has the purpose or effect of unreasonably interfering with an individual's work or academic performance or creating an intimidating, hostile, or offensive working or academic environment in any University activity or program. Such behavior is not acceptable in the University setting. For additional information, please consult Board of Regents Policy:

<http://regents.umn.edu/sites/default/files/policies/SexHarassment.pdf>

Equity, Diversity, Equal Opportunity, and Affirmative Action:

The University will provide equal access to and opportunity in its programs and facilities, without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression. For more information, please consult Board of Regents Policy:

http://regents.umn.edu/sites/default/files/policies/Equity_Diversity_EO_AA.pdf.

Disability Accommodations:

The University of Minnesota is committed to providing equitable access to learning opportunities for all students. The Disability Resource Center Student Services is the campus office that collaborates with students who have disabilities to provide and/or arrange reasonable accommodations.

If you have, or think you may have, a disability (e.g., mental health, attentional, learning, chronic health, sensory, or physical), please contact DRC at 612-626-1333 or drc@umn.edu to arrange a confidential discussion regarding equitable access and reasonable accommodations.

If you are registered with DS and have a current letter requesting reasonable accommodations, please contact your instructor as early in the semester as possible to discuss how the accommodations will be applied in the course.

For more information, please see the DS website, <https://diversity.umn.edu/disability/>.

Mental Health and Stress Management:

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance and may reduce your ability to participate in daily activities. University of Minnesota services are available to assist you. You can learn more about the broad range of confidential mental health services available on campus via the Student Mental Health Website: <http://www.mentalhealth.umn.edu>.

The Office of Student Affairs at the University of Minnesota:

The Office for Student Affairs provides services, programs, and facilities that advance student success, inspire students to make life-long positive contributions to society, promote an inclusive environment, and enrich the University of Minnesota community.

Units within the Office for Student Affairs include, the Aurora Center for Advocacy & Education, Boynton Health Service, Central Career Initiatives (CCE, CDes, CFANS), Leadership Education and Development –Undergraduate Programs (LEAD-UP), the Office for Fraternity and Sorority Life, the Office for Student Conduct and Academic Integrity, the Office for Student Engagement, the Parent Program, Recreational Sports, Student and Community Relations, the Student Conflict Resolution Center, the Student Parent HELP Center, Student Unions & Activities, University Counseling & Consulting Services, and University Student Legal Service.

For more information, please see the Office of Student Affairs at <http://www.osa.umn.edu/index.html>.

Academic Freedom and Responsibility: *for courses that do not involve students in research:*

Academic freedom is a cornerstone of the University. Within the scope and content of the course as defined by the instructor, it includes the freedom to discuss relevant matters in the classroom. Along with this freedom comes responsibility. Students are encouraged to develop the capacity for critical judgment

and to engage in a sustained and independent search for truth. Students are free to take reasoned exception to the views offered in any course of study and to reserve judgment about matters of opinion, but they are responsible for learning the content of any course of study for which they are enrolled.*

Reports of concerns about academic freedom are taken seriously, and there are individuals and offices available for help. Contact the instructor, the Department Chair, your adviser, the associate dean of the college (Dr. Kristin Anderson, SPH Dean of Student Affairs), or the Vice Provost for Faculty and Academic Affairs in the Office of the Provost.

- *Language adapted from the American Association of University Professors "Joint Statement on Rights and Freedoms of Students".*

Student Academic Success Services (SASS): <http://www.sass.umn.edu>:

Students who wish to improve their academic performance may find assistance from Student Academic Support Services. While tutoring and advising are not offered, SASS provides resources such as individual consultations, workshops, and self-help materials.