

PUBH 6301, SECTION 320

Fundamentals of Clinical Research
 Fall 2019

COURSE & CONTACT INFORMATION

Credits: 3 credits

Online Course: This course is entirely web-based, delivered via Canvas at <http://canvas.umn.edu>

Online Meeting Sessions: This course also meets online each week in a live/synchronous session using Zoom video conferencing: Thursdays from 11:15am - 1:10pm.

Contact Type	Contact Information	Role	When to Contact
Instructors	Russell V. Luepker, MD, MS luepk001@umn.edu [Phone] 612/624-6362 [Fax] 612/624-0315 Kamakshi Lakshminarayan, MD, PhD, MS laksh004@umn.edu [Phone] 612/624-9492 [Fax] 612/624-0315	Primary instructor for this course	Contact your instructors via the <i>Course Q&A</i> link on the Canvas home page, or in lesson-specific forums. Your instructors will check the forums at least once a day and returning emails within 48 hours M-F. You can also contact the instructors directly via email. Please use email for private matters.
Technical Support	Technical support options are available on the SPH website. https://z.umn.edu/sphquickhelp	Troubleshoots technical issues related to the course site or course content.	Technical issues with the course site, media, quizzes or assignments.

Please save this contact information to your computer or print it. That way, you can still contact us in the event that you have difficulty connecting to the Internet or accessing the syllabus.

Communication in Online Courses

Communication is especially important in an online course. The course site announcement forums/discussions and email will be used to communicate with students. You are responsible for reading all course-related emails sent to your University email account and contacting us in a timely manner with any questions you may have. We strongly recommend that you check your U of M email daily. Our goal is to respond to emails within 48 hours Monday-Friday.

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.

COURSE PREREQUISITES

This course is a core requirement for Clinical Research MS 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.

COURSE GOALS & 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 population groups;
- Understand the ethical issues with research in humans;
- Be familiar with the resources that are available for clinical research within the Academic Health Center.

METHODS OF INSTRUCTION AND WORK EXPECTATIONS

Course Workload Expectations

PubH 6301, Fundamentals of Clinical Research, is a 3-credit course. The University expects that for each credit, you will spend a minimum of three hours per week attending class or comparable online activity, reading, studying, completing assignments, etc. over the course of a 15-week term. Thus, this course requires approximately 135 hours of effort spread over the course of the term in order to earn an average grade. Therefore, time you would otherwise be in class will be incorporated into work for the course in the form of online discussions, lectures, etc.

This course is entirely online with a live/synchronous class session each week using Zoom video conferencing.

- Thursdays from 11:15am - 1:10pm
- Attendance is mandatory for the in-person sessions. Contact your instructors if you are unable to attend a live class session. Unexcused absences: missing >5 = loss of 10 points; >3 = loss of 5 points.

Technology

You will use the following technology tools in this course. Please make yourself familiar with them.

- **Zoom video conferencing software:** <https://umn.zoom.us/>

Learning Community

School of Public Health courses ask students to discuss frameworks, theory, policy, and more, often in the context of past and current events and policy debates. Many of our courses also ask students to work in teams or discussion groups. We do not come to our courses with identical backgrounds and experiences and building on what we already know about collaborating, listening, and engaging is critical to successful professional, academic, and scientific engagement with topics.

In this course, students are expected to engage with each other in respectful and thoughtful ways.

In group work, this can mean:

- Setting expectations with your groups about communication and response time during the first week of the semester (or as soon as groups are assigned) and contacting the TA or instructor if scheduling problems cannot be overcome.
- Setting clear deadlines and holding yourself and each other accountable.
- Determining the roles group members need to fulfill to successfully complete the project on time.
- Developing a rapport prior to beginning the project (what prior experience are you bringing to the project, what are your strengths as they apply to the project, what do you like to work on?)

In group discussion, this can mean:

- Respecting the identities and experiences of your classmates.
- Avoid broad statements and generalizations. Group discussions are another form of academic communication and responses to instructor questions in a group discussion are evaluated. Apply the same rigor to crafting discussion posts as you would for a paper.
- Consider your tone and language, especially when communicating in text format, as the lack of other cues can lead to misinterpretation.

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

Textbook:

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

- ****Please note:** the required textbook for this course is available as an eBook for free via the University of Minnesota Libraries. Please check the course Canvas site—the link appears under Required Readings in Lesson pages).

This course uses journal articles, which are available via the University Libraries' E-Reserves and will be linked from the course site. It is good practice to use a citation manager to keep track of your readings. More information about citation managers is available at <https://www.lib.umn.edu/pim/citation>.

COURSE OUTLINE/WEEKLY SCHEDULE

This course has specific deadlines. All coursework must be submitted via the course site before the date and time specified on the site. **Note: assignments are due by 11:55pm CST unless indicated otherwise.**

Week		Lesson	Lecturer	Readings	Assignments
1 9/5/19	1a	Course Introduction	<ul style="list-style-type: none"> Course Introduction (Luepker) 		<ul style="list-style-type: none"> Post Discussion Questions (due Monday) Begin working on Assignment 1 (due 9/19)
	1b	Current Context of Clinical Research History of Clinical Research	<ul style="list-style-type: none"> Current Context of Clinical Research (Luepker) History of Clinical Research (Luepker) 	<ul style="list-style-type: none"> Chapters 1, 2 Additional readings - see the Canvas site 	
2 9/12/19	2a	Study Designs	<ul style="list-style-type: none"> Study Designs (Luepker) 	<ul style="list-style-type: none"> Chapters 7, 8 	<ul style="list-style-type: none"> Post Discussion Questions (due Monday) Begin working on Assignment 2 (due 9/26)
	2b	Recruitment and Retention	<ul style="list-style-type: none"> Recruitment and Retention (Luepker) 	<ul style="list-style-type: none"> Additional readings - see the Canvas site 	
3 9/19/19	3a	Clinical Trials I and II	<ul style="list-style-type: none"> Clinical Trials I and II (Luepker) 	<ul style="list-style-type: none"> Chapters 4, 10-12 Additional readings - see the Canvas site 	<ul style="list-style-type: none"> Submit Assignment 1: Online Module Introduction to Good Clinical Practice (due 9/19) Post Discussion Questions (due Monday) Begin working on Assignment 3 (due 10/3)
	3b	IND Application, Process, and Responsibility	<ul style="list-style-type: none"> IND Application, Process, and Responsibility (Arbit & Teeple) 		
4 9/26/19	4a	Management of the Clinical Research Team	<ul style="list-style-type: none"> Management of the Clinical Research Team (Begun) 		<ul style="list-style-type: none"> Submit Assignment 2: Special Population Exercise (due 9/26) Post Discussion Questions (due Monday)
	4b	Research in the International Setting: Research in Resource-Poor Settings: Challenges and Issues	<ul style="list-style-type: none"> Research in the International Setting: Research in Resource-Poor Settings: Challenges and Issues (Lifson) 		
5 10/3/19	5a	Meta-analysis	<ul style="list-style-type: none"> Meta-analysis (Duval) 		<ul style="list-style-type: none"> Submit Assignment 3: Abstracts (due 10/3) Post Discussion Questions (due Monday) Begin working on Assignment 4 (due 10/17)
	5b	Role of the NIH in Clinical Research	<ul style="list-style-type: none"> Role of the NIH in Clinical Research (Lakshminarayan) 	<ul style="list-style-type: none"> Additional readings - see the Canvas site 	
6 10/10/19	6a	Safeguarding Trust: The Ethics of Research Involving Human Participants	<ul style="list-style-type: none"> Safeguarding Trust: The Ethics of Research Involving Human Participants (DeBruin) 	<ul style="list-style-type: none"> Chapter 14 Additional readings - see the Canvas site 	<ul style="list-style-type: none"> Post Discussion Questions (due Monday)
	6b	Utility of Biomarkers in Clinical Research	<ul style="list-style-type: none"> Utility of Biomarkers in Clinical Research (Thyagarajan) 		
7 10/17/19	7a	Introduction to Health Outcomes Research	<ul style="list-style-type: none"> Introduction to Health Outcomes Research (Lakshminarayan) 	<ul style="list-style-type: none"> Additional readings - see the Canvas site 	<ul style="list-style-type: none"> Submit Assignment 4: Clinical Trial Exercise (due 10/17) Post Discussion Questions (due Monday)
	7b	Clinical Research in Private Practice	<ul style="list-style-type: none"> Clinical Research in Private Practice (Tadros) 		
8	8a	Clinical Research with Pharmaceutical	<ul style="list-style-type: none"> Clinical Research with 	<ul style="list-style-type: none"> Additional readings - see the Canvas 	MIDTERM EXAM (on-line)

10/24/19		Companies: Practical Issues	Pharmaceutical Companies: Practical Issues (Eid)	site	<ul style="list-style-type: none"> • <i>Begin working on Assignment 5 (due 11/7)</i>
	8b	Mid-Term Exam			
9	9a	Challenges in Emergency and Acute Care Research	<ul style="list-style-type: none"> • Challenges in Emergency and Acute Care Research (Biros) 		<ul style="list-style-type: none"> • Post Discussion Questions (due Monday)
10/31/19	9b	How to Develop a Medical Device	<ul style="list-style-type: none"> • How to Develop a Medical Device (Wilson) 		
10	10a	Conflict of Interests in Clinical Medicine and Research	<ul style="list-style-type: none"> • Conflict of Interests in Clinical Medicine and Research (Oakes) 	<ul style="list-style-type: none"> • Additional readings - see the Canvas site 	<ul style="list-style-type: none"> • Submit Assignment 5: Investigator-Initiated Research Contract Exercise (due 10/31) • Post Discussion Questions (due Monday)
11/7/19	10	Working with Racial/Ethnic Minorities and Marginalized Populations in Clinical Research	<ul style="list-style-type: none"> • Working with Racial/Ethnic Minorities and Marginalized Populations in Clinical Research (Allen) 		
	10c	Group Presentation (1)			
11	11a	Clinical Research in Children	<ul style="list-style-type: none"> • Clinical Research in Children (Steinberger) 	<ul style="list-style-type: none"> • Additional readings - see the Canvas site 	<ul style="list-style-type: none"> • Post Discussion Questions (due Monday) • <i>Begin working on Assignment 6 (due 12/5)</i>
11/14/19	11b	Data and Safety Monitoring Boards	<ul style="list-style-type: none"> • Data and Safety Monitoring Boards (Lakshminarayan) 	<ul style="list-style-type: none"> • Additional readings - see the Canvas site 	
	11c	Adverse Events in Clinical Research	<ul style="list-style-type: none"> • Adverse Events in Clinical Research (Lakshminarayan) 	<ul style="list-style-type: none"> • Additional readings - see the Canvas site 	
	11d	Group Presentation (2)			
12	12a	An Overview of Mental Health Research	<ul style="list-style-type: none"> • An Overview of Mental Health Research (Wozniak) 		<ul style="list-style-type: none"> • Post Discussion Questions (due Monday)
11/21/19	12b	Working with the Elderly in Clinical Research	<ul style="list-style-type: none"> • Working with the Elderly in Clinical Research (Pacala) 		
	12c	Group Presentation (3)			
11/28/19		Thanksgiving (no class)			
13	13a	Precision and Accuracy	<ul style="list-style-type: none"> • Precision and Accuracy (Luepker) 	<ul style="list-style-type: none"> • Additional readings - see the Canvas site 	<ul style="list-style-type: none"> • Submit Assignment 6: Adverse Effects (due 12/5)
12/5/19	13b	Surgical Research: Unique Problems and Potential Solutions	<ul style="list-style-type: none"> • Surgical Research: Unique Problems and Potential Solutions (Ikramuddin) 		
	13c	Group Presentation (4)			
14		Study Day			
12/12/19					
15		FINAL EXAM: emphasizes last half [classes 8-13] but includes materials from the entire course			FINAL EXAM (on-line)

12/19/19				
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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

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

Activity	Point value
Mid-Term Exam	20
Final Exam	20
Assignment 1	5
Assignment 2	5
Assignment 3	10
Assignment 4	10
Assignment 5	10
Assignment 6	10
Group Project, Participation, Lecturer Questions, and Attendance	10
TOTAL POINTS	100 points
Unexcused Attendance	(missing >5 = loss of 10 points; >3 = loss of 5 points)

Grading Scale

The University uses plus and minus grading on a 4.000 cumulative grade point scale in accordance with the following, and you can expect the grade lines to be drawn as follows:

% In Class	Grade	GPA
93 - 100%	A	4.000
90 - 92%	A-	3.667
87 - 89%	B+	3.333
83 - 86%	B	3.000
80 - 82%	B-	2.667
77 - 79%	C+	2.333
73 - 76%	C	2.000
70 - 72%	C-	1.667
67 - 69%	D+	1.333
63 - 66%	D	1.000
< 62%	F	

- A = achievement that is outstanding relative to the level necessary to meet course requirements.
- B = achievement that is significantly above the level necessary to meet course requirements.
- C = achievement that meets the course requirements in every respect.
- D = achievement that is worthy of credit even though it fails to meet fully the course requirements.
- F = failure because 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 (Incomplete).
- S = achievement that is satisfactory, which is equivalent to a C- or better
- N = achievement that is not satisfactory and signifies that the work was either 1) completed but at a level that is not worthy of credit, or 2) not completed and there was no agreement between the instructor and student that the student would receive an I (Incomplete).

Evaluation/Grading Policy	Evaluation/Grading Policy Description
<p>Scholastic Dishonesty, Plagiarism, Cheating, etc.</p>	<p>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</p> <p>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.</p> <p>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.</p> <p>Indiana University offers a clear description of plagiarism and an online quiz to check your understanding (http://z.umn.edu/iuplagiarism).</p>
<p>Late Assignments</p>	<p>1 point deducted for late assignments of a week or less.</p>
<p>Attendance Requirements</p>	<p>Attendance at the live online class sessions is required. Missing >5 = loss of 10 points; >3 = loss of 5 points</p>
<p>Makeup Work for Legitimate Reasons</p>	<p>If you experience an extraordinary event that prevents you from completing coursework on time and you would like to make arrangements to make up your work, contact your instructor within 24 hours of the missed deadline if an event could not have been anticipated and at least 48 hours prior if it is anticipated.</p> <p>University policy recognizes that there are a variety of legitimate circumstances in which students will miss coursework, and that accommodations for makeup work will be made. This policy applies to all course requirements, including any final examination. Students are responsible for planning their schedules to avoid excessive conflicts with course requirements.</p> <ol style="list-style-type: none"> 1. Instructors may not penalize students for absence during the academic term due to the following unavoidable or legitimate circumstances: illness, physical or mental, of the student or a student's dependent; medical conditions related to pregnancy; participation in intercollegiate athletic events; subpoenas; jury duty; military service; bereavement, including travel related to bereavement; religious observances; participation in formal University system governance, including the University Senate, Student Senate, and Board of Regents meetings, by students selected as representatives to those bodies; and activities sponsored by the University if identified by the senior academic officer for the campus or the officer's designee as the basis for excused absences. 2. Voting in a regional, state, or national election is not an unavoidable or legitimate absence. 3. Instructors are expected to accommodate students who wish to participate in party caucuses, pursuant to Board of Regents resolution (see December 2005 Board of Regents Minutes, p 147.) 4. For circumstances not listed in (1), the instructor has primary responsibility to decide on a case-by-case basis if an absence is due to unavoidable or legitimate circumstances and grant a request for makeup work. <p>Because this course is entirely online and all materials are available to students from the first day of the term, we expect students to plan accordingly if travels or access to internet will cause them to miss a deadline. Note that our deadlines are generally set for 11:55 p.m. CST, so traveling to a different time zone will require additional planning. Further, circumstances that qualify for making up missed work will be handled by the instructor on a case-by-case basis; they will always be considered but not always granted. For complete information, view the U of M's policy on Makeup Work for Legitimate Absences (http://z.umn.edu/sphmakeupwork).</p>
<p>Extra Credit</p>	

Saving & Submitting Coursework	Documents that students submit are considered final; students may not submit more than one version or draft of each assignment.
Technical Issues with Course Materials	You are expected to submit all coursework on time and it is your responsibility to ensure that your work is submitted properly before the deadline. If you experience technical difficulties while navigating through the course site or attempting to submit coursework: <ul style="list-style-type: none">• Go to Quick Help: http://z.umn.edu/sphquickhelp.• Connect with the appropriate person or office within 30 minutes of the problem's occurrence.<ul style="list-style-type: none">○ Provide as much information as possible, so the tech team can best help you as soon as possible.○ You can expect a response within 1-2 business days to help resolve the problem.