SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF MINNESOTA

PUBH 3415/7415, SECTION 320

Introduction to Clinical Trials - Online

Fall 2018

COURSE & CONTACT INFORMATION

Credits: 3 credits
Meeting Day(s), Time, and Place: This course is entirely web-based, delivered via Moodle at http://moodle.umn.edu.

Contact Type	Contact Information	Role	When to Contact
Instructor	Andrew Mugglin, PhD amugglin@umn.edu	Co-instructor for this course	Students should post questions on lectures, readings, group projects, and exams to the weekly Q & A forums in the Moodle site. Instructors and Teaching Assistants (TAs) will respond on a regular basis to posted questions. Students with questions or concerns they do not wish to share with the entire class may email the instructors directly.
Instructor	Ann Brearley, PhD brea0022@umn.edu	Co-instructor for this course	
Teaching Assistants	Shruti Vempati vempa007@umn.edu Quiyu Yang yang5836@umn.edu	Teaching assistants for this course	Contact your assigned TA via email if you have questions about the Island projects (PubH 3415).
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 24 hours.

COURSE DESCRIPTION

Participating either as a consumer, adviser, or contributor to evidence-based medical and public health decisions requires an understanding of the quality of that evidence. A strong foundation in clinical trials helps prepare scientists to evaluate published medical advances and to implement well-designed pioneering health research. The topics of this Introduction to Clinical Trials class follow the natural sequence in a protocol, and will include: phases of trials, hypotheses and endpoints, choice of intervention and control, ethical

considerations, blinding and randomization, data collection and monitoring, sample size, and analysis strategies. Motivating examples from published research will be used throughout. All course interactions occur in an on-line environment. Weekly lessons on each topic have audio lecture presentations; readings in texts and research literature, short video delivered by experts, and optional enrichment materials. Students will participate in protocol development and implementation, interactive discussion boards, and exams. All these interactions will occur on-line.

Acknowledgments
PubH 3415/7415: Introduction to Clinical Trials (Online) was originally developed by Susan Telke, MS, in collaboration with James Neaton, PhD, with contributions from numerous other Biostatistics faculty, staff and graduate students, as well as from the clinical research experts whose insights and experiences (conveyed via video interviews) provide depth to the course materials. The current instructors, Lynn Eberly, PhD, Andrew Mugglin, PhD, and Ann Brearley, PhD, have been involved with the majority of recent content and modifications. We would like to acknowledge contributions from past instructors Kyle Rudser, PhD, and Eric Weber, PhD; the School of Public Health's Office of E-learning Services (ELS), under the direction of Sara Hurley, PhD; former student worker Karie Ouellette and former graduate students Emily Zabor, MS, and Nick Salkowski, PhD, for countless hours helping us gather and organize reference materials; and Kurtis Scaletta from the University Office of Information Technology (OIT) for his expertise with online instructional design.

COURSE PREREQUISITES

(1) PUBH 7415 enrollees must have one semester of graduate level introductory biostatistics or statistics (PUBH 6414, PUBH 6450, STAT 5021, EPSY 5261, or instructor consent)

(2) PUBH 3415 enrollees must have one semester of undergraduate level introductory biostatistics or statistics (STAT 3011, EPSY 3264, SOC 3811, BIOL 3272, or instructor consent) **AND** junior or senior standing or instructor consent.

COURSE GOALS & OBJECTIVES

The overall goal of this course is to provide students with a strong foundation in clinical trials, in order to prepare them to evaluate published medical advances and to implement well-designed pioneering health research.
By the end of this course, students should be able to:

1. Identify basic characteristics of a medical/public health investigation and describe the advantages and disadvantages of randomized clinical trials as compared to other epidemiological and clinical investigations.
2. Compare and contrast common designs for randomized clinical trials for addressing medical/public health questions and understand the advantages and disadvantages of different study designs.
3. Explain using examples how the primary and secondary objectives are linked to the endpoint measures of a clinical trial. Distinguish between single, composite, safety and surrogate endpoints, describing strengths/weaknesses.
4. Understand different randomization techniques and justification for use. Describe basic randomization and blinding implementation strategies.
5. Discuss different conflicts and ethical issues that arise from the implementation of clinical trials both domestically and internationally. Describe the purposes of and differences between an Institutional Review Board (IRB) and a Data Safety and Monitoring Board (DSMB) in terms of protection of human subjects in the setting of clinical research.
6. Describe with examples the difference between bias and random error and strategies for minimizing each. Understand the impacts of randomization and of inclusion/exclusion criteria on each.
7. Identify factors important for appropriately defining an intervention group and a control group. Discuss how the definition influences our understanding and interpretation of the results of a clinical trial.
8. Determine sample sizes for clinical trials of simple design and understand ingredients in the sample size determination for more complex designs.
9. Identify special requirements of collaborative clinical trials, their organization and operation.
10. Determine the data collection requirements of clinical trials. Recommend different data types and data collection form techniques to ensure quality data.
11. Understand the advantages of intent-to-treat analysis and differentiate its interpretation from that of an on-treatment analysis.
12. Recommend an interim analysis plan for a clinical trial and understand the role of independent data monitoring committees (DSMB) in reviewing interim analysis results.
13. Review critically the published results of clinical trials.

METHODS OF INSTRUCTION AND WORK EXPECTATIONS

Methods of Instruction

- Course web page: moodle.umn.edu (or access it through MyCourses in your MyU Portal)
- Online course content (1-3 topics per week (split into bite size pieces), 28 topics in total)
- Published journal article readings
- Discussion forums (2 per week)
- 1 written group project and 1 structured feedback activity. **The project and the feedback are different for 3415 enrollees vs. 7415 enrollees**; details are given in the Course Outline/Weekly Schedule.
- 2 exams (administered online)
- Students should post questions on lectures, readings, group projects, and exams to the "General Q & A" forums in the Moodle site. Instructors and Teaching Assistants (TAs) will respond on a regular basis to posted questions.
- Students with questions or concerns they do not wish to share with the entire class may email the instructors directly.
- Students should be aware that the expectations and requirements in this course are no different from the expectations and requirements in a typical classroom offering. In particular, this is not a self-paced course; students are expected to review course content, participate in the discussion fora, and complete activities by posted deadlines in order to stay on pace with the course.
- As a general rule, ***prior notification is essential*** to our accepting a late assignment of any kind. If illness or travel is going to cause you to miss a deadline, don't surprise us -- send an e-mail as soon as you can or call the Biostatistics main office (612-624-4655) to leave a message.

Course Workload Expectations

Introduction to Clinical Trials 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.

This course is entirely online. Therefore, time you would otherwise be in class will be incorporated into work for the course in the form of online discussions, lectures, etc.

Technology

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

- (PubH 3415) Google Docs: training is available via OIT https://it.umn.edu/self-help-guide/google-drive-work-files-folders.

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

Optional recommended texts:

- Fundamentals of Clinical Trials (3rd, 4th or 5th Edition), by Friedman, Furberg, and DeMets, ISBN-13: 978-1441915856
    - FREE ONLINE with U of MN login
- Clinical Trials: A Methodologic Perspective (2nd or 3rd Edition), by Piantadosi, ISBN-13: 978-0471727811
    - FREE ONLINE with U of MN login

  Both of these textbooks are available **free online** through the University of Minnesota libraries. Go to lib.umn.edu, log in with your X.500 username and password, and then search the book title to find the online access link.

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.**

- **3415 enrollees:** In general, group assignments will be made available online every 2 weeks, and will be due via online submission of an electronic document by 23:55 US Central time 1-2 weeks later. See schedule below for details.
- **7415 enrollees:** In general, group assignments will be made available online every fourth week, and will be due via online submission of an electronic document by 23:55 US Central time three to four weeks later. See schedule below for details.
- Discussion fora will be made available online every Monday, and will be due by 23:55 US Central time on the Tuesday one week later. See schedule below for details.
- Exams will be made available online by 1:00 (am) US Central time on the Wednesday of the schedule-specified exam week, can be accessed until 23:55 US Central time the following Sunday, and will be due via online submission of answers within 2 hours of the student's accessing the exam. *If you want a full 2 hours for taking the exam, you must access it at least 2 hours prior to the deadline!!* Students may access each exam ***only once***; it will not be possible to partially complete the exam and then return to it later. *You are expected to complete the exams independently (by yourself).* See schedule below for details.

Week	Course Dates (Fall 2018)	3415 Group Island Study Project: Activity Summaries[#]	7415 Group Protocol Project: Activity Summaries[#]	Reading/ Reflections Forums	Units
1	Sept 4 – Sept 9	**Activity 1/Island Exploration**: Review Overall Instructions for Islands Project. Complete and submit "Islands Exploration" activity; due Monday, week 2.	**Activity 1/Choose Project**: Review proposed protocol project concepts, protocol template, and schedule of interim deadlines. Submit your ranked choices of protocol concepts; due Monday, week 2.	Introduction Forum; Forums 1 & 2 due Tuesday, week 2.	**Taxonomy of Studies** Unit 1: Observational Studies *Expert Connection: Kristin Anderson* Unit 2: Experimental Studies *Expert Connection: Jim Neaton* *(Optional enrichment: Ancel Keys interview/ Henry Blackburn)*
2	Sept 10 – Sept 16	**Activity 2/Research Question**: Groups will be assigned by the instructor and posted in Moodle by Monday of Week 2. Submit ideas for 3 scientific questions that your group may be interested in studying on the Islands; due Thursday, week 2.	**Activity 2/Initial Meeting**: You will be assigned to a group by the instructors. Find a time to all 'meet' together online to decide on roles within the group. Review the assigned concept and the included background literature.	Forums 3 & 4; due Tuesday week 3.	Unit 3: Early Phase Studies *Expert Connection: Russell Luepker* **Research Preliminaries** Unit 4: Defining the Research Question Unit 5: Research Considerations & Structure of a Protocol *Expert Connection: Jim Neaton* *(Optional enrichment: FDA 101: Harvey Arbit)*
3	Sept 17 – Sept 23	Activity 3/CONSORT: Complete and submit the "CONSORT Guidelines Activity"; due Thursday, week 3.	**Activity 3**: Over the remainder of the semester, your group will be writing a full protocol for your assigned protocol concept. Find other background literature related to your concept. Draft background, rationale, and risks/benefits of your concept.	Forums 5 & 6; due Tuesday week 4.	Unit 6: Ethics I: Introduction to Human Subjects Research and the IRB. **Guest Lecturer** - Michael Oakes: *Expert Connections: Jeffrey Kahn, Michael Oakes* **Treatment Allocation** Unit 7: Blinding *Expert Connection: John Connett*

					(Optional enrichment: Ethics: Kristine Ensrud)
4	Sept 24 – Sept 30	**Activity 4/Exploring**: Your group will be informed which of the 3 scientific questions to study by the TA or instructor by Monday of Week 3. Practice collecting some data and consider study objective and primary endpoint. Start a draft of the Introduction and Methods Sections.	**Activity 4/Background**: Submit background, rationale, and risks/benefits; due Thursday, week 4. (Your group will be able to modify this and other submitted sections before final submission in Week 16.)	Forums 7 & 8; due Tuesday week 5.	Unit 8: Implementation Unit 9: Fixed Methods *Expert Connection: Michael Oakes*
5	Oct 1 – Oct 7	**Activity 5/Introduction**: Submit your Introduction Section; due Thursday, week 5. (Your group will be able to modify this and other submitted sections before final submission in Week 16.)	**Activity 5**: Discuss your protocol's objectives, endpoints, and treatment allocation.	Forums 9 & 10; due Tuesday week 6.	Unit 10: Adaptive Methods *Expert Connections: Greg Thompson, Don Berry* **Endpoints** Unit 11 : Composite *Expert Connection: Jim Neaton* Unit 12 : Surrogate **Guest Lecturer** - Dan Sargent
6	Oct 8 – Oct 14	**Activity 6/Meeting #1 with TA**: Review thoughts on study methods. Receive feedback on Introduction Section.	**Activity 6**: Begin drafting objectives, endpoints, and treatment allocation.	Forums 11 & 12; due Tuesday week 7.	Unit 13: Safety *Expert Connections: John Connett, Jim Neaton* **EXAM I: opens Wednesday, covers weeks 1-5 (units 1-12)**
7	Oct 15 – Oct 21	**Activity 7/Pilot Data**: Submit planning dataset. Try out some sample size calculations; due Thursday, week 7.	**Activity 7**: Continue drafting objectives, endpoints, and treatment allocation.	Forums 13 & 14; due Tuesday week 8.	**Study Population** Unit 14: Eligibility Criteria, Recruitment & Run-ins *Expert Connections: John Connett, Russell Luepker* Unit 15: Ethics II: International & Vulnerable Populations *Expert Connection: Jeffrey Kahn* *(Optional enrichment: Ethics: Kelvin Lim, Chandy John)*
8	Oct 22 – Oct 28	**Activity 8/Meeting #2 with TA**: Review thoughts on study methods. Receive feedback on sample size calculations.	**Activity 8/Objectives, endpoints and treatment allocation**: Submit work on objectives, endpoints, and treatment allocation; due Thursday, week 8.	Forums 15 & 16; due Tuesday week 9.	Unit 16: Control Group Selection *Expert Connection: Jim Hodges* Unit 17: Regression Towards the Mean *(Optional enrichment: Stanford Medicine: Placebo Effect; Andrew Porter poem: Regression to the Mean)*
9	Oct 29 – Nov 4	**Activity 9/Methods**: Submit Methods section, including randomization and statistical methods; due Thursday, week 9.	**Activity 9**: Draft study design and inclusion/exclusion criteria	Forums 17 & 18; due Tuesday week 10.	**Study Design** Unit 18: Parallel Group *Expert Connection: Jeffrey Kahn* Unit 19: Crossover *Expert Connection: John Connett* *(Optional enrichment: Michael Gibson and Michael Gaziano: Physicians Health Study II)*

10	Nov 5 – Nov 11	**Activity 10/Meeting #3 with TA**: Receive feedback on Methods, Randomization and Statistical Methods Sections.	**Activity 10/Design and incl/excl criteria**: Submit study design and inclusion/exclusion criteria; due Thursday, week 10.	Forums 19 & 20; due Tuesday week 11.	***Sample Size*** Unit 20: Continuous and Binary Outcomes *Expert Connections: Jim Neaton, Brad Carlin* Unit 21: Complications, Part 1 [losses, non-compliance, lag time, changing event rates]
11	Nov 12 – Nov 18	**Activity 11/Dataset**: Submit your Islands study dataset. Begin draft of results section; due Thursday, week 11.	**Activity 11**: Begin drafting sample size and procedures.	Forums 21 & 22; due Tuesday week 12.	Unit 22: Complications, Part 2 [unequal follow-up, event rate mis-specification, negative studies] *Expert Connection: Jim Hodges* **EXAM II: opens Wednesday, covers weeks 6-10 (units 13-21)**
12	Nov 19 – Nov 25 **NOTE: Thursday is Thanksgiving**	**Activity 12/Meeting #4 with TA**: Review study data and discuss results section ideas.	**Activity 12**: Continue drafting sample size and procedures.	Forums 23 & 24; due Tuesday week 13.	**Analysis** Unit 23: Intention-to-Treat & Per-Protocol *Expert Connection: Brad Carlin* Unit 24: Interim *Expert Connections: Jeffrey Kahn, Jim Hodges*
13	Nov 26 – Dec 2	**Activity 13/Mock IRB Activity**: (There is no Islands study project activity this week.) **Mock IRB Activity**: Each 3415 group will review a draft study protocol. Give feedback using the Mock IRB assignment provided; due Monday, week 14.	**Activity 13/Mock DSMB Activity**: (There is no protocol project activity this week.); **Mock DSMB Activity**: Each 7415 group will review a DSMB report. Give feedback using the Mock DSMB assignment provided; due Monday, week 14.	Forums 25 & 26; due Tuesday week 14.	**Data** Unit 25: Collection *Expert Connection: John Connett* Unit 26: Quality *Expert Connections: Jim Hodges, Kelvin Lim*
14	Dec 3 – Dec 9	**Activity 14/Results**: Submit your Results Section (all participants in Islands study); due Thursday, week 14.	**Activity 14/Sample size and procedures**: Submit work on sample size and clinic procedures; due Thursday, week 14.	Forums 27 & 28; due Tuesday week 15.	Unit 27: Ethics III: Scientific Fraud and Misconduct *Expert Connections: John Connett, Jeffrey Kahn*
15	Dec 10 – Dec 16	**Activity 15/Discussion**: Submit Discussion Section; due Thursday, week 15. **Optional Meeting #5 with TA**: Receive feedback on Results and Discussion Sections.	**Activity 15**: Based on the feedback received from instructors since Week 4, polish your entire protocol document.	No Forums this week.	**Reporting** Unit 28: CONSORT guidelines *Expert Connection: John Connett*
16	Dec 17 – Dec 20	**Activity 16/Full Report**: Polish and submit your entire scientific brief report; due Thursday, week 16.	**Activity 16/Full Protocol**: Polish and submit your entire protocol document; due Thursday, week 16.		**No Final Exam.** **Island study reports and protocol projects are due.**

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

500 points total, distributed as follows:

- Discussion forums (28 at 5 points each for a total of 140 points)
- Group activities:
    - 3415 enrollees
        - Island study project - 10 assignments at 12 points each for a total of 120 points
        - 2 project participation evaluations at 10 points each for a total of 20 points
        - Mock IRB structured feedback activity for 20 points
    - 7415 enrollees
        - Protocol project – 5 assignments at 24 points each for a total of 120 points
        - 2 project participation evaluations at 10 points each for a total of 20 points
        - Mock DSMB structured feedback activity for 20 points
- Two exams (2 at 100 points each for a total of 200 points)

- Each **Discussion forum** is graded on a scale totaling five points: three possible points for your initial posting and two possible points for responding to a classmate's post. Points will be added across the semester and used to compute the proportion of points earned out of total possible points. There are two discussion forums per week for 14 weeks.
- **Group Activities for 3415 enrollees:** The Islands study project, created by a team of 4-8 students, will be developed throughout the semester, with a scientific brief report of the study's results submitted in the final week of the semester. Students will evaluate their own participation, as well as the participation of others in their group, at the end of the semester. TAs will evaluate student participation once mid-semester. The project's 140 points total will be divided up as 120 points possible for the paper (same grade given to all members of the group), 10 points possible for peer evaluation of your participation in the group, and 10 points possible for TA evaluations of your participation in the group. Each group will carry out a study planning data collection (for sample size estimation) and a main study in a virtual environment, including finding, consenting, randomizing, and collecting data on virtual participants. The structured feedback Mock IRB activity, also carried out by your group, will be worth an additional 20 points.
- **Group Activities for 7415 enrollees:** The protocol project, created by a team of 4-8 students, will be developed throughout the semester, with a full protocol submitted in the final week of the semester. Students will evaluate their own participation, as well as the participation of others in their group, twice during the semester. The project's 140 points total will be divided up as 120 points possible for the paper (same grade given to all members of the group), and 10 points possible for each evaluation (based on the numeric evaluation of a student's participation by her/himself and by others in that student's group). The structured feedback Mock DSMB activity, also carried out by your group, will be worth 20 points.
- **Two exams** will be given at approximately 5 weeks and 10 weeks, each graded on a scale of 0 to 100 points. The exams are focused on the most recent information presented.

Note: Moodle does not differentiate between the 3415 group activities and the 7415 group activities, so it thinks the denominator for the grade calculation is 160 points higher than it should be, at 660 points. Therefore, the overall grade percentage listed in Moodle is incorrect. We will use the correct denominator of 500 points when we assign the final course grades.

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
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	As a general rule, ***prior notification is essential*** to our accepting a late assignment of any kind. If illness or travel is going to cause you to miss a deadline, don't surprise us -- send an e-mail as soon as you can or call the Biostatistics main office (612-624-4655) to leave a message.
Attendance Requirements	N/A
Makeup Work for Legitimate Reasons	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. Per University policy, legitimate reasons for making up work may include: • illness • serious accident or personal injury • hospitalization • death or serious illness within the family • bereavement • religious observances • subpoenas • jury duty • military service • participation in intercollegiate athletic events 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).
Extra Credit	N/A
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:
	
	• Go to Quick Help: http://z.umn.edu/sphquickhelp.
	• Connect with the appropriate person or office within 30 minutes of the problem's occurrence.
	  ○ 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.