



PubH 3415/7415 - Section 1

Introduction to Clinical Trials - Online

Fall 2016

Credits:	3 credits
Meeting Days:	online
Meeting Time:	online
Meeting Place:	online
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Teaching Assistants:	TBA
Office Hours:	via discussion forums or in person (please request an appointment at any time)

I. 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

The contents of PubH 3415/7415 have been developed based on the contributions of numerous experts in clinical trials research and teaching, in particular, Jim Neaton. Lynn Eberly and Susan Telke, the current instructors, have been involved with the majority of recent content and modifications. Former instructors, Eric Weber and Kyle Rudser, both are acknowledged for their teaching and contributions. We give ongoing thanks to the School of Public Health Digital Learning Group (now the

Office of E-Learning Services) for their expertise and help with presentation and storage of content, videography, Moodle site creation and management, and many technical issues. We thank Division Heads, John Connett (former) and Brad Carlin (current), for financial support and enthusiasm! Finally, thank you to all the clinical research experts whose insights and experiences have provided depth to our course materials.

II. 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.

III. Course Goals and Objectives

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.

IV. Methods of Instruction and Work Expectations

- Course web page: moodle.umn.edu (or access it through MyCourses in your MyU Portal)
- Online course content (1-3 topics per section (split into bite size pieces), 15 sections)
- Published journal article readings
- Discussion fora (2 per section)
- 1 written group project and structured feedback. **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” discussion forum on the left sidebar of the Moodle site. Instructors and the Teaching Assistants (TA) 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.

V. Course Text and Readings

Optional recommended texts:

- Fundamentals of Clinical Trials (3rd or 4th Edition), by Friedman, Furberg, and DeMets, ISBN-13: 978-1441915856
 - FREE ONLINE with U of MN login
<http://link.springer.com/book/10.1007/978-1-4419-1586-3/page/1>
- Clinical Trials: A Methodologic Perspective (2nd Edition), by Piantadosi, ISBN-13: 978-0471727811

- FREE ONLINE with U of MN Login
<http://onlinelibrary.wiley.com/book/10.1002/0471740136>

VI. Course Outline/Weekly Schedule

- **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 23:59 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 23:59 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 23:59 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.

Section (Week)	Course Dates	3415 Group Island Study Project: Activity Summaries #	7415 Group Protocol Project: Activity Summaries #	3415 Group Structured Feedback: Activity Summaries #	7415 Group Structured Feedback: Activity Summaries #	Expert Connections	Topics
1	Sept 6 – Sept 11	Activity 1: Review Overall Instructions for Islands Project. Complete and submit "Explore the Islands"; due Monday, week 2.	Activity 1: Review proposed protocol project concepts, protocol template, and schedule of interim deadlines. Submit your ranked choices of protocol concepts; due Monday, week 2.	No activity.	No activity.	Kristin Anderson Jim Neaton	Observational Studies Experimental Studies
2	Sept 12 – Sept 18	Activity 2: Submit ideas for 3 scientific questions that your group may be interested in studying on the Islands; due Thursday, week 2. (Groups will be assigned by the instructor and posted in Moodle by Monday of Week 2)	Activity 2: 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.	No activity.	No activity.	Russell Luepker Jim Neaton	Clinical Trial Phases Defining a Research Question Research Considerations & Structure of a Protocol
3	Sept 19 – Sept 25	Activity 3: Practice collecting some data and consider study objective and primary endpoint. Start a draft of the Introduction and Methods Sections. (Your group will	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.	No activity.	No activity.	Jeff Kahn Michael Oakes John Connett	Ethics I: <i>Guest Lecturer -Michael Oakes</i> : Introduction to Human Subjects Research and IRB Blinding

		be informed which of the 3 scientific questions to study by the TA or instructor by Monday of Week 3).	Draft background, rationale, and risks/benefits of your concept.				
4	Sept 26 – Oct 2	Activity 4: Submit your Introduction Section; due Thursday, week 4. (Your group will be able to modify this and other submitted sections before final submission in Week 16.)	Activity 4: 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.)	No activity.	No activity.	John Connett Michael Oakes	Treatment Allocation [Implementation] Treatment Allocation [Fixed Methods]
5	Oct 3 – Oct 9	Activity 5: Meeting #1 with TA: Review thoughts on study methods. Receive feedback on Introduction Section.	Activity 5: Discuss your protocol's objectives, endpoints, and treatment allocation.	No activity.	No activity.	Don Berry Greg Thompson	Treatment Allocation [Adaptive Methods] EXAM I: opens Wednesday, covers weeks 1-5
6	Oct 10 – Oct 16	Activity 6: Submit planning dataset. Try out some sample size calculations; due Thursday, week 6	Activity 6: Begin drafting objectives, endpoints, and treatment allocation.	No activity.	No activity.	Jim Neaton John Connett Kristin Ensrud	Endpoints [Composite] Endpoints [Surrogate] <i>Guest Lecturer- Dan Sargent</i> Endpoints [Safety]
7	Oct 17 – Oct 23	Activity 7: Meeting #2 with TA: Review thoughts on study methods. Receive feedback on sample size calculations.	Activity 7: Continue drafting objectives, endpoints, and treatment allocation.	No activity.	No activity.	John Connett Kelvin Lim Russell Luepker Jeffery Kahn Chandy John	Study Population [Eligibility Criteria, Recruitment & Run-ins] Ethics II: International & Vulnerable Populations
8	Oct 24 – Oct 30	Activity 8: Submit Methods Section; due Thursday, week 8	Activity 8: Submit work on objectives, endpoints, and treatment allocation; due Thursday, week 8.	No activity.	No activity.	Jim Hodges Poem by Andrew Porter	Control Group Selection Regression Towards the Mean
9	Oct 31 – Nov 6	Activity 9: Submit Randomization and Statistical Methods Sections; due Thursday, week 9	Activity 9: Draft study design and inclusion/exclusion	No activity.	No activity.	Jeffrey Kahn John Connett	Study Design [Parallel Group] Study Design [Crossover]
10	Nov 7 – Nov 13	Activity 10: Meeting #3 with TA: Receive feedback on Methods, Randomization and Statistical Methods Sections.	Activity 10: Submit study design and inclusion/exclusion; due Thursday, week 10.	No activity.	No activity.	Brad Carlin Jim Neaton	Sample Size [Continuous and Binary Outcomes] EXAM II: opens Wednesday, covers weeks 6-10

11	Nov 14 – Nov 20	Activity 11: Submit your dataset for the first 20 participants in the Islands study. Begin draft of results section; due Thursday, week 11	Activity 11: sample size and procedures.	No activity.	No activity.	James Hodges	Sample Size Complications [Time-to-Event]
12	Nov 21 – Nov 27	Activity 12: Meeting #4 with TA: Review data from first 20 participants and discuss results section ideas. NOTE: Thursday is Thanksgiving	Activity 12: Continue drafting sample size and procedures.	No activity.	No activity.	James Hodges Jeffrey Kahn	Analysis [Intention-to-Treat & Per-Protocol] Analysis [Interim]
13	Nov 28 – Dec 4	Activity 13: No Islands study project activity; complete the Mock IRB activity this week.	Activity 13: No protocol. project activity; complete the Mock DSMB activity this week	Mock IRB Activity: Each 3415 group will review the draft protocol submitted over weeks 4-10 by one 7415 group. Give feedback using the Mock IRB assignment provided; ; due Monday, week 14	Mock DSMB Activity: Each 7415 group will review the DSMB report submitted by a 3415 group in week 12. Give feedback using the Mock DSMB assignment provided; due Monday, week 14.	John Connett James Hodges Kelvin Lim	Data [Collection] Data [Quality]
14	Dec 5 – Dec 11	Activity 14: Submit your Results Section (all participants in Islands study); due Thursday, week 14	Activity 14: Submit work on sample size and clinic procedures; due Thursday, week 14.	No activity.	No activity.	John Connett Jeffrey Kahn	Ethics III: Scientific Fraud and Misconduct
15	Dec 12 – Dec 18	Activity 15: 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 activity.	No activity.		Reading and Reporting, CONSORT guidelines
16	Dec 19 – Dec 22	Activity 16: Polish and submit your entire scientific brief report; due Thursday, week 16	Activity 16: Polish and submit your entire protocol document; due Thursday, week 16.	No activity.	No activity.		No Final Exam. Island study reports and protocol projects are due.

Detailed instructions, and suggestions on content and length of the written scientific brief report (3415 enrollees) and protocol (7415 enrollees), for each activity are posted in each week's Moodle page.

VII. Evaluation and Grading

Evaluation and 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 at 20 points
 - Two exams (2 at 100 points each for a total of 200 points)
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- 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 section for 14 sections.
 - **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.

The University utilizes plus and minus grading on a 4.000 cumulative grade point scale in accordance with the following:

- A 4.000 - Represents achievement that is outstanding relative to the level necessary to meet course requirements
- A- 3.667
- B+ 3.333
- B 3.000 - Represents achievement that is significantly above the level necessary to meet course requirements
- B- 2.667
- C+ 2.333
- C 2.000 - Represents achievement that meets the course requirements in every respect
- C- 1.667
- D+ 1.333
- D 1.000 - Represents achievement that is worthy of credit even though it fails to meet fully the course requirements
- S Represents achievement that is satisfactory, which is equivalent to a C- or better.

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/courseeval. 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.*

OR:

Academic Freedom and Responsibility, for courses that 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 and conduct relevant research. 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.* When conducting research, pertinent institutional approvals must be obtained and the research must be consistent with University policies.

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.

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