PubH 6342
Epidemiologic Methods II
Spring 2017

Credits: 3
Meeting Days: Tuesdays and Thursdays
Meeting Time: 4:00-5:15 p.m.
Meeting Place: Moos Tower 1-450

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Fax: 612-624-0315
E-mail: pankow@umn.edu
Office Hours: Tuesdays, 2:30-3:30pm, A310 Mayo

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Fax: 612-624-0315
E-mail: munozzan@umn.edu
Office Hours: Thursdays, 2:30-3:30pm, A310 Mayo

Teaching Assistant: Ian Rapson, MPH
E-mail: rapson@umn.edu
Office Hours: Wednesdays, noon-1:00pm, SPHere
I. Course Description

This intermediate course covers methods and techniques for designing, implementing, analyzing, and interpreting observational epidemiologic studies, including cohort, case-control, and cross-sectional studies. It is the second course in a three course sequence (PubH 6341, 6342, 6343) on the theory and practice of epidemiology. This course is designed primarily for MPH students majoring in epidemiology. Students from other programs, particularly those who seek a more in-depth coverage of epidemiologic concepts and methods beyond those provided by an introductory course, are also welcome to enroll. Students primarily interested in the design and analysis of experimental studies are encouraged to take PubH 7420 (Clinical Trials: Design, Implementation, and Analysis), PubH 7415 (Introduction to Clinical Trials), or PubH 6363 (Design and Analysis of Group-Randomized Trials in Epidemiology).

Acknowledgments

The content of PubH 6342 has been developed by Jim Pankow and Claudia Muñoz-Zanzi. Dr. Eyal Shahar contributed to the early conceptual development of the course. The instructors also acknowledge former teaching assistants for their contributions to the course.

II. Course Prerequisites

a. Epidemiologic Methods I (PubH 6341; grade of B- or higher), Fundamentals of Epidemiology (PubH 6320; grade of A- or higher), or equivalent

b. Biostatistics I (PubH 6450; grade of B- or higher), Biostatistical Literacy (PubH 6414; grade of B- or higher), or equivalent

Students who wish to proceed to Epidemiologic Methods III (PubH 6343) should note that Biostatistics II (PubH 6451) is a prerequisite for Epidemiologic Methods III.

III. Course Goals and Objectives

As a result of this course, students will be able to:

1. Develop procedures for subject selection and recruitment, including sampling and methods to enhance participation rates and response.
2. Apply principles of observational study design, including variants of the case-control design, use of matching, and sample size and power calculations.
3. Select and develop appropriate exposure and outcome measurement procedures, including questionnaires, interviews, collection of biological specimens, physical measurements, and quality control and assurance methods.
4. Apply principles of observational study analysis, including survival analysis through Kaplan-Meier and person-time approaches.
5. Identify major sources of bias (i.e., information, selection, and confounding bias) in observational epidemiologic studies and ways to evaluate their likely direction, magnitude, and nature of their threat to causal inference.
6. Apply strategies to assess joint effects of exposures.
7. Apply epidemiologic study designs and methods in public health surveillance and evaluation of screening.
8. Evaluate epidemiologic methods through critical review of published epidemiologic research.

IV. Methods of Instruction and Work Expectations

Instruction will be through a combination of lectures, discussions, in-class exercises, reviews of published articles, and assignments. Students are expected to come to class having read the assigned readings and notes for the class. Students are expected to turn in assignments on time and take exams at the scheduled times as well. Exceptions to deadlines will be determined on a case-by-case basis.

Communication about course materials

We ask you to post questions about the course assignments and materials in the “Q&A Discussion Forum” near the top of the Moodle course site. The instructors and teaching assistant will monitor the discussion forum to answer questions, but active discussion between students is encouraged as well. Please post any
questions you have in the discussion forum, as opposed to emailing questions to the instructors and teaching assistant directly, so that everyone in the class can benefit from the discussion.

V. Course Text and Readings

The course does not have a required text. We have assigned a number of chapters from Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. *Designing Clinical Research* (4th ed.). Readings from Hulley and other sources are provided through links on the course Moodle site.

VI. Course Outline / Weekly Schedule

The schedule for the semester is organized according to the foundational steps for designing and implementing an epidemiologic study:

1. **Study design (4 sessions)**, including identifying the research question, population of interest, study design, sampling approach, and sample size planning.

2. **Data collection (4 sessions)**, including designing questionnaires and interviews, diagnostic tests, quality assurance and quality control procedures, and data management.

3. **Data analysis (7 sessions)**, including controlling for confounding, assessing effect modification, addressing various kinds of bias.

We will also cover some special topics (7 sessions), including recent methodological innovations (e.g., Mendelian randomization; building risk prediction models) and topics relevant for epidemiologists in public health practice (e.g., screening; public health surveillance; infectious disease modeling).

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<thead>
<tr>
<th>Class</th>
<th>Date</th>
<th>Topic</th>
<th>Title</th>
<th>Instructor(s)</th>
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<tbody>
<tr>
<td>1</td>
<td>17-Jan</td>
<td>Introduction</td>
<td>Review of key epidemiologic terms and concepts</td>
<td>Pankow</td>
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<td>Reading:</td>
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<tr>
<td>2</td>
<td>19-Jan</td>
<td>Study design</td>
<td>Research question, study population, and sampling</td>
<td>Pankow</td>
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<td></td>
<td>Reading:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Hulley, Chapter 3: Choosing the study subjects: specification, sampling, and recruitment. <em>Am J Epidemiol</em> 2012; 175: 733-738.</td>
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<tr>
<td>3</td>
<td>24-Jan</td>
<td>Study design</td>
<td>Cross-sectional and cohort studies</td>
<td>Pankow</td>
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<td>Reading:</td>
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<td>Hulley, Chapter 7: Designing cross-sectional and cohort studies.</td>
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<td>Date</td>
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<td>4</td>
<td>26-Jan Study design</td>
<td>Case-control studies</td>
<td>Pankow</td>
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<td>Readings:</td>
<td>Hulley, Chapter 8: Designing case-control studies.</td>
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<td>Connor J, et al. Situational and contextual factors that increase the risk of harm when students drink: case-control and case-crossover investigation. <em>Drug Alcohol Rev</em> 2014; 33: 401-411.</td>
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<tr>
<td>5</td>
<td>31-Jan Project</td>
<td>Background, options, and expectations</td>
<td>All</td>
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<td>Note: Some students will meet in Mayo D199 and not in the regular classroom</td>
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<td></td>
<td>Readings:</td>
<td>Oakes JM and Andrade KE. The measurement of socioeconomic status.</td>
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<td>TBD: infectious disease paper</td>
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<td>6</td>
<td>2-Feb Study design</td>
<td>Sample size estimation</td>
<td>Pankow</td>
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<td></td>
<td>Readings:</td>
<td>Hulley, Chapter 5: Getting ready to estimate sample size: hypotheses and underlying principles.</td>
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<td>Hulley, Chapter 6: Estimating sample size and power: applications and examples.</td>
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<td>Due today:</td>
<td>Homework #1: case-control designs (5%)</td>
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<tr>
<td>7</td>
<td>7-Feb Project</td>
<td>Research question, study population, and study design</td>
<td>All</td>
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<td>Note: Some students will meet in Mayo D199 and not in the regular classroom</td>
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<td>Class participation day (1%)</td>
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<td>8</td>
<td>9-Feb Data collection</td>
<td>Exposures; quality assurance and quality control</td>
<td>Muñoz-Zanzi</td>
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<td>Readings:</td>
<td>Hulley, Chapter 4: Planning the measurements: precision, accuracy, and validity.</td>
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<td>Hulley, Chapter 17: Implementing the study and quality control.</td>
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<td>9</td>
<td>14-Feb Data collection</td>
<td>Designing questionnaires and interviews</td>
<td>Pankow</td>
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<td>Readings:</td>
<td>Hulley, Chapter 15: Designing questionnaires, interviews, and online surveys.</td>
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<td>Due today:</td>
<td>Preliminary project report: research question, population, design (2%)</td>
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10 16-Feb Data collection  Validation and use of diagnostic tests  Muñoz-Zanzi

Readings:
Hulley, Chapter 12: Designing studies of medical tests.

11 21-Feb Project  Data collection procedures  All
Note: Some students will meet in Mayo D199 and not in the regular classroom
Class participation day (1%)

12 23-Feb Data collection  Managing epidemiologic data  Muñoz-Zanzi

Readings:
Hulley, Chapter 16: Data management.
Due today:
Homework #2: diagnostic tests (5%)

13 28-Feb Special topic  Review of published paper and discussion  All
Class participation day (1%)

Readings:
Due today:
Preliminary project report: data collection procedures (2%)

14 2-Mar Special topic  Secondary data to address epidemiologic questions  Pankow

Readings:

15 7-Mar Special topic  Methods in infectious disease epidemiology  Muñoz-Zanzi

Reading:

16 9-Mar Midterm exam (15%)  All
Note: exam is online, and we will not meet in person today

14-Mar Spring Break

16-Mar Spring Break
17 21-Mar Data analysis Using causal models to identify confounders Pankow

Reading:

Due today:
Homework #3: infectious disease modeling (5%)

18 23-Mar Data analysis Strategies to address confounding Pankow

Readings:
Hulley, Chapter 9: Enhancing causal inference in observational studies, p. 122-132.

19 28-Mar Data analysis Strategies to address effect modification Pankow

Readings:

20 30-Mar Data analysis Strategies to address selection and information bias Pankow

Readings:
Hulley, Chapter 9: Enhancing causal inference in observational studies, p. 117-121.

Due today:
Homework #4: confounding adjustment (5%)

21 4-Apr Project Data analysis and interpretation All
Class participation day (1%)
Note: Some students will meet in Mayo D199 and not in the regular classroom

22 6-Apr Data analysis Case-control and cross-sectional study analysis Pankow

Readings:

Due today:
Homework #5: bias analysis and effect modification (5%)
<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Reading</th>
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<tbody>
<tr>
<td>23</td>
<td>11-Apr Data analysis</td>
<td>Longitudinal data analysis</td>
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<tr>
<td>24</td>
<td>13-Apr Data analysis</td>
<td>Building risk prediction models</td>
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<td>25</td>
<td>18-Apr Project</td>
<td>Synthesis and final discussion</td>
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<td>All</td>
<td>Note: Some students will meet in Mayo D199 and not in the regular classroom</td>
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<td>Class participation day (1%)</td>
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<td>Due today:</td>
<td>Final project report (25%)</td>
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<tr>
<td>26</td>
<td>20-Apr Special topic</td>
<td>Screening</td>
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<td></td>
<td>Muñoz-Zanzi</td>
<td>Harris R. Overview of screening: where we are and where we may be headed. <em>Epidemiologic Reviews</em> 2011: 33: 1-6.</td>
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<td></td>
<td>Due today:</td>
<td>Homework #6: analysis of longitudinal data (5%)</td>
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<td>27</td>
<td>25-Apr Special topic</td>
<td>Mendelian randomization</td>
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<td>28</td>
<td>27-Apr Special topic</td>
<td>Public health surveillance: study design, analysis, bias</td>
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<td>Due by Monday, 1-May at 9am</td>
<td>Question for expert panel on public health surveillance (1%)</td>
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<td>29</td>
<td>2-May Special topic</td>
<td>Public health surveillance: expert panel discussion</td>
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<td></td>
<td>Muñoz-Zanzi</td>
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<td>30</td>
<td>4-May Wrap-up and final exam review session</td>
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<td>All</td>
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<td>9-May</td>
<td>Final exam:</td>
<td>4:00-6:00pm in regular classroom (25%)</td>
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VII. Evaluation and Grading

Students will be evaluated through a combination of class participation, homework assignments, midterm exam, study design project, and final exam. Both A/F and S/N grading options are available. MPH students majoring in epidemiology are required to take the A/F option and achieve a grade of B- or higher to advance in the program.

Class participation - 6%

Class participation (1% each) will be based on attendance and participation in six discussion sessions for the study design project (2/7, 2/21, 4/4, and 4/18), published paper review (2/28), and public health surveillance expert panel (5/2). Under some circumstances, make-ups for class participation may be granted if the student sends an e-mail notification to one of the instructors before the class in which the class participation point is offered to indicate the reason for the anticipated absence.

Homework Assignments – 25%

There will be six homework assignments. Students will submit five of these for evaluation; each contributes 5% toward the final grade. If a student chooses to complete all six assignments, the highest five scores will be counted toward the final grade. All assignments are due at the beginning of class (4:00pm) on the date indicated in the class schedule. Unless otherwise directed, please upload your assignment to the Moodle site. Late assignments will lose 1% (i.e., 1 point out of 5) per business day (Saturdays and Sundays excluded).

1. Case-control designs (due 2/2)
2. Diagnostic tests (due 2/23)
3. Infectious disease modeling (due 3/21)
4. Confounding adjustment (due 3/30)
5. Bias analysis and effect modification (due 4/6)
6. Analysis of longitudinal data (due 4/20)

Midterm Exam – 15%

There will be a midterm exam during class on 3/9 covering course material through 3/2 (class 14).

Study design project: preliminary reports – 4%

Students will initially work together in groups of 3-4 to select a tentative research hypothesis, study population, study design, and data collection methods to investigate an infectious or noninfectious health outcome. Students will be able to choose which of the available exposures and outcomes they wish to study, but membership in groups will be assigned by the instructors. Short reports (one from each group) are due on 2/14 (research question, population, design, 2%) and 2/28 (data collection, 2%).

Study design project: final report - 25%

Each student will submit a final report due 4/18 detailing their research project plan.

Final exam – 25%

There will be a comprehensive final exam during finals week (5/9, 4-6pm).
Final grades will be assigned as follows:

100.0 - 92.5  A  Represents achievement that is outstanding relative to the level necessary to meet course requirements
90.0 - 92.4  A-
87.5 - 89.9  B+  Represents achievement that is significantly above the level necessary to meet course requirements
82.5 - 87.4  B
80.0 - 82.4  B-
77.5 - 79.9  C+
72.5 - 77.4  C
70.0 - 72.4  C-
67.5 - 69.9  D+
62.5 - 67.4  D
60.0 - 62.4  D-
< 60  F  Represents failure and signifies that the work was completed but not a level of achievement worthy of credit.
S  Represents achievement that is satisfactory, which is equivalent to a C- or better
N  Represents no credit and signifies that the work was not completed at a satisfactory level of achievement and carries no grade points.

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 CoursEval: 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:

**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:**
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](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.

Out-of-Class Meetings
To meet with the instructors outside of class or regularly scheduled office hours, it is best to arrange an appointment. As faculty members who have extensive research and service obligations, we are juggling many responsibilities. At times, we may be able to talk with you in our office at the spur of the moment outside of office hours. Sometimes we cannot, and this can be disappointing if you have made the long trek over to the WBOB building without an appointment.

Course Web Site
The course web site is hosted on Moodle. Log on using your UMN internet ID and password.