PUBH 7465, SECTION 001
Biostatistics Consulting
Spring 2019

COURSE & CONTACT INFORMATION
Credits: 3 credits
Meeting Day(s), Time, and Place: MWF 11:15-12:05, Moos 2-116 (Mayo A434 for some consulting sessions)

<table>
<thead>
<tr>
<th>Contact Type</th>
<th>Contact Information</th>
</tr>
</thead>
</table>
| Co-instructor | Kyle Rudser, PhD                  
|               | Office: 717 Delaware St. SE, Room 134  
|               | Phone: 612-626-6814            
|               | E-mail: rudser@umn.edu        
|               | Office hours by appointment  |
| Co-instructor | Ann Brearley, PhD              
|               | Office: Mayo A444             
|               | Phone: 612-624-7656           
|               | E-mail: brea0022@umn.edu      
|               | Office hours by appointment  |

COURSE DESCRIPTION
This course examines the professional roles, responsibilities and analytic skills of the practicing biostatistician as consultant and collaborator in health science research. The spectrum of roles will be explored through lecture, readings, discussion, written assignments, and participation in statistical consulting sessions with investigators at the University of Minnesota.

Acknowledgments
PubH 7465 was originally developed by Dr. Kyle Rudser and Dr. Joe Koopmeiners.

COURSE PREREQUISITES
PubH 7405-7406 (or Stat 8051-8052) and Stat 5101-5102 (or Stat 8101-8102); Biostatistics graduate student.

COURSE GOALS & OBJECTIVES
Expose students to a variety of projects to gain experience as statistical consultants. By the conclusion of the course students should be able to:

1. Describe methods of establishing an effective collaboration with a researcher or co-investigator.
2. Facilitate discussion and conduct an effective meeting, discerning the overall goal of the investigator and determining specific aims of the project.
3. Translate a client's scientific questions of interest into statistical questions, chose an appropriate statistical method to address the scientific objectives, and defend that choice by articulating pros and cons of it and alternatives.
4. Explain the content and purpose of each standard section of a journal article in the health sciences.
5. Explain the outline of a research grant and the requirements of the analysis section.
6. Critique a clinical trial protocol.
7. Calculate sample size, power, and randomization schedule for a variety of observational and clinical trial designs.
8. Understand issues with safety and efficacy analyses, interim analyses, multiple endpoints, missing data, and model subset selection.
9. Write a report of a consulting session and an analysis, prepare publication-quality tables and graphics, and make an oral presentation of results.

METHODS OF INSTRUCTION AND WORK EXPECTATIONS

Methods of Instruction
Lecture, readings, videos, student individual and group projects and presentations, participation in statistical consulting sessions with investigators at the University of Minnesota.

Course Workload Expectations
PubH 7465 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 out of class or 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.

Technology
You will use the following technology tools in this course. Please make yourself familiar with them.
- Canvas (course learning management system)
- Google Docs (training is available via OIT https://it.umn.edu/self-help-guide/google-drive-work-files-folders)
- R, SAS or your statistical software of choice
- Rmd, Word, LaTeX, or your document preparation software of choice

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
All of these listed texts are optional. They are all available on reserve in the Biostatistics main office.

In addition, the following *optional* article may be a useful reference:

This course also 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

Each week will consist of three class periods:

- Discussion of a consulting case-study (as well as review of the previous week’s consulting sessions)
- Lecture on a topic relevant to biostatistical consulting
- Consulting session with a researcher from the Academic Health Center (AHC)

The case-study/discussion and lecture will be completed during the Monday and Wednesday class periods. We will make our best effort to schedule consulting sessions during the Friday class periods (from 11:15-12:05 on Fridays) but some flexibility will be required from the students. Please contact the instructors if this is a problem.

The consulting sessions are an important aspect of the class and will provide students with practical consulting experience, providing biostatistical consulting for members of the university community. Students will provide consulting in groups of two and will be supervised by a faculty member. It is expected that the faculty member will take the lead in consulting sessions during the first few weeks of the semester but that the students will take an increased leadership role in these sessions as the semester progresses.

Approximate timing and content of lectures:
Week 1: Structure of class, effective communication with clients
Week 2: Approach to consulting
Week 3: Writing for scientific manuscripts
Week 4: Approach to data analysis
Week 5: Presenting results
Week 6: Sample size and power calculations
Week 7: Statistical vs. scientific significance; scientist game
Week 8: Analysis of observational data
Week --: Spring Break (no class)
Week 9: Analysis of experimental data
Week 10: Analysis for prediction I
Week 11: Analysis for prediction II
Week 12: Model fit and robustness I
Week 13: Model fit and robustness II
Week 14: Missing data; Protocols & grant proposals
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/](http://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

Course grade will be based on participation/attendance (20%), weekly consulting session written summary reports and related assignments (40%), and case-study assignments (40%).

**Attendance** will be kept and will be formally incorporated into the final grade for the course. Excused absences for lectures and case-studies will be granted at the discretion of the instructors for students to attend conferences, job interviews, etc. It is the responsibility of the student to contact the instructors in advance if an excused absence is to be requested. Weekly consulting sessions will include two students and one instructor. It is the student's responsibility to find a replacement if they are to miss a consulting session. This should also be communicated with the instructors in advance of the session.

**Participation** includes: 1.) reviewing problem descriptions from investigators and arriving prepared to consulting sessions (e.g., completing tasks/analyses determined at a previous consulting session), 2.) participating in the discussion during the consulting session with investigators and 3.) participating in class discussions of consults and of case studies. During the first few weeks of the semester the senior (faculty) consultant will take the responsibility for leading the consulting session discussion. Later in the semester, the roles will reverse and students will take primary responsibility for leading discussions.

**Written summary reports** will be made by each student for each consulting session they attend. These reports will include a brief summary of the background and scientific/statistical questions, a summary of the discussion during the consulting session, and an indication of what is to be done as follow-up both by the client and by the statisticians.

**Case-study assignments** will be assigned weekly and will include writing analysis plans, performing data analysis, and writing analysis reports for the case studies discussed in class. Late work will not be accepted. Students may be called on to present their analysis plan/data analysis for the class but this will be done on a case-by-case basis and students are not expected to have a prepared presentation.

**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:
<table>
<thead>
<tr>
<th>% In Class</th>
<th>Grade</th>
<th>GPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>93 - 100%</td>
<td>A</td>
<td>4.000</td>
</tr>
<tr>
<td>90 - 92%</td>
<td>A-</td>
<td>3.667</td>
</tr>
<tr>
<td>87 - 89%</td>
<td>B+</td>
<td>3.333</td>
</tr>
<tr>
<td>83 - 86%</td>
<td>B</td>
<td>3.000</td>
</tr>
<tr>
<td>80 - 82%</td>
<td>B-</td>
<td>2.667</td>
</tr>
<tr>
<td>77 - 79%</td>
<td>C+</td>
<td>2.333</td>
</tr>
<tr>
<td>73 - 76%</td>
<td>C</td>
<td>2.000</td>
</tr>
<tr>
<td>70 - 72%</td>
<td>C-</td>
<td>1.667</td>
</tr>
<tr>
<td>67 - 69%</td>
<td>D+</td>
<td>1.333</td>
</tr>
<tr>
<td>63 - 66%</td>
<td>D</td>
<td>1.000</td>
</tr>
<tr>
<td>&lt; 62%</td>
<td>F</td>
<td></td>
</tr>
</tbody>
</table>

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).
<table>
<thead>
<tr>
<th>Evaluation/Grading Policy</th>
<th>Evaluation/Grading Policy Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scholastic Dishonesty, Plagiarism, Cheating, etc.</td>
<td>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 <a href="https://z.umn.edu/dishonesty">https://z.umn.edu/dishonesty</a>. The Office for Student Conduct and Academic Integrity has compiled a useful list of Frequently Asked Questions pertaining to scholastic dishonesty: <a href="https://z.umn.edu/integrity">https://z.umn.edu/integrity</a>. 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 (<a href="http://z.umn.edu/iuplagiarism">http://z.umn.edu/iuplagiarism</a>).</td>
</tr>
<tr>
<td>Late Assignments</td>
<td>See above.</td>
</tr>
<tr>
<td>Attendance Requirements</td>
<td>See above.</td>
</tr>
</tbody>
</table>
| 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 quality 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](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. 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. |