



PubH 7465-001
Biostatistics Consulting
Spring 2018

Credits: 3
Meeting Days: MWF
Meeting Time: 11:15 – 12:05
Meeting Place: Moos Tower 1-440 for class and Kyle’s consulting sessions;
Mayo A434 for Ann’s consulting sessions

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I. 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.

II. Course Prerequisites

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

III. Course Goals and 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.

IV. Methods of Instruction and Work Expectations

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

V. Course Text and Readings

All texts *optional*:

Janice Derr (2000) **Statistical Consulting: A Guide to Effective Communication**. Duxbury

Javier Cabrera and Andrew McDougall (2002) **Statistical Consulting**. Springer

J Boen and D Zahn (1982) **The Human Side of Statistical Consulting**

D.J. Hand & B.S. Everitt (1987) **The Statistical Consultant in Action**. Cambridge

E Tufte (2001) **The Visual Display of Quantitative Information, 2nd edition**

George D. Gopen and Judith A. Swan (1990) The Science of Scientific Writing. *American Scientist*, 78: 550-558.

VI. Course Outline/Weekly Schedule

Each week will consist of three class periods:

- a discussion of a consulting case-study (as well as review of the previous week's consulting sessions)
- a lecture on a topic relevant to biostatistical consulting
- a 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 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 be supervised by a faculty member. It is expected 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 client
- Week 2: Approach to consulting
- Week 3: Approach to data analysis
- Week 4: Presenting results
- Week 5: Sample size and power calculations
- Week 6: Statistical vs. scientific significance; scientist game
- Week 7: Scientific writing: sections for journal articles in health sciences
- Week 8: Analysis for prediction
- Week --: *Spring Break (no class)*
- Week 9: Analysis for prediction, cont.
- Week 10: Analysis of observational data
- Week 11: Analysis of experimental data
- Week 12: Model fit vs. robustness
- Week 13: Protocols & grant proposals
- Week 14: Model fit vs. robustness, cont.
- Week 15: Missing data

VII. Evaluation and 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. A letter grade will be determined from the percentage of points each student receives as follows:

		B+	87-89%	C+	77-79%	D+	67-69%
A	93-100%	B	83-86%	C	73-76%	D	63-66%
A-	90-92%	B-	80-82%	C-	70-72%	F	0-62%

For those enrolled S/N, a letter grade of C or better must be achieved to receive an S. If you would like to switch grading options (e.g., A/F to S/N), it must be done within the first two weeks of the semester. Please refer to the University's Uniform Grading Policy found at www.umn.edu/usenate/user/policies.htm.

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: https://regents.umn.edu/sites/regents.umn.edu/files/policies/Sexual_Harassment_Sexual_Assault_Stalking_Relationship_Violence.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.

Template update 9/2014