# UNIVERSITY OF MINNESOTA

# **Course Syllabus**

School of Public Health

# PubH 7465-001 Biostatistics Consulting Spring 2012

| Credits:              | 3                                                                                                                                                 |  |  |  |  |  |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
| Meeting Days:         | MWF                                                                                                                                               |  |  |  |  |  |
| Meeting Time:         | 11:15-12:05                                                                                                                                       |  |  |  |  |  |
| Meeting Place:        | Moos 2-639 and Mayo A434                                                                                                                          |  |  |  |  |  |
| Instructors:          | Joe Koopmeiners, PhD<br>A454-2 Mayo Building<br>420 Delaware Street SE<br>Minneapolis, MN 55455<br>Email: koopm007@umn.edu<br>Phone: 612-624-7486 |  |  |  |  |  |
|                       | Kyle Rudser, PhD<br>717 Delaware St SE, Room 219<br>Minneapolis, MN 55414<br>Email: rudser@umn.edu<br>Phone: 612-626-6814                         |  |  |  |  |  |
| Fax:<br>Office Hours: | <b>612-626-0660</b><br>Joe Koopmeiners: Fridays 2:00 – 3:00 p.m., Mayo A454-2<br>Kyle Rudser: Wednesdays 12:30-1:30pm or by appointment           |  |  |  |  |  |

## I. Course Description

This seminar 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, discussion, written assignments, and student presentations of work on consulting projects.

## II. Course Prerequisites

Pubh 7405, 7406, and 7407 (or Stat 8051-8052) and Stat 5101-5102 (or Stat 8101-2), 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, video, student 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 lecture on a topic relevant to biostatistical consulting
- a discussion of a consulting case-study
- a consulting session with a researcher from the AHC

The lecture and case-study 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 Friday's 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 be 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 2-3: Approach to consulting/data analysis
- Week 4: Sample Size and power calculations

- Week 5: Scientist Game
- Week 6: Analysis of observational data
- Week 7: Analysis of experimental data
- Week 8: Model fit vs. Robustness
- Week 9: Spring Break (no class)
- Week 10: Analysis for prediction
- Week 11: Missing Data
- Week 12: Design of Observational studies
- Week 13: Design of experiments
- Week 14: Randomization
- Week 15: Writing reports, presenting results

Week 16: Scientific writing: sections for journal articles in health sciences

### VII. Evaluation and Grading

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

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. During the first few weeks of the semester the senior (faculty) consultant will take the responsibility for leading the consulting session. Later in the semester, the roles will reverse and students will take primary responsibility for leading discussions.

Written summary reports will be made for each consultation. 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 statisticians.

Case-study assignments will be assigned weekly and will include writing analysis plans and performing data analysis for the case-studies discussed in class. 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% |
|----|---------|----|--------|----|--------|----|--------|
| А  | 93-100% | В  | 83-86% | С  | 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. The University Senate has established a uniform grading policy for all letter grades:

wwwl.umn.edu/usenate/policies/ gradingpolicy.html. 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.

### **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 <u>onestop.umn.edu</u>.

#### **Course Withdrawal**

Students should refer to the Refund and Drop/Add Deadlines for the particular term at <u>onestop.umn.edu</u> 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 Student Services Center at <u>sph-ssc@umn.edu</u> for further information.

#### Student Conduct, Scholastic Dishonesty and Sexual Harassment Policies

Students are responsible for knowing the University of Minnesota, Board of Regents' policy on Student Conduct and Sexual Harassment found at <u>www.umn.edu/regents/polindex.html</u>.

Students are responsible for maintaining scholastic honesty in their work at all times. Students engaged in scholastic dishonesty will be penalized, and offenses will be reported to the SPH Associate Dean for Academic Affairs who may file a report with the University's Academic Integrity Officer.

The University's Student Conduct Code defines scholastic dishonesty as "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; or altering, forging, or misusing a University academic record; or fabricating or falsifying of data, research procedures, or data analysis."

Plagiarism is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: <u>http://writing.umn.edu/tww/plagiarism/</u>.

Students are urged to be careful that they properly attribute and cite others' work in their own writing. For guidelines for correctly citing sources, go to <u>http://tutorial.lib.umn.edu/</u> and click on "Citing Sources".

In addition, original work is expected in this course. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable.

#### **Disability Statement**

It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have a documented disability (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services to have a confidential discussion of their individual needs for accommodations. Disability Services is located in Suite180 McNamara Alumni Center, 200 Oak Street. Staff can be reached by calling 612/626-1333 (voice or TTY).