

Ethical Issues for Biostatisticians

Lianne Sheppard, PhD

Course objectives: To expose students to ethical issues in the conduct of biomedical research, particularly as pertinent to the computation, interpretation, and communication of statistics, and to provide students with the knowledge and the resources needed to practice statistics ethically in this domain. To help students formulate justified responses to ethical challenges, and to nurture a sense of professional responsibility to take action.

Format: The second offering of this course will be a special topics class spring quarter 2011. It will be two credits meeting for 20 hours during the quarter for up to 3 hours in any given week during some combination of the following times: Wednesdays 2:30-3:30 (HSB T-635) and Thursdays from 1:30-3:20 (HSB T474). Sessions will consist of a combination of lecture and discussion. Often Thursday sessions will be given by invited speakers; most speakers will discuss their own experiences wrestling with ethical challenges. Student presentations will be incorporated.

Learning objectives: By the end of this course, students should be able to

- Identify the major principles guiding ethical scientific research in general and ethical biomedical research in particular
- Evaluate ethical aspects of decisions arising in the production and communication of biomedical statistical analyses
- Describe the unique role of statisticians in the ethical conduct of biomedical science
- Apply four steps of ethical analysis (recognition, reasoning, responsibility, action) to situations commonly confronting statisticians in the biomedical sciences
- Summarize a short list of specific historical and current examples

CLASS WEB PAGE: <http://courses.washington.edu/bethics/index.html>

CONTACT INFORMATION:

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Academic Accommodations: To request academic accommodations due to disability, please contact Disabled Student Services, 448 Schmitz, (206) 543-8924(V/TTY). If you have a letter from Disabled Student Services indicating that you have a disability that requires academic accommodations, please bring this to the instructor.

READINGS:

Required Readings: These are listed by week on the class website readings page. The reading list will be updated as the quarter proceeds.

Supplemental Readings: There are many additional readings listed on the class website (check back for changes over the quarter). I recommend students look over all supplemental readings and selectively review some in detail. See also the resources page.

HOMEWORK:

In addition to readings there will be some reflections or other homework exercises. See assignments linked from on the class readings page:

<http://courses.washington.edu/bethics/readings/index.html>

Course schedule outline (subject to change):

1 Wed March 30	Introduction, overview, case study discussion
Thus March 31	Human subjects research – Guest speaker from Human Subjects Division, Sharon Elsayed
2 Wed April 6	NO CLASS
Thus April 7	NO CLASS
3 Wed April 13	Data access and reporting: The Remune story preparation
Thus April 14	The Remune story – Guest speaker Dave Glidden, UCSF
4 Wed April 20	NO CLASS
Thus April 21	Guest speaker Bruce Psaty: Conflict of interest, disclosure, guest authorship and ghostwriting NOTE: Room today will be F648
5 Wed April 27	Prepare for discussion of bias of positive findings
Thus April 28	NO CLASS
6 Wed May 4	NO CLASS
Thus May 5	Guest lecture: Tom Fleming discusses the bias for positive findings in biomedical research
7 Wed May 11	Ethical issues in epidemiological research
Thus May 12	Guest lecture Bruce Lanphear (Simon Fraser University) - - Low dose lead and residual confounding
8 Wed May 18	TBA
Thus May 19	Guest lecture: Dick Kronmal discusses the Vioxx story
9 Wed May 25	Student presentations or TBA
Thus May 26	Student presentations or TBA
10 Wed June 1	Student presentations or TBA
Thus June 2	Student presentations or TBA
June 8-12 -- final exam time or other time TBA	Student presentations if more time is needed

GRADING: This is a Credit/No Credit course. Students are expected to:

- Complete the required readings
- Participate in class discussions every week
- Hand in homework assignments
- Complete a class project related to the subject matter of the course. Project is due no later than final exam week (June 8-12) with specific date and time arranged by week 6. The class projects may be delivered either as a written paper (approximately 6 pages) or as a presentation to the class (approximately 20 minutes).

CLASS PROJECT: Each student will complete one project. Please seek advance approval for your topic and schedule your presentation by week 6. Project options include:

- **Paper review:** The student will review a paper or a set of papers on a particular scientific study. The oral or written presentation will discuss the ethical issues related to the study and the presentation of its results. Students may select their own papers or choose one/a set from the additional resources on the course website.
- **Lead a class discussion:** The student will review an ethical principle and lead the class discussion on this topic.
- **Statistical methods topic:** The student will review a methodological issue in statistics and discuss its ethical implications in biomedical research.