

BIOST 532: Research Ethics in the Data Sciences

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.

NIH RESPONSIBLE CONDUCT OF RESEARCH (RCR) TRAINING REQUIREMENTS

Responsible conduct of research is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

NIH requires the following topics be addressed in RCR training:

- Collaborative research (including collaboration with industry)
- Conflict of interest (personal, professional, financial)
- Data acquisition and laboratory tools: data management, sharing and ownership
- Human subjects, live vertebrate animals in research, and safe laboratory practices
- Mentor/mentee responsibilities and relationships
- Peer review
- Research misconduct and policies for handling misconduct
- Responsible authorship and publication
- Scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

This course strives to cover all topics required by NIH, with particular emphasis on the collection, analysis and reporting of data.

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 and data scientists 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

Format: This course is two credits meeting for 20 hours during the quarter on **Mondays 3:30-5:20 (HSB T-474)**. Sessions will consist of a combination of lecture and discussion. There will be invited speakers; most speakers will discuss their own experiences wrestling with ethical challenges. Student-led discussions will be incorporated.

CONTACT INFORMATION:

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CLASS WEB PAGE: <https://canvas.uw.edu/courses/1203586>

ADDITIONAL WEB RESOURCES – COMPANION BIostat ETHICS WEBSITE: In conjunction with the course, many additional materials have been assembled on the companion “biostat ethics” website: <http://courses.washington.edu/bethics/index.html>

Multi-cultural Inclusion Commitment: Diverse backgrounds, embodiments, and experiences are essential to the critical thinking endeavor at the heart of university education. Therefore, I expect our interactions in this course will respect the many social and cultural differences among us, which may include, but are not limited to: age, cultural background, disability, ethnicity, family status, gender identity and presentation, citizenship and immigration status, national origin, race, religious and political beliefs, sex, sexual orientation, socioeconomic status, and veteran status. Please talk with me right away if you experience disrespect in this class, and I will work to address it in an educational manner. UW students can also report incidents of bias or violations of UW policies for non-discrimination using the Bias Reporting Tool available at: <http://www.washington.edu/bias/>.

Academic Integrity Statement: Students at the University of Washington (UW) are expected to maintain the highest standards of academic conduct, professional honesty, and personal integrity. The UW School of Public Health (SPH) is committed to upholding standards of academic integrity consistent with the academic and professional communities of which it is a part. Plagiarism, cheating, and other misconduct are serious violations of the University of Washington Student Conduct Code (WAC 478-120). We expect you to know and follow the university's policies on cheating and plagiarism, and the [SPH Academic Integrity Policy](#). Any suspected cases of academic misconduct will be handled according to University of Washington regulations. For more information, see the University of Washington [Community Standards and Student Conduct website](#).

Access and Accommodations: Your experience in this class is important to me. If you have already established accommodations with Disability Resources for Students (DRS), please communicate your approved accommodations to me at your earliest convenience so we can discuss your needs in this course.

If you have not yet established services through DRS, but have a temporary health condition or permanent disability that requires accommodations (conditions include but not limited to; mental health, attention-related, learning, vision, hearing, physical or health impacts), you are welcome to contact DRS at 206-543-8924 or uwdrs@uw.edu or disability.uw.edu. DRS offers resources and coordinates reasonable accommodations for students with disabilities and/or temporary health conditions. Reasonable accommodations are established through an interactive process between you, your instructor(s) and DRS. It is the policy and practice of the University of Washington to create inclusive and accessible learning environments consistent with federal and state law.

READINGS:

Required Readings: These are listed by week on the class website in the modules section. The reading list may be updated as the quarter proceeds.

Supplemental Readings: There are many additional readings you could explore. See both optional readings linked from the reading assignments page and additional materials posted on the companion website. I recommend students look over all supplemental readings and selectively review some in detail.

HOMEWORK:

- **Readings:** These will be posted on the class canvas site, modules section. There are also many other related readings you can find in the files section and in the companion website.
- **Written reviews and online discussions:** See the canvas website for the schedule of due dates and for links to the assignments
- **Student-led discussions:** Students will choose a topic of interest to them and lead a discussion during class. This could include small group discussion time. Students are responsible for choosing class reading(s) for this topic, introducing the topic, and managing the class discussion. The goal of the student-led discussions is to increase the diversity and relevance to the students of the topics discussed by the class.
- **Analysis homework:** This will due in three phases. The first phase will focus on reading the reports for the study and the results as initially obtained, along with designing an analysis plan for replicating the published analysis. The second phase will be an attempt to replicate the published analysis from the 1970's. The third phase will be to use modern statistical tools to conduct a new analysis that should better addresses the study goals.
- **Final reflection:** Write a short reflection on the subject matter of the course and how that potentially relates to your work and education. Include examples from the course. This reflection is due during final exam week (June 4-8).

GRADING:

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

- Complete the required readings
- Participate in class discussions every week
- Lead and actively contribute to the student-led discussions
- Hand in written assignments including
 - Online discussions
 - Peer reviews of two papers
 - Data analysis
 - Final reflection

Course schedule (subject to change):

Week Number and Date	Topics	Assignments Due
1 Mar 26	Introduction, overview, case study discussion, prepare for the Remune story	Readings
2 April 2	Data access and reporting: The Remune story with guest Dave Glidden	Readings Hand in reviews
3 Mon April 9 8:00-9:20 am	Discerning hype from substance in reporting results Strongly encouraged: Attend BIOST 524 8-9:20 a.m. in HST 531	Readings
3 April 9	Remune story debrief; reporting results and random high bias; moral reasoning case study on modifying the study protocol	Readings
4 Mon April 16	Conflict of interest, disclosure, guest authorship and ghostwriting; industry influence on results; guest speaker Garnet Anderson on COI in the WHI study	Readings Online discussion
5 Mon April 23	Introduce analysis homework; Human subjects research; Belmont Report; Professional standards; Impacts of race on research; student-led discussion	Readings
6 April 30	Ethical issues in clinical trials (the actimmune study example) AND introduction to the Duke saga with guest Tom Fleming (LS out of town)	Hand in analysis phase 1
7 May 7	ASA Statement on p-values; p-hacking; reproducibility, student-led discussions	Readings
7 TBD	Optional meeting to support the statistical analysis for the analysis homework	--
8 May 14	Institutional responsibility; the Duke saga; student-led discussions; Discuss analysis project	Readings Hand in analysis phase 2
9 May 21	Open science and sound science; social responsibility; student-led discussion; course wrap-up	Readings
10 May 28	NO CLASS – Memorial Day	Hand in analysis phase 3
June 4-8 -- Due date TBD	–	Hand in final reflection