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.

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 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 for up to 3 hours in any given week during a subset of the following times: Mondays and Wednesdays 2:30-4:20 (HSB T-478). Note: Most weeks we will only meet between 2:30 and 3:20. Sessions will consist of a combination of lecture and discussion. The longer sessions will be led by invited speakers; most speakers will discuss their own experiences wrestling with ethical challenges. Student-led discussions will be incorporated.
CONTACT INFORMATION:

Lianne Sheppard, PhD
Office Hours: By appointment;
Office: HSB F-672 or Roosevelt 203
Phone: (206)616-2722
E-mail: sheppard@uw.edu

CLASS WEB PAGE: https://canvas.uw.edu/courses/1038843

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

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.

Multi-cultural Inclusion Commitment: The UW School of Public Health seeks to ensure all students are fully included in each course. We strive to create an environment that reflects community and mutual caring. As your instructor, I encourage students with concerns about classroom climate to talk to me if you have any concerns. You may also choose to seek out others such as your advisor, a member of your Department’s or the SPH Diversity Committee and/or a program director.
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: https://canvas.uw.edu/courses/1038843/modules
- **Written reviews and online discussions**: See the canvas website for the schedule of due dates and for links to the assignments: https://canvas.uw.edu/courses/1038843/assignments
- **Student-led discussions**: Students should divide into approximately three small groups to develop and lead a class discussion on May 16 on an ethics-related topic.
- **Analysis homework**: This will be 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 paper**: 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 6-10).

GRADING:

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

- Complete the required readings
- Participate in class discussions every week
- Actively contribute to the student-led discussions
- Hand in written assignments including
  - Online discussions
  - Peer reviews of two papers
  - Data analysis
  - Final reflection paper
## Course schedule (subject to change):

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Topics</th>
<th>Assignments Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Mon Mar 28</td>
<td>2:30-3:20</td>
<td>Introduction, overview, case study discussion</td>
<td>Readings</td>
</tr>
<tr>
<td>1 Wed Mar 30</td>
<td>2:30-3:20</td>
<td>Human subjects research; Belmont Report; Professional standards</td>
<td>Readings Online discussion</td>
</tr>
<tr>
<td>2 Mon April 4</td>
<td>2:30-3:20</td>
<td>Data access and reporting: The Remune story preparation</td>
<td>Readings</td>
</tr>
<tr>
<td>2 Wed April 6</td>
<td>2:30-3:20</td>
<td>The Remune story</td>
<td></td>
</tr>
<tr>
<td>3 Mon April 11</td>
<td>2:30-3:20</td>
<td>Discerning hype from substance in reporting results</td>
<td>Readings</td>
</tr>
<tr>
<td>3 Wed April 13</td>
<td>2:30-3:20</td>
<td>Discuss reporting results</td>
<td>Readings Online discussion</td>
</tr>
<tr>
<td>4 Mon April 18</td>
<td>2:30-3:20</td>
<td>Conflict of interest, disclosure, guest authorship and ghostwriting</td>
<td>Readings</td>
</tr>
<tr>
<td>4 Wed April 20</td>
<td>2:30-3:20</td>
<td>ASA Statement on p-values</td>
<td>Readings Online discussion</td>
</tr>
<tr>
<td>5 Mon April 25</td>
<td>2:30-3:20</td>
<td>Student-led discussions of p-values</td>
<td>Readings</td>
</tr>
<tr>
<td>5 Wed April 27</td>
<td>2:30-3:20</td>
<td>Discussion on reproducible research and introduce analysis homework</td>
<td>Readings Online discussion</td>
</tr>
<tr>
<td>6 Mon May 2</td>
<td>NO CLASS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Wed May 4</td>
<td>NO CLASS</td>
<td></td>
<td>Hand in analysis phase 1</td>
</tr>
<tr>
<td>7 Mon May 9</td>
<td>2:30-4:20</td>
<td>Tom Fleming: Ethical considerations of the actimmune study</td>
<td>Readings</td>
</tr>
<tr>
<td>7 Wed May 11</td>
<td>2:30-4:20</td>
<td>NO CLASS Optional meeting to support the statistical analysis for the analysis homework</td>
<td>Hand in analysis phase 2</td>
</tr>
<tr>
<td>8 Mon May 16</td>
<td>2:30-4:20</td>
<td>Scott Emerson: Topic TBD</td>
<td>Readings; Prepare for discussion</td>
</tr>
<tr>
<td>8 Wed May 18</td>
<td>2:30-4:20</td>
<td>Discuss analysis project Student-led discussions</td>
<td>Lead discussion Student-assigned readings, if any Hand in analysis phase 3</td>
</tr>
<tr>
<td>9 Mon May 23</td>
<td>2:30-4:20</td>
<td>Begin discussing the Duke Saga with Daniela Witten, member of the IOM Omics panel</td>
<td>Readings</td>
</tr>
<tr>
<td>9 Wed May 25</td>
<td>2:30-4:20</td>
<td>The Duke Saga – Guest speaker Keith Baggerly, Texas A&amp;M Note: Combined with Student Seminar</td>
<td>Readings Online discussion</td>
</tr>
<tr>
<td>10 Mon May 30</td>
<td>NO CLASS – Memorial Day</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>10 Wed June 1</td>
<td>2:30-3:20</td>
<td>The Duke Saga debrief and course wrap-up</td>
<td>–</td>
</tr>
<tr>
<td>June 6-10 -- Due date TBD</td>
<td></td>
<td>–</td>
<td>Hand in course reflection</td>
</tr>
</tbody>
</table>