Ethics in Biostatistics  
(M21 512)  
Spring 2018 Syllabus

Mondays 4:00 – 6:00 pm  
January 22 – May 7  
TAB Classroom B

Instructor and Teaching Assistant  
Alison L. Antes, PhD, aantes@wustl.edu, 314-362-6006  
Tim Rubbelke, PhD, trubbelke@wustl.edu

Office Hours  
Both the instructor and teaching assistant are glad to schedule meetings with students at a mutually convenient time and location. Please email or speak with us in class.

Course Description  
This course prepares biostatisticians to analyze and address ethical and professional issues in the practice of biostatistics across the range of professional roles and responsibilities of a biostatistician. The primary goals are for biostatisticians to recognize complex situational dynamics and ethical issues in their work and to develop professional and ethical problem-solving skills. The course specifically examines ethical challenges related to research design, data collection, data management, ownership, security, and sharing, data analysis and interpretation, and data reporting and provides practical guidance on these issues. The course also examines fundamentals of the broader research environment in which biostatisticians work, including principles of ethics in human subjects and animal research, regulatory and compliance issues in biomedical research, publication and authorship, and collaboration in science.

Course Competencies  
By the conclusion of this course, students will be able to:

- Promote ethical standards and practices in data management, research design, and statistical analysis and reporting
- Analyze ethical problems using a systematic decision-making framework
- Communicate about ethical and professional issues to address challenges and facilitate research integrity
- Contribute to collaborations with professionalism and personal integrity

Course Format and Learning Environment  
This course is interactive; it will include short didactic lectures, discussion of literature, case studies, and activities. Activities and case analyses will allow us to engage in dialogue about ethics in research, to share perspectives, and to discuss strategies for solving professional and ethical problems. It is important that the learning environment is open, engaged, and collaborative. The course incorporates essential content and readings to establish knowledge, and it focuses on building skills related to professional and ethical thinking, problem-solving, and working effectively with others. Students are expected to participate actively and contribute each week by coming to class prepared to share ideas and discuss with classmates.

Readings  
Readings include a collection of articles and books chapters available on Blackboard through the “Course Readings” link. The readings are provided via Ares, the Washington University Library eReserves system. Please access the articles early each week to ensure that you have them for the weekly assignment. The readings provide content related to each week’s topic and journal assignment. Please read for key ideas and lessons important to your career as a biostatistician. As noted on the course calendar, some readings are required and some are optional.
Blackboard
Assignments, readings, and grades will be posted via Blackboard (https://blackboard.wustl.edu). Important course updates and announcements will be sent to students via Blackboard as well.

Blackboard Menu
- **Announcements**: Information from the instructor will be posted here, and a copy will be emailed to students. Please check announcements/email regularly for updates from the instructor.
- **Calendar Quick View**: Immediate access to the course calendar outlining the weekly topic & readings.
- **Syllabus**: Contains the course syllabus.
- **Course Readings**: Provides access to the course readings through the library’s Ares Course eReserves system.
- **Weekly Journals**: The weekly journals will be available here and submitted by students in this area.
- **Course Documents**: Materials such as PowerPoints and handouts will be shared with students here.
- **Assignments**: Contains information for completing the Case Assignment and the “Top 5” Final Paper. A link to turn-in your paper will also be available here.
- **My Grades**: A running account of your grades for the class.
- **Attendance Records**: A running account of your attendance for the class.

Assignments
The assignments are described below, in addition to grading criteria. Assignments will also be discussed in class, and students are encouraged to ask questions about assignments and grading criteria.

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>1 Weekly Journal Entry</td>
<td>20%</td>
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<tr>
<td>2 Weekly Participation</td>
<td>20%</td>
</tr>
<tr>
<td>3 Current Issue</td>
<td>10%</td>
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<tr>
<td>4 Group Case Analysis</td>
<td>20%</td>
</tr>
<tr>
<td>5 “Top 5” Final Paper</td>
<td>30%</td>
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**Grading Scale**

- A+ (98%-100%) B- (80%-82%)
- A (93%-97%) C+ (78%-79%)
- A- (90%-92%) C (73%-77%)
- B+ (88%-89%) C- (70%-72%)
- B (83%-87%) D+ (68%-69%)

**Weekly Journal Entry**
Each week a writing prompt or question will be available on Blackboard. The prompt or question will relate to the week’s topic and readings. Students should write a response that is about one single-spaced page in length that is informed by the readings and personal perspective. The writing will be approximately 500-650 words in length, or about 4-5 paragraphs. **The depth of critical thought is more important than the specific length. The purpose of the assignment is to encourage critical thinking and reflection on the weekly topic, which will provide a “warm-up” for the course session each week.** Students may utilize the thoughts articulated in their journal entries to contribute to the in-class discussions.

- **Submission**: Submit entries under “Weekly Journals” on Blackboard by **12pm (noon) each Sunday**.
- Please copy and paste your response into the box provided after clicking “Create Journal Entry”.
- **“Freebie” Journal**: You may skip ONE of the journals without losing credit. If a student completes all of the journal entries, the “freebie” will count for up to 5 extra credit points.
- **“Redo” Option**: During the first four weeks of class, as students are becoming familiar with the journal writing assignment, students are permitted to “redo” and resubmit up to two journal entries and have them re-graded. The re-graded score will be the final score received for the journal. If a student elects to re-submit a journal entry, it is due by Friday at 12am (midnight) the week it was originally due.
- **Referencing Sources**: When referring to information contained in the **assigned readings**, students should refer to these resources in their writing in the following fashion: “According to Williams (1999)...”, “Miller and colleagues (2003) discuss...” Or, you can include a reference at the end of a sentence like this (Baker 2010). The teaching assistant and instructor will know which references from the reading list you are citing.
If students utilize **outside resources** of any kind, they must reference the resource in their writing using the author name and date, such as “Self et al. (1998) stated…”, AND provide the full reference at the bottom of their writing. For example, the full reference for a journal article and website are provided below. Students must put quotation marks (""") around direct, word-for-word quotes taken from a reference. It is imperative that proper credit is given for information that students obtain from resources. Without this credit, the student has engaged in plagiarism, a serious form of academic misconduct. Outside references are encouraged but not required. Please ask if you have any questions about appropriate citation practices. This is an essential skill, and we are glad to help clarify.


**Grading Criteria:** Grades will be based on (a) relevance to the question/topic, (b) depth and diligence of critical thinking, (c) writing clarity, and (d) timeliness.

**Weekly Participation**

Class meetings will be interactive. Please arrive in class prepared to engage and discuss. Students will be rewarded with participation points for active participation in class. Students are encouraged to actively ask questions of the instructor and classmates. Students are encouraged to share their perspective or challenge the ideas discussed in class. The classroom will be a safe place for students to engage in discussion. All dialogue is expected to be collegial and open. If classroom discussion happens to elicit differences in opinion, these differing views will *focus on the issue or problem, rather than on the person* challenging us to consider different views. In addition to in-class discussion, active participation in all in-class activities (for example, analysis of case scenarios or quizzes to review material) will count as participation. Students are also welcome to email links or online resources to their classmates using the Blackboard email tool. If a student would like feedback on his/her progress regarding course participation, he/she should please feel welcome to ask the instructor.

**Grading Criteria:** Grades will be based on contributions such as the following: sharing ideas and raising points during class discussions, asking questions, bringing examples and/or resources to class (or sharing via Blackboard), participating in individual and group in-class activities, and paying attention actively in class—ultimately participation means that students are actively engaged in their learning. Active learners are willing to share and learn from others, contribute to the learning of their classmates, and try to apply what they are learning to their life outside of the class.

**Current Issue**

Once during the semester, each student will be asked to present a current issue to the class. The current issue will relate to ethical or professional issues in biomedical research or technology. Students will be asked to: (a) summarize the issue, and specifically note what they perceive to be the key ethical or professional concerns, and (b) engage classmates in discussion about the current issue. Please bring to class 2 or 3 specific discussion questions to ask the class after you summarize the issue. Challenge your classmates with your question and simulate thinking—perhaps there is not even a true answer to your question! The goal is to practice communicating about the topics in the course and facilitating discussion with colleagues.

**Grading Criteria:** Grades will be based on preparation, clarity of summary, identification of ethical/professional concerns, and facilitation of discussion with classmates.

**Group Case Analysis**

Students will be assigned to small teams for this assignment. The small groups will review, analyze, and present a case to their classmates. The goal of the assignment is to practice ethical reasoning, professional problem-solving, and discussion of ethical issues with colleagues. Additional instructions will be provided.
Grading Criteria: Grades will be based on (a) depth and diligence of critical thinking about the case, (b) clarity of ideas, arguments, and points, (c) engagement of classmates/contribution to classmates’ learning, and (d) coordination of the presentation given by group members. These four elements of the grade will be scored for the entire group collectively. One individual score for effectiveness of delivery/communication will be provided with feedback to individual students.

“Top 5” Final Paper
The final assignment will be a culminating paper reflecting on the student’s learning in the course. Students will consider the 5 most important things that they have learned in the course and explain (a) what each point or lesson is, and (b) why it is important, including specifically commenting on why or how it will be useful to them in their career. The 5 points may be anything at all from the course, however, one point must include something you learned about yourself. The key aspects of this assignment are that the student explains each item clearly and convincingly describes why each item was selected. The length should be approximately 4-6 double-spaced pages with 1 inch margins. Please include an introduction paragraph and a conclusion paragraph in your paper.

- Submission: The paper should be submitted on Blackboard under “Assignments” by 12pm (noon) on Sunday, May 6. Please upload your paper as a Word document.
- Referencing Sources: Please follow the same instructions as described for the Weekly Journal Entry.

Grading Criteria: Grades will be based on (a) depth and diligence of critical thinking, (b) demonstration of learning from the course (i.e., sophistication of reasoning about course topics), and (c) writing clarity.

Course Policies, Expectations, and Wash U Resources
By participating in this course, students agree to the policies and expectations outlined in the syllabus. If questions arise at any point in the course, students are encouraged and expected to ask the instructor.

Writing and Speaking Skills: This course offers students the opportunity to enhance their writing and speaking skills. Students interested in taking additional initiative to improve their writing skills are encouraged to consult the Wash U Writing Center (http://writingcenter.wustl.edu/) for assistance. In the instructor’s experience, writing center assistance significantly enhances students’ writing and their grades. Additionally, for non-native English speakers in the Wash U community, the English Language Programs (https://oiss.wustl.edu/english-language-programs/) located in the Office of International Students and Scholars (https://oiss.wustl.edu/) offers some outstanding courses, tutorials, and events for students (including ones that are free); to find out more, contact elp@wustl.edu.

Attendance: Attendance in this course is expected and essential to meet the learning objectives. Students may miss one class (for any reason) without penalty. After one missed class, students will lose participation points for missing a second and third class (for any reason). Missing a fourth class will result in one full letter grade deduction of the final course grade. Missing more than four classes would result in failing the course. Please make the most of your learning opportunity in this course.

Professionalism: Classmates are expected to treat each other with dignity and respect. In this course, all opinions and perspectives are valued and encouraged.
**Academic Integrity**: Students are responsible for completing their own work, and academic dishonesty of any kind will not be tolerated and will be dealt with seriously by the instructor. Penalties range from receiving a zero on the assignment to failure of the course. Violations of academic integrity include but are not limited to:

1. Submitting material written by another person but represented as the student’s own work;
2. Copying a passage or text directly from a book, journal, website, etc., or using extensive paraphrasing, without indicating the source using a citation for referencing material;
3. Writing a paper or completing an assignment for another student;
4. Submitting an assignment as new work when the assignment was completed for another course.

The Master of Science in Biostatistics program expects students to adhere to the academic and research integrity policies published by Washington University. In particular, students should consult the [Graduate Student Academic Integrity Policy](#) regarding academic and professional integrity.

Students must understand that being unaware or lacking knowledge about exactly what constitutes cheating or academic dishonesty is not an acceptable justification. College students are responsible for educating themselves about cheating and academic dishonesty. They are also responsible for maintaining an open dialogue with their instructors if they have questions. Cheating and dishonesty in the college classroom are similar to issues encountered in the work world; responsible students and professionals must learn about these issues and address them appropriately.

**Late Assignment Policy**: All assignments must be turned in by their due dates. Incomplete assignments or assignments less than 24 hours late will receive partial credit. Assignments turned in more than 24 hours late receive no credit. Reasonable requests for assignment deadline extensions due to extenuating circumstances will be considered by the instructor; please speak with the instructor as far in advance as possible.

**Changes to Course Plan**: Any changes to the course schedule or plan will be communicated in class and via Blackboard.

**Academic Accommodations**: Washington University is committed to providing accommodations and/or services to students with documented disabilities. Students who are seeking support for a disability should contact Disability Resources at [disabilityresources@wustl.edu](mailto:disabilityresources@wustl.edu). Disability Resources is responsible for approving all disability-related accommodations for WU students, and students are responsible for providing faculty members with formal documentation of their approved accommodations at least two weeks prior to using those accommodations.
### Course Calendar

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<tr>
<th>Date</th>
<th>Topic</th>
<th>Readings</th>
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<tr>
<td><strong>Week 1</strong></td>
<td><strong>January 22</strong></td>
<td><strong>Introduction to Ethics and Professionalism</strong></td>
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WUSTL Research integrity policy. Available at: [http://research.wustl.edu/PoliciesGuidelines/Pages/ResearchIntegrityPolicy.aspx](http://research.wustl.edu/PoliciesGuidelines/Pages/ResearchIntegrityPolicy.aspx)  

### Ethics in Research Design and Data Analysis, Interpretation, Reporting, and Management

| **Week 6** | Ethics in Clinical | Halpern SD, Karlawich JHT, Berlin JA. *The continuing unethical conduct of underpowered|
### February 26
**Trial Design**


**Optional:**

### March 5
**Ethical Issues in Data Analysis**


**Optional:**

### March 12—Spring Break—No class

### March 19
**Ethics in Big Data and Genetic Research**


Article on returning genetic results. (To be determined and announced.)

### March 26
**Reproducibility in Science**


Week 10
April 2
Data Integrity and Data Stewardship
(Managing, Storing, Sharing, and Securing Data and Research Records)


Optional:

Ethics and Professionalism in the Workplace

Week 11
April 9
Collaboration, Communication, and Authorship


WUSTL Policy for authorship on scientific and scholarly publications. Available at: http://www.wustl.edu/policies/authorship.html

Optional:
  • Kempers RD. Ethical issues in biomedical publications. Fertility and sterility. 2002;77:883-888.

Week 12
April 16
Group Case Presentations

Week 13
April 23
Leadership and Professional Development


Optional:

Week 14
April 30
Working in Industry and Commercializing Science


Week 15
May 7
Course Review and Reflections

*Note: Typically to access the Harvard Business Review articles, students will need to search for the article title within the database.