The Master of Population Health Sciences

Ethics in Clinical and Population Health Research (M19-505)
Spring 2019 (01/28/19 – 4/15/19)
Mondays, 12:30 to 1:30 pm
Location: Taylor Avenue Building
2nd floor, Richmond Room

INSTRUCTORS:

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Department of Surgery       Department of Surgery
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Office Hours: By appointment       Office Hours: By appointment

COURSE DESCRIPTION & OBJECTIVES

This course will expose population and clinical health researchers to some of the ethical issues, challenges, and situations encountered in their research and clinical duties, with a focus on devising solutions. It will also familiarize them with principles of responsible conduct of research and available ethics and compliance resources. Case studies and scenario presentations will supplement discussion on topics such as informed consent and human subjects research, responsible conduct of research and allegations of misconduct, research with vulnerable populations, data management and presentation, publications and peer review, collaboration and sharing data, societal impact of research, and mentee-mentor relationships. This course meets the National Institutes of Health recommendations for training in responsible conduct of research.

COMPETENCIES

- Recognize ethical issues and situations encountered in your profession
- Identify resources for handling ethical dilemmas in clinical and public health research
- Recognize professional norms and ethical principles and how they apply to scientific research activities

COURSE FORMAT & EXPECTATIONS

This class is a seminar. This is different from lecture courses in that it is primarily based on discussion and thus relies on the full participation of all students. Students must come to each session prepared to be active, thoughtful, and energetic participants. This requires thoughtful and careful reading of assigned course materials prior to each class session. Reflection papers that are due at the start of each class will evaluate comprehension of the issues.
Each student will be required to co-lead one class discussion. The student leaders will develop the discussion questions and additional readings in consultation with one of the instructors. Even though there are two leaders during each class meeting, the discussion depends on everyone’s participation and each student should come ready to discuss (and respectfully debate) the readings. The instructors will be available to students during and after class and by appointment, and provide clear, timely feedback on student performance. Depending on class size, the discussion will be for a whole class or part of a class.

STUDENT RESPONSIBILITIES

✓ Attend each class.
✓ Come to class on-time, prepared, and having read all required readings.
✓ Participate in class discussions.
✓ Complete assignments on time.
✓ Seek any necessary clarification regarding course expectations.

Any issues with attendance, deadlines, or completion of assignments should be discussed before the deadline/class with the instructor. Email is the best way to contact the instructor. Emails will be answered within two business days with the exception of weekends and holidays.

CLASSROOM ETIQUETTE

✓ Please turn all cellphones and pagers to silent or vibrate.
✓ If you need to answer a call or page, please leave the room quietly to do so.
✓ **Do not use the internet, social media sites, and BJC clinical sites for non-class purposes, or check email during class time.**
✓ Please be respectful of differences in viewpoints expressed during class discussion.
✓ Please keep any sensitive information that arises during discussion confidential.

CANVAS

We will use Canvas to manage our class, access assignment instructions and post course-related questions. Canvas can be accessed at [https://mycanvas.wustl.edu/](https://mycanvas.wustl.edu/). Log in to the **Wash U MyCanvas** version (NOT the MD program version) with your WUSTLKey and the class should appear on the homepage.

- All updates and reminders will be posted on Canvas.
- Lecture notes and additional readings and assignment instructions will be posted on Canvas throughout the semester.

We may utilize the Discussion threads for general questions related to lectures and assignments. Students should post all general questions that may be relevant to others in class to the Discussion thread. Student-specific questions (e.g. related to a grade or exam conflict) should be emailed directly to the instructors. Every effort will be made to answer student emails within 48-hours (excluding weekends). Students are encouraged to post materials related to class (e.g. link to a news story) on Canvas for the rest of the class to access.

EVALUATION AND GRADING
1. **Participation (24 points):** The participation portion of the course grade is based upon regular and timely attendance, as well as active, meaningful contributions to class discussion. Students are expected to read the required readings even when not presenting. Participation points are earned by arriving to class on time and being an active and thoughtful contributor to class discussions.

2. **Session lead (28 points):** You will be required to lead a session along with a group of your classmates. Size of the group presentation varies based on the class enrollment. This portion of the course grade is based on the extent to which you come prepared to lead the discussion of your assigned session, as evidenced by level of preparation and discussion questions, and incorporation of recommended or other resources. Your selected reading, slides, and discussion questions are due to the instructors by the WEDNESDAY before your class, by 5pm. This allows time for the instructor to review materials and to get readings out to your classmates in a timely manner. You are welcome to meet with an instructor in person if you would like before your session.

3. **Reflection papers (48 points):** Beginning with class 2, students are expected to write and turn in a reflection paper each week except for the week that they lead the class session. Students can skip 2 additional reflection papers, which means each student will submit a total of 8 reflection papers. Papers must relate to the topic and the readings covered in each class session, except the introduction class. Papers are due at the beginning of the class they cover.

Each paper should be 1-1.5 single spaced pages and be comprised of 3 paragraphs. The first paragraph should briefly describe the ideas and issues expressed in that week’s readings, but they should not summarize each article individually. In the second paragraph, identify a “keeper” – that is, a key idea that you wish to carry with you as you move through your public health or medical career. It is something that you think is profound or significant. Then, for the rest of the 2nd paragraph, elaborate on why you chose the keeper. Finally, for the 3rd paragraph, identify a “query” – that is, a question about the material. This can be something that you did not understand, a thoughtful prompt for discussion, or a point that you disagree with. Elaborate upon why you chose the query in the same way as you elaborated upon the reasons for choosing the keeper.

Examples of things you may want to consider when writing the reflection papers include: What is the significance of the topic to research practice? What are the stakes involved for researchers, research participants, and institutions? Come prepared to share your “keepers” and “queries” during class. Any references used must be properly cited; references do not count towards the page limit. Each paper is worth 6 points.

**Grading:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Points</th>
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<tbody>
<tr>
<td>Participation</td>
<td>24</td>
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<tr>
<td>Session lead</td>
<td>28</td>
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<tr>
<td>Reflection papers</td>
<td>48</td>
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<tr>
<td>(8 papers at 6 points each)</td>
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<tr>
<td><strong>Total</strong></td>
<td>100</td>
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**Grading scale:**

- A: 90-100 points
- B: 80-89 points
- C: 70-79 points
- F: less than 70 points

**POLICY ON CLASS ATTENDANCE AND DEADLINES**
Class attendance and participation is critical. Participation (and therefore attendance) is part of your grade. More than two absences from class may result in a lowered grade. Do not enroll if you have more than two absences already planned. Students who are taking this class to fulfill NIH requirements for instruction in the responsible conduct of research must attend at least 8 sessions to meet the requirements.

There will be NO make-up opportunities for missed reflection papers. You are expected to plan ahead with your reflection papers. Two papers can be dropped, so if you miss a class or are late, that can count as one of your dropped grades. Again, no make-up papers will be offered.

There are point penalties for late submissions. One point will be deducted per 24 hour period for assignments that are turned in late. For example, if your discussion questions/slides are due on Wednesday at 5pm, and are turned in after Wednesday 5:00pm but before 5:00pm on Thursday, you would lose one point from your session lead grade. Materials turned in on Thursday after 5:00 pm would lose 2 points. The same point deduction rubric will be used for reflection papers: they are due at the start of class and a point is deducted for every 24 hour period thereafter.

COURSE SCHEDULE

**The syllabus is subject to change at the discretion of the instructors.**

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>Topic</th>
<th>Instructor</th>
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<tbody>
<tr>
<td>1</td>
<td>Jan 28</td>
<td>Introduction to course and the responsible conduct of research</td>
<td>Hunleth and Waters</td>
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<tr>
<td>2</td>
<td>Feb 4</td>
<td>Research misconduct and policies for handling misconduct</td>
<td>Hunleth</td>
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<tr>
<td>3</td>
<td>Feb 11</td>
<td>Societal impact of research and research misconduct</td>
<td>Hunleth</td>
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<tr>
<td>4</td>
<td>Feb 18</td>
<td>Human subjects research and research with vulnerable populations</td>
<td>Hunleth</td>
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<td>5</td>
<td>Feb 25</td>
<td>Student/Mentee and mentor relationships</td>
<td>Hunleth</td>
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<td>6</td>
<td>Mar 4</td>
<td>Collaboration, data ownership, and resource sharing</td>
<td>Waters</td>
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<tr>
<td>7</td>
<td>Mar 11</td>
<td>Data acquisition, management, and sharing</td>
<td>Waters</td>
</tr>
<tr>
<td>8</td>
<td>Mar 18</td>
<td>Data interpretation and presentation</td>
<td>Waters</td>
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<tr>
<td>9</td>
<td>Mar 25</td>
<td>Safe laboratory and research practices and responsibilities as a PI</td>
<td>Waters</td>
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<tr>
<td>10</td>
<td>Apr 1</td>
<td>Animal research</td>
<td>Waters</td>
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<tr>
<td>11</td>
<td>Apr 8</td>
<td>Conflicts of interest – personal, professional, financial</td>
<td>Waters</td>
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<tr>
<td>12</td>
<td>Apr 15</td>
<td>Responsible authorship and publication, peer review</td>
<td>Waters and Hunleth</td>
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READINGS AND RESOURCES

Students should read all “required” readings and the additional readings related to student presentations. Readings for student presentations will be distributed a few days before each class. The “additional readings and recommended resources” are optional for class, but students should consider keeping them to use in their future research. Additional general references and resources to consider keeping are below:

General References and Useful Web Pages:

- “On Being a Scientist: Responsible Conduct in Research” National Academy of Sciences Committee on Science, Engineering and Public Policy
  https://www.nap.edu/catalog/12192/on-being-a-scientist-a-guide-to-responsible-conduct-in
“Fostering integrity in Research” National Academies of Sciences, Engineering, and Medicine
[https://www.nap.edu/catalog/21896/fostering-integrity-in-research](https://www.nap.edu/catalog/21896/fostering-integrity-in-research)

"The Lab: Avoiding Research Misconduct" is now available on the ORI web site. Interactive video simulation of decisions that affect the integrity of research. [http://ori.hhs.gov/TheLab/](http://ori.hhs.gov/TheLab/)


Other Ethics Resources and Sources for Finding Case Studies:

- NIH Office of Research Integrity
  - [https://ori.hhs.gov/general-resources-0](https://ori.hhs.gov/general-resources-0)
  - [https://ori.hhs.gov/research-misconduct-0](https://ori.hhs.gov/research-misconduct-0)
  - [https://ori.hhs.gov/newsletters](https://ori.hhs.gov/newsletters)
- Online Ethics Center for Engineering and Science at Case Western Reserve University [http://onlineethics.org/](http://onlineethics.org/)


Session 2: Research misconduct and policies for handling misconduct

Required:

1. **University policy.** Research Integrity Policy for Washington University [https://research.wustl.edu/washington-university-research-integrity-policy/](https://research.wustl.edu/washington-university-research-integrity-policy/)
2. **NIH on misconduct.** Brief NIH definition of misconduct and federal process for handling allegations [https://grants.nih.gov/grants/research_integrity/research_misconduct.htm](https://grants.nih.gov/grants/research_integrity/research_misconduct.htm)

Optional Readings and Recommended Resources:

- NIH Office of Research Integrity, on handling misconduct. [https://ori.hhs.gov/handling-misconduct](https://ori.hhs.gov/handling-misconduct)

Session 3: Societal Impact of Research and the Impact of Research Misconduct

Required Reading(s):

2. **Research consequences on families, minorities, and underserved communities.** Audio interview with R.
https://www.npr.org/templates/story/story.php?storyId=123472238. See also

http://www.annfammed.org/content/8/5/433.full.pdf+html

4. **Local commentaries on research and the need for dialogue between scientists and communities.** Fairhead, J, Leach, M, Small, M. Where techno-science meets poverty: Medical research and the economy of blood in The Gambia, West Africa. Social Science and Medicine  
http://linkinghub.elsevier.com/retrieve/pii/S0277953606001092

Optional Readings and Recommended Resources:
- Grimes vs Kennedy Krieger.  
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447191/;  

Session 4: Human Subjects Research and Research with Vulnerable Populations

**Required Readings:**

1. **Getting started.** List of considerations for research with children. Note: this list offers important considerations for research with other vulnerable groups as well.  

2. **Consent guidelines** for the Human Research Protection Office (HRPO) at Washington University p. 32-35 of  

3. **Challenges of informed examined.** Grady, C. Enduring and emerging challenges of informed consent.  

4. **Incentives.** Young Lives case study on paying youth for participation in research.  


Optional Readings and Recommended Resources:
- NIH on research involving vulnerable persons. Definitions and roles and responsibilities. Example, prisoners:  
https://humansubjects.nih.gov/prisoners Note: see bottom left corner of page for links to other vulnerable populations.
- Certificates of confidentiality (CoC) to protect the privacy of research participants.  
https://humansubjects.nih.gov/coc/index
- Ethical research involving children website with key topics, case studies, and help.  
http://childethics.com/
- Emanuel E, Grady C, Menikoff J on informed consent. Is longer always better?  
http://muse.jhu.edu/journals/hastings_center_report/v038/38.3.article.pdf

Session 5: Student-mentor relationships

**Required Readings:**

1. **Nature’s guide for mentors:** Lee, et al.  
https://www.nature.com/articles/447791a

2. **Training for mentors.**  
http://www.scientemag.org/content/311/5760/473.summary?sid=99c2c85f-0d5e-4f8c-aac2-b6c447d2103c
4. **Successful and failed mentoring relationships**: Strauss, et al. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/)
5. **Choosing a research mentor**: [https://www.niaid.nih.gov/grants-contracts/tips-choosing-mentor](https://www.niaid.nih.gov/grants-contracts/tips-choosing-mentor)

Optional Readings and Recommended Resources:

- **Thoughts on Choosing a Research Mentor.** NIH Office of Intramural Research and Training. [https://www.training.nih.gov/mentoring_guidelines](https://www.training.nih.gov/mentoring_guidelines)
- **Are you a good protégé?** [http://chronicle.com/article/Are-You-a-Good-Prot-g-/45755/](http://chronicle.com/article/Are-You-a-Good-Prot-g-/45755/)
- **Resources for Research Ethics Education’s website, with readings and discussion questions for mentors and mentees.** [http://research-ethics.org/topics/mentoring/index2.php](http://research-ethics.org/topics/mentoring/index2.php)

**Session 6: Collaboration, data ownership, and resource sharing**

**Required:**

1. **Team science.** Bennett & Gadlin. Collaboration and Team Science: From Theory to Practice. Journal of Investigative Medicine; 60(5): 768-775. [https://jim.bmj.com/content/jim/60/5/768.full.pdf](https://jim.bmj.com/content/jim/60/5/768.full.pdf)
2. **WU policy.** Washington University Policy on Intellectual Property [https://wustl.edu/about/compliance-policies/intellectual-property-research-policies/intellectual-property/](https://wustl.edu/about/compliance-policies/intellectual-property-research-policies/intellectual-property/)
3. **Who owns research products?** Kaiser J. Court Decides Tissue Samples Belong to the University. Science; 312(5772): 346-347. [http://www.sciencemag.org/content/312/5772/346.full?sid=2156b53a-80a3-4676-a262-8f8b47a7064](http://www.sciencemag.org/content/312/5772/346.full?sid=2156b53a-80a3-4676-a262-8f8b47a7064)
5. **NIH list of data sharing policies** – review only the table to gain understanding of the scope of the issue. [https://www.nlm.nih.gov/NIHbmic/nihbmicdataSharingPages.html](https://www.nlm.nih.gov/NIHbmic/nihbmicdataSharingPages.html)

*Note: The policies are long but it is important to get the highlights of them. The articles are quite short.*

Optional Readings and Recommended Resources:

- This is a useful but lengthy resource on collaboration and working in teams: [https://www.cancer.gov/about-nci/organization/crs/research-initiatives/team-science-field-guide/collaboration-team-science-guide.pdf](https://www.cancer.gov/about-nci/organization/crs/research-initiatives/team-science-field-guide/collaboration-team-science-guide.pdf)

**Session 7: Data acquisition, management, and sharing**

**Required:**


Optional Readings and Recommended Resources:


- Data Management Plan Tool https://dmptool.org/

**Session 8: Data interpretation and presentation**

Required:


4. **NIH guidelines.** NIH Principles and Guidelines for Reporting Preclinical Research. https://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research Open all subsections by pressing the plus sign (+)


Optional Readings and Recommended Resources:


- Open Science Framework https://osf.io/

- Foster Open Sciences https://www.fosteropenscience.eu/resources

**Session 9: Safe Lab (and Research) Practices and the Responsibility of the PI or supervisor**

Required Readings:

1. **Emotional safety.** Does science have a bullying problem? https://www.nature.com/articles/d41586-018-07532-5


3. **Physical safety.** Professor Charged in Research Assistant’s accident. http://www.the-scientist.com/?articles.view/articleNo/35354/title/Chemist-to-Court-Over-Assistant-s-Death/


Optional Readings and Recommended Resources:

Session 10: Animal Research

Required Readings:
2. **General principles of animal research.** The 3 Rs. [https://www.nc3rs.org.uk/the-3rs](https://www.nc3rs.org.uk/the-3rs)
4. **Reproducibility.** Study questions animal efficacy data behind trials. [http://science.sciencemag.org/content/360/6385/142.long](http://science.sciencemag.org/content/360/6385/142.long)

Optional Readings and Recommended Resources:
- WUSTL animal care and use policies. May require WUSTL login. [https://research.wustl.edu/topics/animal-care-use/](https://research.wustl.edu/topics/animal-care-use/)
- Practical tips are available at the 3 Rs resources website: [https://www.nc3rs.org.uk/3rs-resources](https://www.nc3rs.org.uk/3rs-resources)
- NIH resources [https://olaw.nih.gov/](https://olaw.nih.gov/)
- Nature collection on animal research. [https://www.nature.com/collections/mnzcndqhts](https://www.nature.com/collections/mnzcndqhts)

Session 11: Conflicts of interest – personal, professional, financial

Required Reading
1. **Wash U policy.** Individual (Research) Conflicts of Interest Policy [http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx](http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx)
3. **How funders affect research result reporting.** Publication bias? There are three sides to the story: Industry sponsored studies are more favorable for statins, industry sponsored studies are less favorable statins, or is there no association?
   a. Lundh & Bero. The Ties that Bind. BMJ. 2017; 356:j176. [https://www.bmj.com/content/356/bmj.j176.long](https://www.bmj.com/content/356/bmj.j176.long)

Optional Readings and Recommended Resources:

Session 12: Responsible Authorship, Publication, and Peer Review

Required Readings:
  http://research.wustl.edu/PoliciesGuidelines/Pages/authorshipdisputes.aspx
5. Retractions. Cleaning up the paper trail.  http://science.sciencemag.org/content/312/5770/38.full
  http://www.sciencemag.org/content/342/6154/60.full

Optional Readings and Recommended Resources:
• Defining the Role of Authors and Contributors:  http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
• Guide for avoiding plagiarism:  https://ori.hhs.gov/sites/default/files/plagiarism.pdf

For information about peer review (suggested readings):
• Lovejoy, Revenson, France. Reviewing manuscripts for peer-review journals: A primer for novice and seasoned reviewers. Annals of Behavioral Medicine  
• For a series of articles on writing tips (not necessarily ethics), see:  http://www.jclinepi.com/content/jce-Writing-Tips-Series