Ethics in Clinical and Population Health Research (M19-505)
Spring 2020 (01/13/19 – 4/6/2020)
Mondays, 12:30 to 1:30 pm
Location: Taylor Avenue Building
2nd floor, Richmond Room

INSTRUCTORS
Erika A. Waters, PhD, MPH      Jean Hunleth, PhD, MPH
Division of Public Health Sciences     Division of Public Health Sciences
Department of Surgery       Department of Surgery
waterse@wustl.edu        jean.hunleth@wustl.edu
Phone: 314-747-5705       Phone: 314-747-8066

OFFICE HOURS
By appointment

PREREQUISITES
None

TARGET AUDIENCE
Clinicians or clinicians-in-training who are planning to conduct research in clinical or population health.

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, 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. Students who attend eight course sessions will fulfill the National Institutes of Health requirements for training in responsible conduct of research.

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 and also offer students a chance to grapple with the course material as it relates to their past, current, and future research experiences. Additionally, each student is required to bring in two case studies during the semester and lead a discussion on their chosen case studies.

COMPETENCIES
• Understand WUSM and NIH policies regarding the responsible conduct of research;
• 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

**GRADING**

Your grade will be based on 100 points.

- Class participation: 24 points
- Session leads/Case studies: 28 points (2 sessions @ 14 points each)
- Reflection papers: 48 points (8 papers @ 6 points each)

**Grading Scale**

A+: 97-100; A: 93-96; A-: 90-92; B+: 87-89; B: 83-86; B-: 80-82; C+: 77-79; C: 73-76; C-: 70-72

**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. 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.

**ATTENDANCE AND PARTICIPATION**

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.

- **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.
- **Readings and assignments are due at the beginning of class.** Readings assigned for each class should be read ahead of the class and students should be prepared to discuss the material from readings.
- **Students who attend fewer than 8 class sessions will not be certified as having completed the NIH responsible conduct of research requirements.**

**POLICY ON LATE ASSIGNMENTS**

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.

**ASSIGNMENTS & DUE DATES**
**Class participation:** 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.

**Case study lead (28 points):** You will be required to lead the discussion of two case studies during the semester. You will be responsible for choosing the case studies, which should be real cases reported in journals and other news outlets. Case studies should be brief and should focus on research ethics. They can be in the form of a written account, podcast, or other type of communication, but they must relate to the week’s topic and assigned readings. You will be responsible for developing three discussion questions on the case study and leading the class discussion. See How to Hold a Better Class Discussion for developing discussion questions: https://www.chronicle.com/interactives/20190523-ClassDiscussion.

The case study portion of the course grade is based on the extent to which you come prepared to lead the discussion of a relevant case study that you choose, as evidenced by level of preparation and discussion questions, and incorporation of the week’s readings. **Your selected case study 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 provide feedback to you in a timely manner. You are welcome to meet with an instructor in person if you would like before your session.

**Reflection papers (48 points):** The purpose of the reflection papers is to foster learning by encouraging students to grapple with the concepts being discussed. Beginning with class 2, students are expected to write and turn in a reflection paper each week except for the weeks that they lead the class session. Students can skip 1 additional reflection paper, which means each student will submit a total of 8 reflection papers by the end of the course. 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 contain the following information:

1. A brief, 2-3 sentence description of the ideas and issues expressed in that week’s readings. Do not summarize each individual article.
2. A “keeper” – that is, a key idea that you wish to carry with you as you move through your career. It is something that you think is profound or significant. Then, elaborate on why you chose the keeper.
3. 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 elaborating upon your keepers and queries include: What is the significance of the topic to research practice? What are the stakes involved for researchers, research participants, and institutions? In what situations do the policies fall short? In what situations are they unduly restrictive? Are there situations in which you believe the policies do not apply?

Reflection papers should use standard fonts and font sizes (e.g., Calibri 11, Times 12, Arial 11), 1” margins, and be double spaced. Do not add extra spaces between paragraphs or use headings to artificially lengthen your work. Any references used must be properly cited; references do not count towards the page limit. Each paper is worth 6 points.
<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Assignment Due</th>
<th>Readings</th>
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<tbody>
<tr>
<td>Class 1</td>
<td>Jan 13</td>
<td>Introduction to course and the responsible conduct of research (Hunleth and Waters)</td>
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<td>General References and Useful Web Pages:</td>
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<td>✓ “Fostering integrity in Research” National Academies of Sciences, Engineering, and Medicine <a href="https://www.nap.edu/catalog/21896/fostering-integrity-in-research">https://www.nap.edu/catalog/21896/fostering-integrity-in-research</a></td>
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<td>✓ “The Lab: Avoiding Research Misconduct” is now available on the ORI web site. Interactive video simulation of decisions that affect the integrity of research. <a href="http://ori.hhs.gov/TheLab">http://ori.hhs.gov/TheLab</a></td>
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<td>✓ Hastings Center <a href="http://www.thehastingscenter.org">http://www.thehastingscenter.org</a></td>
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<td>Other Ethics Resources and Sources for Finding Case Studies:</td>
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<td>✓ NIH Office of Research Integrity</td>
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<td>• <a href="https://ori.hhs.gov/general-resources-0">https://ori.hhs.gov/general-resources-0</a></td>
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<td>✓ Online Ethics Center for Engineering and Science at Case Western Reserve University <a href="http://onlineethics.org">http://onlineethics.org</a></td>
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<td>Also: Science Magazine (<a href="http://www.sciencemag.org/">http://www.sciencemag.org/</a>) and the Chronicle of Higher Education (<a href="http://www.chronicle.com">www.chronicle.com</a>) regularly publish commentaries and stories relevant to the responsible conduct of research.</td>
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<td>Jan 20</td>
<td>No class – Martin Luther King, Jr. Day</td>
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<td>Class 2</td>
<td>Jan 27</td>
<td>Research misconduct and policies for handling misconduct (Hunleth)</td>
<td>Session lead, reflection paper</td>
<td>Required:</td>
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<td>1. <strong>University policy.</strong> Research Integrity Policy for Washington University <a href="https://research.wustl.edu/washington-university-research-integrity-policy/">https://research.wustl.edu/washington-university-research-integrity-policy/</a></td>
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<td>2. <strong>NIH on misconduct.</strong> Brief NIH definition of misconduct and federal process for handling allegations <a href="https://grants.nih.gov/grants/research_integrity/research_misconduct.htm">https://grants.nih.gov/grants/research_integrity/research_misconduct.htm</a></td>
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<td>4. <strong>Long-term consequences of misconduct.</strong> Redman &amp; Merz. <em>Science.</em> <a href="http://science.sciencemag.org/content/321/5890/775">http://science.sciencemag.org/content/321/5890/775</a></td>
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<td>Optional Readings and Recommended Resources:</td>
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<td>• NIH Office of Research Integrity, on handling misconduct. <a href="https://ori.hhs.gov/handling-misconduct">https://ori.hhs.gov/handling-misconduct</a></td>
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Data Management Plan Tool. University of California. [https://dmp-tool.org/](https://dmp-tool.org/) - click "log in", then "option 1", then type "Washington University" and select it from the dropdown list. Click "create plan" and then tick the three boxes for "mock project for testing, practice, or educational purposes" and then "create plan." Review the content under each of the tabs "project details," "plan overview," etc. to see what information is required. | Optional readings and recommended resources:  
National Institutes of Health. ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies. [https://prsinfo.clinicaltrials.gov/definitions.html](https://prsinfo.clinicaltrials.gov/definitions.html)  
Open Science Framework [https://osf.io/](https://osf.io/)  
Foster Open Sciences [https://www.fosteropenscience.eu/resources](https://www.fosteropenscience.eu/resources)  
| 5     | Feb 17| Collaboration, data ownership, and resource sharing (Hunleth) | 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)  
NIH list of data sharing policies – SKIM the table to gain understanding of the scope of the issue. [https://www.nlm.nih.gov/NHbmic/nih_data_sharing_policies.html](https://www.nlm.nih.gov/NHbmic/nih_data_sharing_policies.html) |
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<th>Class</th>
<th>Date</th>
<th>Topic</th>
<th>Session lead, reflection paper</th>
<th>Required Reading</th>
<th>Optional Readings and Recommended Resources</th>
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5. **Public opinion.** Americans are divided over the use of animals in scientific research. http://www.pewresearch.org/fact-tank/2018/08/16/americans-are-divided-over-the-use-of-animals-in-scientific-research/

Optional Readings and Recommended Resources:
- WUSTL animal care and use policies. May require WUSTL login. 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.
- NIH resources https://olaw.nih.gov/
- Nature collection on animal research. https://www.nature.com/collections/mzn参qhts

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**Class 9**

**Session lead, reflection paper**

**March 16**

**Responsible authorship and publication, peer review (Hunleth – Waters out of office)**

Required Readings:

3. **Defining the Role of Authors and Contributors:** http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Optional Readings and Recommended Resources:
- For a series of articles on writing tips (not necessarily ethics), see: http://www.jclinepi.com/content/jce-Writing-Tips-Series

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**Class 10**

**Session lead, reflection paper**

**March 23**

**Human subjects research and research with vulnerable populations (Hunleth – Waters out of office)**

Required Readings:

2. **Getting started.** List of considerations for research with children. Note: this list offers important considerations for research with other vulnerable groups as well. https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-only.pdf

Optional Readings and Recommended Resources:
- NIH on research involving vulnerable persons. Definitions and roles and responsibilities. Example, prisoners:
Certificates of confidentiality (CoC) to protect the privacy of research participants. [https://humansubjects.nih.gov/coc/index](https://humansubjects.nih.gov/coc/index)

Ethical research involving children website with key topics, case studies, and help. [http://childethics.com/](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](http://muse.jhu.edu/journals/hastings_center_report/v038/38.3.article.pdf)


Required Reading(s):
1. **Social responsibility and research ethics.** [https://www.aas.org/news/social-responsibility-and-research-ethics-not-either-or-both](https://www.aas.org/news/social-responsibility-and-research-ethics-not-either-or-both)

Optional Readings and Recommended Resources:

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**Session lead, reflection paper**

**Required Readings:**
1. **Successful and failed mentoring relationships:** Strauss, et al. Characteristics of Successful and Failed Mentoring Relationships. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/)
2. **Choosing a mentor:** [https://www.training.nih.gov/mentoring_guidelines](https://www.training.nih.gov/mentoring_guidelines)
3. **Different types of mentoring relationships:** A Matrix Mentoring Model That Effectively Supports Clinical and Translational Scientists and Increases Inclusion in Biomedical Research. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4811725/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4811725/)

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)
- 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)
- Nature’s guide for mentors: Lee, et al. [https://www.nature.com/articles/447791a](https://www.nature.com/articles/447791a)
- Training for mentors. [http://www.sciencemag.org/content/311/5760/473.summary?sid=99c2c85f-0d5e-4f8c-aac2-b6c447d2103c](http://www.sciencemag.org/content/311/5760/473.summary?sid=99c2c85f-0d5e-4f8c-aac2-b6c447d2103c)
**DROP DATES**
You may drop for any reason during the course of the semester. However, you may only receive a partial or no tuition reimbursement depending upon how far into the semester you drop the course. See the [MPHS Student Handbook](#). Late withdrawals will appear on your transcript as a withdrawal.

**MPHS Academic Policy Guidelines:**

Guidelines regarding MPHS course registration and enrollment, grades, tuition obligation, and academic leave are consolidated in the [MPHS Student Handbook](#). Please review this document.

**MPHS Guidelines for Academic and Non-Academic Transgressions:**

By registering for this course you have agreed to the terms of the [MPHS Academic Integrity Policy](#), outlined below and in more detail in the [MPHS Student Handbook](#). Please review this policy before submitting your first graded assignment.

**Academic Integrity/Plagiarism Policy:**

- Academic dishonesty is a serious offense that may lead to probation, suspension, or dismissal from the University. Academic dishonesty includes plagiarism (the use of someone else’s ideas, statements, or approaches without proper citation). Academic dishonesty also includes copying information from another student, submitting work from a previous class for a new grade without prior approval from your instructor, cheating on exams, etc. You are responsible for reviewing WashU's academic integrity resources to become aware of all the actions that constitute academic dishonesty.
- All instances of academic dishonesty will be reported to the Office of the Registrar for investigation and potential disciplinary action. In addition, the instructor will make an independent decision about the student’s grade on any assignment in question. The MPHS process regarding academic dishonesty is described in the [MPHS Student Handbook](#).

**DISABILITY RESOURCES**

It is the goal of Washington University to assist students with disabilities in removing the barriers their disabilities may pose and provide support in facing the challenge of pursuing an education at Washington University.

Washington University recognizes and accepts its professional, legal and moral responsibility to avoid discrimination in the acceptance and education of qualified students with disabilities and to provide reasonable accommodations to such students consistent with the principles embodied in the law. These guidelines apply to students seeking admittance as well as to those who become disabled while they are enrolled.

Washington University makes every effort to insure that all qualified applicants and students can participate in and take full advantage of all programs and opportunities offered within the university. Washington University encourages and gives full consideration to all applicants for admission. Washington University does not discriminate in access to its programs and activities on the basis of age, sex, sexual orientation, race, disability, religion, color or national origin.

To learn more about services provided to students with disabilities, initiate the process of formal documentation and/or to arrange for accommodations, please review the [Disability Resources](#) for the Med.
School at the start of the course.

MENTAL HEALTH RESOURCES
Mental Health Services’ professional staff members work with students to resolve personal and interpersonal difficulties, many of which can affect the academic experience. These include conflicts with or worry about friends or family, concerns about eating or drinking patterns, and feelings of anxiety and depression. See: shs.wustl.edu/MentalHealth.

SEXUAL ASSAULT RESOURCES
You can also speak confidentially and learn about available resources by contacting Dr. Gladys Smith, PhD, Sexual Violence Prevention Therapist and Licensed Psychologist at the Medical Campus, (314) 362-2404. Additionally, you can report incidents to the Office of Student Affairs or by contacting WUSM Protective Services 314-362-4357 or your local law enforcement agency.

BIAS RESOURCES
The University has a process through which students and staff who have experienced or witnessed bias, prejudice or discrimination against a student can report their experiences to the University’s Bias Report and Support System (BRSS) team. For details see: diversityinclusion.wustl.edu/brss/.

Office of the Associate Vice Chancellor for Diversity, Equity and Inclusion (DEI)
The DEI Training Team designs, facilitates and leads diversity education programming for faculty, staff and students on a wide range of topics including: creating a climate of respect, the value of diversity and the role of biases in our day-to-day lives. diversity.med.wustl.edu/training/

The Office of Diversity Programs promotes diversity among and prepares medical students to lead in a global society. A priority for the Office of Diversity Programs is to cultivate and foster a supportive campus climate for students of all backgrounds, cultures and identities. mddiversity.wustl.edu/

The Diversity and Inclusion Student Council promotes an inclusive campus environment for all School of Medicine students. sites.wustl.edu/disc/

The Office for International Students and Scholars embraces the university’s mission of welcoming promising students from around the world. wumma.wustl.edu/