

**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  
2<sup>nd</sup> floor, Richmond Room

**INSTRUCTORS**

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

Jean Hunleth, PhD, MPH  
Division of Public Health Sciences  
Department of Surgery  
jean.hunleth@wustl.edu  
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 fulfil 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/>. 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.

Week	Date	Topic	Assignment Due	Readings
Class 1	Jan 13	Introduction to course and the responsible conduct of research (Hunleth and Waters)		<p><b>General References and Useful Web Pages:</b></p> <ul style="list-style-type: none"> <li>✓ "On Being a Scientist: Responsible Conduct in Research" National Academy of Sciences Committee on Science, Engineering and Public Policy <a href="https://www.nap.edu/catalog/12192/on-being-a-scientist-a-guide-to-responsible-conduct-in">https://www.nap.edu/catalog/12192/on-being-a-scientist-a-guide-to-responsible-conduct-in</a></li> <li>✓ "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></li> <li>✓ "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></li> <li>✓ Hastings Center <a href="http://www.thehastingscenter.org/">http://www.thehastingscenter.org/</a></li> <li>✓ <i>Dear Labby</i>, a monthly advice column in the American Society of Cell Biology newsletter, deals with practical issues in the science and career advancement. <a href="http://www.ascb.org/dear-labby-archive/">http://www.ascb.org/dear-labby-archive/</a></li> </ul> <p><b>Other Ethics Resources and Sources for Finding Case Studies:</b></p> <ul style="list-style-type: none"> <li>✓ NIH Office of Research Integrity <ul style="list-style-type: none"> <li>• <a href="https://ori.hhs.gov/general-resources-0">https://ori.hhs.gov/general-resources-0</a></li> <li>• <a href="https://ori.hhs.gov/research-misconduct-0">https://ori.hhs.gov/research-misconduct-0</a></li> <li>• <a href="https://ori.hhs.gov/newsletters">https://ori.hhs.gov/newsletters</a></li> </ul> </li> <li>✓ NIH Office of the Director <a href="https://www.nih.gov/institutes-nih/nih-office-director">https://www.nih.gov/institutes-nih/nih-office-director</a></li> <li>✓ Online Ethics Center for Engineering and Science at Case Western Reserve University <a href="http://onlineethics.org/">http://onlineethics.org/</a></li> </ul> <p><b>Also:</b> 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.</p>

Jan 20 **No class – Martin Luther King, Jr. Day**

Class 2	Jan 27	Research misconduct and policies for handling misconduct (Hunleth)	Session lead, reflection paper	<p><b>Required:</b></p> <ol style="list-style-type: none"> <li>1. <b>University policy.</b> 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></li> <li>2. <b>NIH on misconduct.</b> 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></li> <li>3. <b>Practices that build good research behavior.</b> Gunsalus &amp; Robinson. Nine Pitfalls of Research Misconduct. <i>Nature</i>. <a href="https://www.nature.com/articles/d41586-018-05145-6">https://www.nature.com/articles/d41586-018-05145-6</a></li> <li>4. <b>Long-term consequences of misconduct.</b> Redman &amp; Merz. <i>Science</i>. <a href="http://science.sciencemag.org/content/321/5890/775">http://science.sciencemag.org/content/321/5890/775</a></li> </ol> <p><b>Optional Readings and Recommended Resources:</b></p> <ul style="list-style-type: none"> <li>• Official Federal Policy on Misconduct and Handling of allegations <a href="https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf">https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf</a></li> <li>• National Academies, Fostering Integrity in Research. Addressing Research Misconduct and Detrimental Research Practices: Current Knowledge and Issues <a href="https://www.ncbi.nlm.nih.gov/books/NBK475962/">https://www.ncbi.nlm.nih.gov/books/NBK475962/</a></li> <li>• NIH Office of Research Integrity, on handling misconduct. <a href="https://ori.hhs.gov/handling-misconduct">https://ori.hhs.gov/handling-misconduct</a></li> <li>• Steinberg, JA. Misconduct of others: Prevention Techniques for Researchers. <i>Psychological Science Observer</i>. <a href="https://www.psychologicalscience.org/observer/0102/misconduct.html">https://www.psychologicalscience.org/observer/0102/misconduct.html</a></li> </ul>
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Class 3	Feb 3	Data acquisition, management, and sharing (Waters)	Session lead, reflection paper	<p>Required:</p> <ul style="list-style-type: none"> <li>• <b>Data acquisition and management guidelines.</b> Knatterud, Rockhold, et al. Guidelines for quality assurance in multi-center trials: a position paper. <i>Control Clin Trials</i> 1998; 19(5): 477-493. <a href="https://www.ncbi.nlm.nih.gov/pubmed/9741868">https://www.ncbi.nlm.nih.gov/pubmed/9741868</a></li> <li>• <b>NIH data sharing guidelines.</b> NIH Data Sharing Policy and Implementation Guidance. <a href="https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm">https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm</a></li> <li>• <b>Data Management Plan Tool.</b> University of California. <a href="https://dmptool.org/">https://dmptool.org/</a> - 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.</li> </ul> <p>Optional Readings and Recommended Resources:</p> <ul style="list-style-type: none"> <li>• <b>Open data.</b> Schiermeier Q. For the record: Making project data freely available is vital for open science. <i>Nature</i> 2018; 555:403-405. <a href="https://www.nature.com/magazine-assets/d41586-018-03071-1/d41586-018-03071-1.pdf">https://www.nature.com/magazine-assets/d41586-018-03071-1/d41586-018-03071-1.pdf</a></li> <li>• <b>Misadventures in data acquisition.</b> Christian MC, McCabe M, Korn E, Abrams J, Kaplan R, &amp; Friedman M. The NCI Audit of the National Surgical Breast and Bowel Project Protocol B-06. <i>NEJM</i> 1995; 333:1469-1475. <a href="http://www.nejm.org/doi/full/10.1056/NEJM199511303332206#t=articleBackground">http://www.nejm.org/doi/full/10.1056/NEJM199511303332206#t=articleBackground</a></li> <li>• Knatterud GL. Management and conduct of randomized controlled trials. <i>Epimiol Rev</i> 2002; 24(1): 12-25. <a href="https://www.ncbi.nlm.nih.gov/pubmed/12119852">https://www.ncbi.nlm.nih.gov/pubmed/12119852</a></li> </ul>
Class 4	Feb 10	Preregistration, data interpretation, and data presentation (Waters – Hunleth out of the office)	Session lead, reflection paper	<p>Required:</p> <ol style="list-style-type: none"> <li>1. <b>Preregistration of research methods and analytic plan.</b> Nosek et al. The Preregistration Revolution. <i>PNAS</i> 2018; 115(11): 2600-2606. <a href="http://www.pnas.org/content/pnas/115/11/2600.full.pdf">http://www.pnas.org/content/pnas/115/11/2600.full.pdf</a></li> <li>2. <b>Appropriate use of causal language.</b> Zweig. Does the Language Fit the Evidence? <a href="http://www.healthnewsreview.org/toolkit/tips-for-understanding-studies/does-the-language-fit-the-evidence-association-versus-causation/">http://www.healthnewsreview.org/toolkit/tips-for-understanding-studies/does-the-language-fit-the-evidence-association-versus-causation/</a></li> <li>3. <b>Precision of reporting.</b> Wilcox. On Precision. <i>Epidemiology</i> 2004; 15(1):1. <a href="http://www.ncbi.nlm.nih.gov/pubmed/14712138">http://www.ncbi.nlm.nih.gov/pubmed/14712138</a></li> <li>4. <b>Image manipulation.</b> Martin &amp; Blatt. Manipulation and Misconduct in the Handling of Image Data. <i>The Plant Cell</i> 2013; 3147-3148. <a href="https://www.ncbi.nlm.nih.gov/pubmed/24003053">https://www.ncbi.nlm.nih.gov/pubmed/24003053</a></li> </ol> <p>Optional Readings and Recommended Resources:</p> <ul style="list-style-type: none"> <li>• <b>National Institutes of Health.</b> ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies. <a href="https://prsinfo.clinicaltrials.gov/definitions.html">https://prsinfo.clinicaltrials.gov/definitions.html</a>.</li> <li>• Open Science Framework <a href="https://osf.io/">https://osf.io/</a></li> <li>• Foster Open Sciences <a href="https://www.fosteropenscience.eu/resources">https://www.fosteropenscience.eu/resources</a></li> <li>• <b>NIH guidelines.</b> NIH Principles and Guidelines for Reporting Preclinical Research. <a href="https://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research">https://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research</a></li> <li>• <b>Data exploration.</b> Wigboldus et al. Encourage playing with data and discourage questionable reporting practices. <i>Psychometrika</i> 2016; 81(1):27-32. <a href="https://www.ncbi.nlm.nih.gov/pubmed/25820979">https://www.ncbi.nlm.nih.gov/pubmed/25820979</a></li> </ul>
Class 5	Feb 17	Collaboration, data ownership, and resource sharing (Hunleth)	Session lead, reflection paper	<p>Required:</p> <ol style="list-style-type: none"> <li>1. <b>Team science.</b> Bennett &amp; Gadlin. Collaboration and Team Science: From Theory to Practice. <i>Journal of Investigative Medicine</i>; 60(5): 768-775. <a href="https://jimm.bmi.com/content/jimm/60/5/768.full.pdf">https://jimm.bmi.com/content/jimm/60/5/768.full.pdf</a></li> <li>2. <b>WU policy.</b> Washington University Policy on Intellectual Property <a href="https://wustl.edu/about/compliance-policies/intellectual-property-research-policies/intellectual-property/">https://wustl.edu/about/compliance-policies/intellectual-property-research-policies/intellectual-property/</a></li> <li>3. <b>NIH list of data sharing policies</b> – SKIM the table to gain understanding of the scope of the issue. <a href="https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html">https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html</a></li> </ol>

				<p>4. <b>WU policy.</b> Washington University Policies and Procedures on Material Transfer  <a href="https://otm.wustl.edu/for-innovators/material-transfer-agreements-mtas/material-transfer-agreement-fags/">https://otm.wustl.edu/for-innovators/material-transfer-agreements-mtas/material-transfer-agreement-fags/</a> <b>Make sure to click the “read more” links for details</b></p> <p><u>Optional Readings and Recommended Resources:</u></p> <ul style="list-style-type: none"> <li>This is a useful but lengthy resource on collaboration and working in teams:  <a href="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</a></li> <li>Allen MJ et al. Human Tissue Ownership and Use in Research. Clinical Chemistry; 56(11):1675-1682.  <a href="http://www.clinchem.org/content/56/11/1675.full.pdf+html">http://www.clinchem.org/content/56/11/1675.full.pdf+html</a></li> </ul>
Class 6	Feb 24	Conflicts of interest – personal, professional, financial (Waters)	Session lead, reflection paper	<p><u>Required Reading</u></p> <ol style="list-style-type: none"> <li><b>Wash U policy.</b> Individual (Research) Conflicts of Interest Policy  <a href="http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx">http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx</a></li> <li><b>Reporting COIs.</b> Mole B. Top cancer expert forgot to mention \$3.5M industry ties – he just resigned. Ars Technica.  <a href="https://arstechnica.com/science/2018/09/top-cancer-expert-forgot-to-mention-3-5m-industry-ties-he-just-resigned/">https://arstechnica.com/science/2018/09/top-cancer-expert-forgot-to-mention-3-5m-industry-ties-he-just-resigned/</a></li> <li><b>How funders affect research result reporting.</b> Lundh &amp; Bero. The Ties that Bind. BMJ. 2017; 356:j176.  <a href="https://www.bmj.com/content/356/bmj.j176.long">https://www.bmj.com/content/356/bmj.j176.long</a></li> </ol> <p><u>Optional Readings and Recommended Resources:</u></p> <ul style="list-style-type: none"> <li>NIH Conflict of Interest Information Page.  <a href="http://grants2.nih.gov/grants/policy/coi/index.htm">http://grants2.nih.gov/grants/policy/coi/index.htm</a></li> <li>American Association of Universities. Task Force on Research Accountability. Report on Individual and Institutional Conflict of Interest.  <a href="http://ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/misc/Ref/AAU_Col.pdf">http://ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/misc/Ref/AAU_Col.pdf</a></li> <li>Lundh et al. Industry sponsorship and research outcome. Cochrane Review. 2017.  <a href="https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000033.pub3/full">https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000033.pub3/full</a></li> <li>van Lent M, Overbeke J, Out HJ Role of Editorial and Peer Review Processes in Publication Bias: Analysis of Drug Trials Submitted to Eight Medical Journals. PLOS One. 2014; 9(8): 1-8.  <a href="http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0104846">http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0104846</a></li> <li>Krauth D, Anglemeyer A, Philipps R, Bero L. Nonindustry-Sponsored Preclinical Studies. PLOS One. 2014; 12(1): 1-10.  <a href="http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.1001770">http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.1001770</a> <b>Read only through the end of the discussion section – not the methods/materials</b></li> </ul>
Class 7	Mar 2	Safe laboratory and research practices and responsibilities as a PI (Waters)	Session lead, reflection paper	<p><u>Required Readings:</u></p> <ol style="list-style-type: none"> <li><b>Emotional safety.</b> Does science have a bullying problem?  <a href="https://www.nature.com/articles/d41586-018-07532-5">https://www.nature.com/articles/d41586-018-07532-5</a></li> <li><b>Physical safety.</b> A Death in the Lab.  <a href="http://www.nature.com/news/2011/110418/full/472270a.html">http://www.nature.com/news/2011/110418/full/472270a.html</a></li> <li><b>Overall safety.</b> Safety in Academic Field Research.  <a href="http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0102172">http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0102172</a></li> </ol> <p><u>Optional Readings and Recommended Resources:</u></p> <ul style="list-style-type: none"> <li>Safe Science: Promoting a Culture of Safety in Academic Chemical Research  <a href="http://www.nap.edu/catalog/18706/safe-science-promoting-a-culture-of-safety-in-academic-chemical">http://www.nap.edu/catalog/18706/safe-science-promoting-a-culture-of-safety-in-academic-chemical</a></li> <li>The Ethical Treatment of Research Assistants.  <a href="http://jrp.icaap.org/index.php/jrp/article/view/360">http://jrp.icaap.org/index.php/jrp/article/view/360</a></li> </ul>
Class 8	Mar 9	Animal research (Waters)	Session lead, reflection paper	<p><u>Required Readings:</u></p> <ol style="list-style-type: none"> <li><b>NIH requirement to account for sex.</b> Policy: NIH to balance sex in cell and animal studies. <a href="https://www.nature.com/news/policy-nih-to-balance-sex-in-cell-and-animal-studies-1.15195">https://www.nature.com/news/policy-nih-to-balance-sex-in-cell-and-animal-studies-1.15195</a></li> <li><b>General principles of animal research.</b> The 3 Rs.  <a href="https://www.nc3rs.org.uk/the-3rs">https://www.nc3rs.org.uk/the-3rs</a>.</li> </ol>

			<p>3. <b>Reporting guidelines.</b> Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. <a href="https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1000412">https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1000412</a></p> <p>4. <b>Reproducibility.</b> The Interplay of Ethics, Animal Welfare, and IACUC Oversight on the Reproducibility of Animal Studies. <a href="https://www.ncbi.nlm.nih.gov/pubmed/28381309">https://www.ncbi.nlm.nih.gov/pubmed/28381309</a></p> <p>5. <b>Public opinion.</b> Americans are divided over the use of animals in scientific research. <a href="http://www.pewresearch.org/fact-tank/2018/08/16/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/</a></p> <p><u>Optional Readings and Recommended Resources:</u></p> <ul style="list-style-type: none"> <li>• WUSTL animal care and use policies. May require WUSTL login. <a href="https://research.wustl.edu/topics/animal-care-use/">https://research.wustl.edu/topics/animal-care-use/</a></li> <li>• Practical tips are available at the 3 Rs resources website: <a href="https://www.nc3rs.org.uk/3rs-resources">https://www.nc3rs.org.uk/3rs-resources</a>.</li> <li>• NAS Guide for the Care and Use of Laboratory Animals. <a href="https://research.wustl.edu/wp-content/uploads/2018/11/guide-for-the-care-and-use-of-laboratory-animals.pdf">https://research.wustl.edu/wp-content/uploads/2018/11/guide-for-the-care-and-use-of-laboratory-animals.pdf</a></li> <li>• NIH resources <a href="https://olaw.nih.gov/">https://olaw.nih.gov/</a></li> <li>• Nature collection on animal research. <a href="https://www.nature.com/collections/mnzcndqhts">https://www.nature.com/collections/mnzcndqhts</a></li> </ul>
Class 9	Mar 16	Responsible authorship and publication, peer review (Hunleth – Waters out of office)	<p>Session lead, reflection paper</p> <p><u>Required Readings:</u></p> <ol style="list-style-type: none"> <li>1. <b>Wash U policy.</b> Wash U Authorship Policy. <a href="http://www.wustl.edu/policies/authorship.html">http://www.wustl.edu/policies/authorship.html</a></li> <li>2. <b>Authorship issues.</b> Guidelines for Avoiding and Resolving Authorship Disputes. <a href="http://research.wustl.edu/PoliciesGuidelines/Pages/authorshipdisputes.aspx">http://research.wustl.edu/PoliciesGuidelines/Pages/authorshipdisputes.aspx</a></li> <li>3. <b>Defining the Role of Authors and Contributors:</b> <a href="http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html">http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html</a></li> <li>4. <b>Peer review.</b> NIH grant reviewer responsibilities <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-115.html">https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-115.html</a></li> </ol> <p><u>Optional Readings and Recommended Resources:</u></p> <ul style="list-style-type: none"> <li>• International Committee of Medical Journal Editors. Recommendations for Reporting and Publishing Scholarly Work: <a href="http://www.icmje.org/icmje-recommendations.pdf">http://www.icmje.org/icmje-recommendations.pdf</a></li> <li>• Predatory journals: <a href="https://bmccmedicine.biomedcentral.com/articles/10.1186/s12916-015-0469-2">https://bmccmedicine.biomedcentral.com/articles/10.1186/s12916-015-0469-2</a></li> <li>• Guide for avoiding plagiarism: <a href="https://ori.hhs.gov/sites/default/files/plagiarism.pdf">https://ori.hhs.gov/sites/default/files/plagiarism.pdf</a></li> </ul> <p><u>For information about peer review (suggested readings):</u></p> <ul style="list-style-type: none"> <li>• Lovejoy, Revenson, France. Reviewing manuscripts for peer-review journals: A primer for novice and seasoned reviewers. <i>Annals of Behavioral Medicine</i> <a href="http://link.springer.com/article/10.1007/s12160-011-9269-x">http://link.springer.com/article/10.1007/s12160-011-9269-x</a></li> <li>• For a series of articles on writing tips (not necessarily ethics), see: <a href="http://www.jclinepi.com/content/jce-Writing-Tips-Series">http://www.jclinepi.com/content/jce-Writing-Tips-Series</a></li> </ul>
Class 10	Mar 23	Human subjects research and research with vulnerable populations (Hunleth – Waters out of office)	<p>Session lead, reflection paper</p> <p><u>Required Readings:</u></p> <ol style="list-style-type: none"> <li>1. <b>Consent guidelines</b> for the Human Research Protection Office (HRPO) at Washington University p. 31-24 <a href="https://hrpo.wustl.edu/wp-content/uploads/2019/01/WU-IRB-Policies-and-Procedures-2019.01.21.pdf">https://hrpo.wustl.edu/wp-content/uploads/2019/01/WU-IRB-Policies-and-Procedures-2019.01.21.pdf</a></li> <li>2. <b>Getting started.</b> List of considerations for research with children. Note: this list offers important considerations for research with other vulnerable groups as well. <a href="https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-only.pdf">https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-only.pdf</a></li> <li>3. <b>On the ground complexities.</b> Heimer, C. ‘Wicked’ ethics: Compliance work and the practice of ethics in HIV research. <i>Social Science and Medicine</i>. <a href="http://www.sciencedirect.com.libproxy.wustl.edu/science/article/pii/S0277953612008271">http://www.sciencedirect.com.libproxy.wustl.edu/science/article/pii/S0277953612008271</a></li> </ol> <p><u>Optional Readings and Recommended Resources:</u></p> <ul style="list-style-type: none"> <li>• NIH on research involving vulnerable persons. Definitions and roles and responsibilities. Example, prisoners:</li> </ul>

			<p><a href="https://humansubjects.nih.gov/prisoners">https://humansubjects.nih.gov/prisoners</a> Note: see bottom left corner of page for links to other vulnerable populations.</p> <ul style="list-style-type: none"> <li>• Certificates of confidentiality (CoC) to protect the privacy of research participants. <a href="https://humansubjects.nih.gov/coc/index">https://humansubjects.nih.gov/coc/index</a></li> <li>• Ethical research involving children website with key topics, case studies, and help. <a href="http://childethics.com/">http://childethics.com/</a></li> <li>• Emanuel E, Grady C, Menikoff J on informed consent. Is longer always better? <a href="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</a></li> </ul> <p>Grady, C. Enduring and emerging challenges of informed consent. <a href="https://www.nejm.org/doi/full/10.1056/NEJMra1411250">https://www.nejm.org/doi/full/10.1056/NEJMra1411250</a></p>
Class 11	Mar 30	Societal impact of research and research misconduct (Hunleth)	<p>Session lead, reflection paper</p> <p>Required Reading(s):</p> <ol style="list-style-type: none"> <li>1. <b>Social responsibility and research ethics.</b> <a href="https://www.aaas.org/news/social-responsibility-and-research-ethics-not-either-or-both">https://www.aaas.org/news/social-responsibility-and-research-ethics-not-either-or-both</a></li> <li>2. <b>A focus on community priorities in research.</b> Williams RL, Willging CE, Quintero G, et al. Ethics of health research in communities: perspectives from the Southwestern United States. <i>Annals of Family Medicine</i> <a href="http://www.annfammed.org/content/8/5/433.full.pdf+html">http://www.annfammed.org/content/8/5/433.full.pdf+html</a></li> <li>3. <b>Local commentaries on research and the need for dialogue between scientists and communities.</b> Fairhead, J, Leach, M, Small, M. Where techno-science meets poverty: Medical research and the economy of blood in The Gambia, West Africa. <i>Social Science and Medicine</i> <a href="http://linkinghub.elsevier.com/retrieve/pii/S0277953606001092">http://linkinghub.elsevier.com/retrieve/pii/S0277953606001092</a></li> </ol> <p>Optional Readings and Recommended Resources:</p> <ul style="list-style-type: none"> <li>• Skloot, R. <i>The Immortal Life of Henrietta Lacks</i>. Broadway Books. 2010.</li> <li>• Grimes vs Kennedy Krieger. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447191/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447191/</a>; <a href="https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-07/hlaw1-0311.pdf">https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-07/hlaw1-0311.pdf</a></li> <li>• Pickett JT, Roche SP. Questionable, Objectionable or Criminal? Public Opinion on Data Fraud and Selective Reporting in Science. <i>Sci Eng Ethics</i>. 2018 Feb;24(1):151-171. <a href="https://www.ncbi.nlm.nih.gov/pubmed/28281156">https://www.ncbi.nlm.nih.gov/pubmed/28281156</a></li> </ul>
Class 12	Apr 6	Student/Mentee and mentor relationships (Waters – Hunleth out of the office)	<p>Session lead, reflection paper</p> <p>Required Readings:</p> <ol style="list-style-type: none"> <li>1. <b>Successful and failed mentoring relationships:</b> Strauss, et al. Characteristics of Successful and Failed Mentoring Relationships. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/</a></li> <li>2. <b>Choosing a mentor:</b> <a href="https://www.training.nih.gov/mentoring_guidelines">https://www.training.nih.gov/mentoring_guidelines</a></li> <li>3. <b>Different types of mentoring relationships:</b> A Matrix Mentoring Model That Effectively Supports Clinical and Translational Scientists and Increases Inclusion in Biomedical Research. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4811725/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4811725/</a></li> </ol> <p>Optional Readings and Recommended Resources:</p> <ul style="list-style-type: none"> <li>• Advisor, Teacher, Role Model, Friend. On Being a Mentor to Students in Science and Engineering. National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. National Academy Press; Washington, D.C. 1997. <a href="http://www.nap.edu/openbook.php?record_id=5789">http://www.nap.edu/openbook.php?record_id=5789</a></li> <li>• <b>Thoughts on Choosing a Research Mentor.</b> NIH Office of Intramural Research and Training. <a href="https://www.training.nih.gov/mentoring_guidelines">https://www.training.nih.gov/mentoring_guidelines</a></li> <li>• Are you a good protégé? <a href="http://chronicle.com/article/Are-You-a-Good-Prot-g-/45755/">http://chronicle.com/article/Are-You-a-Good-Prot-g-/45755/</a></li> <li>• Resources for Research Ethics Education's website, with readings and discussion questions for mentors and mentees. <a href="http://research-ethics.org/topics/mentoring/index2.php">http://research-ethics.org/topics/mentoring/index2.php</a></li> <li>• <b>Nature's guide for mentors:</b> Lee, et al. <a href="https://www.nature.com/articles/447791a">https://www.nature.com/articles/447791a</a></li> <li>• <i>Training for mentors.</i> <a href="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</a></li> </ul> <p><b>Being a mentee:</b> <a href="http://chronicle.com/blogs/onhiring/how-to-be-a-better-mentee/31973">http://chronicle.com/blogs/onhiring/how-to-be-a-better-mentee/31973</a></p>



## **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](https://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/](https://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/](https://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/](https://mddiversity.wustl.edu/)

**The Diversity and Inclusion Student Council** promotes an inclusive campus environment for all School of Medicine students.

[sites.wustl.edu/disc/](https://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/](https://wumma.wustl.edu/)