Ethics in Clinical and Population Health Research (M19-505)

Spring 2025 (1/13/25 – 4/7/24) Mondays, 12:30 to 1:30pm Doll & Hill Conference Room (#2131), Taylor Ave Building

INSTRUCTORS

Erika A. Waters, PhD, MPH Division of Public Health Sciences Department of Surgery waterse@wustl.edu Jean Hunleth, PhD, MPH Division of Public Health Sciences Department of Surgery jean.hunleth@wustl.edu

OFFICE HOURS

By appointment

PREREQUISITES

None

TARGET AUDIENCE

Clinicians, clinicians-in-training, and postdoctoral researchers 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 from the media 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 that will be held in person. This class is not based on lectures. Instead, it is based on discussion, and thus relies on full participation from all students. Students must come to each session prepared to be active and thoughtful participants. This requires thoughtful and careful reading of assigned course materials prior to each class session. Additionally, the class covers timely research ethics issues in the media, to demonstrate how common ethical concerns arise and the multi-level factors that lead to ethical issues (e.g., system, organization, lab, individual). Students will be responsible for identifying these issues and discussing them in class.

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 64 points.

- Class participation: 24 points
- Media leads: 20 points (2 sessions @ 10 points each)
- Media discussants: 20 points (2 sessions @ 10 points each)

Grading Scale

A: 58-64 points; B: 51-57 points; C: 45-50 points

<u>Canvas</u>

We will use Canvas to manage our class, access assignment instructions and media articles, and post courserelated questions. Canvas can be accessed at <u>https://mycanvas.wustl.edu/</u>. Log in to the <u>Wash U MyCanvas</u> version (<u>NOT</u> 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

We recognize that we are holding this course in an ongoing pandemic. This semester the course will be held inperson, with provisions made if university policies for in-person instruction change. If you anticipate issues with attendance, deadlines, or completion of assignments, please discuss these with the instructors <u>as soon as</u> <u>possible</u>. Email is the best way to contact the instructors. Emails will be answered by one of the two instructors within two business days with the exception of weekends and holidays.

- Class attendance and participation are an NIH requirement to be certified as completing the NIH requirements for Responsible Conduct in Research. Students who attend fewer than 8 sessions will not be certified as having completed the NIH responsible conduct of research requirements.
- **Readings assigned for each class should be read ahead of the class.** Students should be prepared to discuss the material from readings and relate the readings to case studies and their own research experiences (past, present, and imagined future).

ASSIGNMENTS & DUE DATES

Class 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 being an <u>active and</u> <u>thoughtful contributor</u> to class discussions in break out group discussions and in the larger group discussion.

Class format: The class format will be a mixture of full group and break out group discussions. We will utilize break out groups for the discussion of the news media cases. Instructors will assign all students to a **Media**

Team that they will regularly meet with during the class in that group. Each team will have one **Media Lead** and one **Media Discussant** for each class session.

Media Lead (20 points) in Break Out group: You will be required to serve as media lead <u>two times</u> during the semester. You will be responsible for choosing the news reports, which should be real cases reported in news outlets. The news report should be brief and focus on research ethics topic we are covering during the week you lead. The media lead grade is based on the extent to which the lead selects a relevant news report for the week's topic and comes prepared to lead the discussion, as evidenced by level of preparation, and, critically, *incorporation of the week's readings*. Please circulate the report you choose to your Media discussion team no later than the Thursday before the class in which you are assigned to present. Please upload the report in the Canvas discussion thread for the appropriate week (e.g., if you are presenting in week 3, upload it to the week 3 media article discussion thread).

Media Discussant (20 points) in Break Out group and for Full Group: You will be required to serve as discussant <u>two times</u> during the semester. The role of discussant is to support the media lead, to document the discussion in a Google doc provided by the instructors, and to ensure that the discussion stays on track and *incorporates the week's readings*. In addition to speaking, we encourage students to use the chat box to ensure that their questions and responses are heard. The media discussant will report back to the full class on the discussion and the major take home messages. This report back is not a summary of the article but a critical reporting on the article as it relates to the course topic and readings.

Note: The number of times each class member will serve as Media Lead or Media Discussant is subject to change depending on course enrolment. The instructors may also need to adjust the assignment to fit the realities we face during the semester, given the on-line format and the pandemic context.

POLICY ON LATE ASSIGNMENTS

This is a synchronous class, and the class discussions depend on the **Media Lead.** Please support your classmates by selecting a news report and posting it <u>on Canvas for your team and the instructors to see no</u> <u>later than 5:00pm Central Standard Time (CST) the Thursday before the class session</u>. Late assignments will have 1 point deducted.

We ask that students maintain open communication with the instructors about their needs. Media team members may also swap dates for presenting as Media Lead and Media Discussant without penalty, *if agreed upon by team members and if the instructors are notified*.

Week Date	Торіс	Readings
Class 1 Jan 13	Introduction to course and the responsible conduct of research	 General References and Useful Web Pages: "Fostering integrity in Research" National Academies of Sciences, Engineering, and Medicine <u>https://www.nap.edu/catalog/21896/fostering-integrity-in-</u>
	(Hunleth and Waters)	 <u>research</u> NIH Investigator Manual for Human Subjects Research <u>https://irbo.nih.gov/confluence/display/ohsrp/Investigator+Manu</u> <u>al</u>

	 Hastings Center <u>http://www.thehastingscenter.org/</u>
	 "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
	• Dear Labby, a monthly advice column in the American Society of
	Cell Biology newsletter, deals with practical issues in the science
	and career advancement.
	https://www.ascb.org/category/publications-columns/dear-labby/
0	ther Ethics Resources and Sources for Finding Case Studies:
	NIH Office of Research Integrity
	 <u>https://ori.hhs.gov/general-resources-0</u>
	https://ori.hhs.gov/research-misconduct-0
	• NIH Office of the Director https://www.nih.gov/institutes-nih/nih-
	office-director
	Online Ethics Center for Engineering and Science at Case Western

 Online Ethics Center for Engineering and Science at Case Western Reserve University <u>https://onlineethics.org/</u>

Also: Science Magazine (<u>http://www.sciencemag.org/</u>) and the Chronicle of Higher Education (<u>www.chronicle.com</u>) regularly publish commentaries and stories relevant to the responsible conduct of research.

MLK Day	, NO CLASS		
Jan 20			
Class 2	Research	Rec	<u>quired:</u>
Jan 27	misconduct and policies for handling misconduct (Hunleth)	1.	University policy. [skim] Research Integrity Policy for Washington University <u>https://research.wustl.edu/washington-university-</u> research-integrity-policy/
		2.	NIH on misconduct. [skim] Brief NIH definition of misconduct and federal process for handling allegations https://grants.nih.gov/grants/research_integrity/research_miscondu
		3.	<u>t.htm</u> <u>Scientific integrity policy of the National Institutes of Health. [read]</u> This policy codifies NIH's expectations to preserve scientific integrity.
		4.	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-178.htm <u>NIH and scientific integrity. [read]</u> Stuart Black on fraud by a leader i Alzheimer's research. <u>https://goodscience.substack.com/p/nih-and-</u> scientific-integrity
		5.	Practices that build good research behavior. [read] Gunsalus & Robinson. Nine Pitfalls of Research Misconduct. <i>Nature.</i> <u>https://www.nature.com/articles/d41586-018-05145-6</u>
		Rec	commended Resources:
		•	Handling misconduct. Official Federal Policy on Misconduct and Handling of allegations (HHS will update policy at the end of January 2025) https://ori.hhs.gov/sites/default/files/42 cfr_parts 50 and 93 2005

		 <u>pdf</u> Handling misconduct. NIH Office of Research Integrity, on handling misconduct. <u>https://ori.hhs.gov/handling-misconduct</u>
Class 3 Feb 3	Data acquisition and analysis, management, and sharing (Waters)	Required:1. Practical data acquisition and management guidelines. [read]Knatterud GL. Management and conduct of randomized controlledtrials. Epidemiol Rev 2002; 24(1): 12-25.https://www.ncbi.nlm.nih.gov/pubmed/12119852
		 2. Data sharing. [mix of reading and skimming] NIH data sharing mandate [read] https://www.nature.com/articles/d41586-022-00402-1 Elements of an NIH data management and sharing plan [read] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21- 014.html Allowable costs for data management and sharing [skim] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21- 015.html Selecting a repository for data resulting from NIH-supported research [skim] https://grants.nih.gov/grants/guide/notice- files/NOT-OD-21-016.html [Also relevant for Class 5]
		 [Also relevant for class 5] Data Management Plan Tool. [explore for 5 mins] University of California. <u>https://dmptool.org/</u> - 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. You can also type in placeholder information in each section (e.g., "Test") to see what ir looks like when put all together.
		 Keeping records, from conceptualization through data analysis. [read] How to keep a lab notebook.
		 https://www.science.org/content/article/how-keep-lab-notebook LabArchives Electronic Laboratory Notebook. [explore for 5 mins] - go to https://auth-service.labarchives.com/ and click "Go to Institution's login." Choose Washington University and log in. Review the options on the far left side, and experiment with adding text.
		 <u>Optional Readings and Recommended Resources:</u> Knatterud, Rockhold, et al. Guidelines for quality assurance in multi- center trials: a position paper. Control Clin Trials 1998; 19(5): 477-493 <u>https://www.ncbi.nlm.nih.gov/pubmed/9741868</u>
Class 4 Feb 10	Collaboration, data ownership, and resource sharing	 <u>Required:</u> 1. <i>Team science.</i> [read] Bennett & Gadlin. Collaboration and Team Science: From Theory to Practice. Journal of Investigative Medicine;

	(Hunleth)	 60(5): 768-775. <u>https://pmc.ncbi.nlm.nih.gov/articles/PMC3652225/</u> 2. Power asymmetries in global health research. [read] Abimbola et al. Addressing power asymmetries in global health. PLOS Medicine; 18(6): e1003667. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pm ed.1003604 3. NIH list of data sharing policies – [skim the table to gain understanding of the scope of the issue.] [Also relevant for Class 3] https://sharing.nih.gov/other-sharing-policies/nih-institute-and-center-data-sharing-policies
		 <u>WU policy</u>. Washington University Policy on Intellectual Property https://wustl.edu/about/compliance-policies/intellectual-property- research-policies/intellectual-property/ <u>Collaboration and working in teams</u>: <u>https://www.cancer.gov/about- nci/organization/crs/research-initiatives/team-science-field- guide/collaboration-team-science-guide.pdf</u> <u>Building Successful Research Teams</u>. [requires logging in- all WashU students have access to these resources] <u>https://www.facultydiversity.org/webinars/researchteams</u>
Class 5 Feb 17	Data exploration, interpretation, and presentation (Waters)	 Required: 1. Data exploration and interpretation. [read] Wigboldus et al. Encourage playing with data and discourage questionable reporting practices. Psychometrika 2016; 81(1):27-32. https://www.ncbi.nlm.nih.gov/pubmed/25820979 2. Precision of reporting and replicability. [read] Buck. Hot dogs, cancer cells, replication, and Al. The Good Science Project. 2024. https://open.substack.com/pub/goodscience/p/hot-dogs-cancer-cells- replication?utm_campaign=post&utm_medium=web 3. Image manipulation. [read] Avoiding image fraud: 7 rules for editing images. https://www.aje.com/en/arc/avoiding-image-fraud-7-rules- editing-images/ 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. Open Science Framework https://osf.io/ NIH Principles and Guidelines for Reporting Preclinical Research. https://www.nih.gov/research-training/rigor- reproducibility/principles-guidelines-reporting-preclinical-research Preregistration of research methods and analytic plan. Nosek et al. The Preregistration Revolution. PNAS 2018; 115(11): 2600-2606. http://www.pnas.org/content/pnas/115/11/2600.full.pdf

Class 6 Feb 24	Conflicts of interest – personal, professional, financial, and commitment (in allocating time, effort, and other resources) (Waters)	 <u>Wash U policy.</u> [skim] Individual (Research) Conflicts of Interest Policy https://research.wustl.edu/research-conflicts-interest-policy- guidelines/ Industry payments. [read] Financial conflicts of interest among US physician authors of 2020 clinical practice guidelines. Mooghali et al., BMC Open. 2023. <u>https://bmjopen.bmj.com/content/13/1/e069115</u> Reporting COIs. [read] Mole B. Top cancer expert forgot to mention \$3.5M industry ties – he just resigned. Ars Technica. https://arstechnica.com/science/2018/09/top-cancer-expert-forgot- to-mention-3-5m-industry-ties-he-just-resigned/ Foreign Interference. [skim] About foreign interference. https://grants.nih.gov/policy/foreign-interference/about-foreign- interference How funders affect research result reporting. [skim results section] Østengaard et al. Influence and management of COI in RCTs. BMJ. 2020. https://www.bmj.com/content/371/bmj.m3764 Optional Readings and Recommended Resources: NIH Conflict of Interest Information Page. http://grants2.nih.gov/grants/policy/coi/index.htm Lundh et al. Industry sponsorship and research outcome. Cochrane Review. 2017. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR00 0033.pub3/full
Class 7 Mar 3	Animal research (Waters)	 <u>Required Readings:</u> <i>NIH requirement to account for sex.</i> [listen to 5-min audiorecording located toward the beginning of the article] Policy: NIH to balance sex in cell and animal studies. <u>https://www.nature.com/news/policy-nih-to-balance-sex-in-cell-and-animal-studies-1.15195</u> <i>General principles of animal research.</i> [read] The 3 Rs. <u>https://www.nc3rs.org.uk/the-3rs.</u> <i>Reporting guidelines.</i> The ARRIVE guidelines 2.0: Updated guidelines for reporting animal research. [read] Percie du Sert et al., PLoS Biol. 2020 18(7): e3000410 <u>https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio. 3000410</u> <i>Reproducibility.</i> The Interplay of Ethics, Animal Welfare, and IACUC Oversight on the Reproducibility of Animal Studies. [skim] Pritt & Hammer, Pritt SL, Hammer RE. The Interplay of Ethics, Animal Welfare, and IACUC Oversight on the Reproducibility of Animal Studies. Comp Med. 2017 Mar 1;67(2):101-105. <u>https://www.ncbi.nlm.nih.gov/pubmed/28381309</u> Optional Readings and Recommended Resources: WUSTL animal care and use policies. May require WUSTL login. <u>https://research.wustl.edu/topics/animal-care-use/</u>

		NIH resources for enhancing rigor of animal research.
		https://nexus.od.nih.gov/all/2023/02/10/take-advantage-of-our-
		many-resources-for-enhancing-the-rigor-of-animal-research/
		• 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/
		 Practical tips are available at the 3 Rs resources website:
		https://www.nc3rs.org.uk/3rs-resources.
		 NAS Guide for the Care and Use of Laboratory Animals.
		https://www.ncbi.nlm.nih.gov/books/NBK54050/
		NIH resources <u>https://olaw.nih.gov/</u>
Class 8	Responsible	Required Readings:
Mar 10	authorship and	1. Wash U policy. [skim] Wash U Authorship Policy.
	publication, peer	https://research.washu.edu/policy-authorship-scientific-scholarly-
	review	publications/
	confidentiality and	2. Defining the Role of Authors and Contributors. [read]
	security	http://www.icmje.org/recommendations/browse/roles-and-
	(Hunleth)	responsibilities/defining-the-role-of-authors-and-contributors.html
		3. Equitable authorship in international partnerships. [read] Morton et
		al. Consensus statement on measure to promote equitable authorship
		in the publication of research from international partnerships.
		Anaesthesia, 2022: 77(3)
		https://associationofanaesthetists-
		publications.onlinelibrary.wiley.com/doi/10.1111/anae.15597
		4. Peer review. [read] Lovejoy, Revenson, France. Reviewing manuscripts
		for peer-review journals: A primer for novice and seasoned reviewers.
		Annals of Behavioral Medicine
		http://link.springer.com/article/10.1007/s12160-011-9269-x
		5. Peer review- preserving confidentiality. [read] Office of Research
		Integrity Introduction to RCR: Chapter 10. Peer Review: Preserving
		Confidentiality
		https://ori.hhs.gov/content/chapter-10-peer-review-Preserving-
		<u>confidentiality</u>
		Recommended Resources:
		• Reporting and Publishing Scholarly Work. International Committee of
		Medical Journal Editors http://www.icmje.org/icmje-
		recommendations.pdf
		Predatory journals:
		https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-
		<u>015-0469-2</u>
		Guide for avoiding plagiarism:
		https://ori.hhs.gov/sites/default/files/plagiarism.pdf

Class 0	Cofo loboratore	Dequired Decidings
Class 9 Mar 17	Safe laboratory	Required Readings:
iviai 17	practices and research environments (Waters)	1. WUSTL policy. [read] Discrimination and harassment.
		https://hr.wustl.edu/items/discrimination-harassment-policy/
		2. WUSTL policy. [read] Abusive conduct.
		https://hr.wustl.edu/items/abusive-conduct-policy/
		3. <i>Physical safety.</i> [read] A decade after a fatal lab safety disaster, what
		have we learned? 2018.
		https://www.science.org/content/article/decade-after-fatal-lab-
		safety-disaster-what-have-we-learned?
		4. <i>NIH response to harassment.</i> [skim] NIH pulls funding. 2021.
		https://www.science.org/content/article/nih-removed-more-70-lab-
		heads-grants-after-harassment-complaints
		5. The Ethical Treatment of Research Assistants. [read] 2016.
		https://files.eric.ed.gov/fulltext/EJ1043543.pdf
		Optional Readings and Recommended Resources:
		• Reporting mistreatment of students, residents, and fellows. [read]
		https://bulletin.wustl.edu/medicine/policies/student-mistreatment/
		Safety in Academic Field Research.
		https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone
		.0102172&type=printable
		 Safe Science: Promoting a Culture of Safety in Academic Chemical
		Research (National Academies report).
		https://www.nap.edu/catalog/18706/safe-science-promoting-a-
		<u>culture-of-safety-in-academic-chemical</u>
Class	Human subjects	
Class 10	Human subjects	Required Readings:
10	research and	Required Readings: 1. What is vulnerability? [read] https://health-policy-
	•	Required Readings: 1. What is vulnerability? [read] <u>https://health-policy-</u> systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6
10	research and research with	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable
10	research and research with vulnerable	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research:
10	research and research with vulnerable populations	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín.
10	research and research with vulnerable populations	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4)
10	research and research with vulnerable populations	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-
10	research and research with vulnerable populations	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217
10	research and research with vulnerable populations	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217 3. Getting started. [skim] List of considerations for research with
10	research and research with vulnerable populations	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) <u>https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217</u> 3. Getting started. [skim] List of considerations for research with children. Note: this list offers important considerations for research
10	research and research with vulnerable populations	 <u>Required Readings:</u> <u>What is vulnerability? [read] https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217 Getting started. [skim] 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-
10	research and research with vulnerable populations	 <u>Required Readings:</u> 1. What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> 2. Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) <u>https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217</u> 3. Getting started. [skim] List of considerations for research with children. Note: this list offers important considerations for research with other vulnerable groups as well. <u>https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-</u>
10	research and research with vulnerable populations	 <u>Required Readings:</u> <u>What is vulnerability? [read] https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4)
10	research and research with vulnerable populations	 <u>Required Readings:</u> What is vulnerability? [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4)
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10	research and research with vulnerable populations	 <u>Required Readings:</u> <u>What is vulnerability?</u> [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) <u>https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217</u> <i>Getting started.</i> [skim] List of considerations for research with children. Note: this list offers important considerations for research with other vulnerable groups as well. <u>https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-only.pdf</u> <i>Consent guidelines.</i> [skim] Guidelines from the Human Research Protection Office (HRPO) at Washington University beginning p. 53 <u>https://bpb-us-</u>
10	research and research with vulnerable populations	 <u>Required Readings:</u> <u>What is vulnerability?</u> [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) <u>https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217</u> <i>Getting started</i>. [skim] List of considerations for research with children. Note: this list offers important considerations for research with other vulnerable groups as well. <u>https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-only.pdf</u> <i>Consent guidelines</i>. [skim] Guidelines from the Human Research Protection Office (HRPO) at Washington University beginning p. 53 <u>https://bpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/2/3030/files/2023/03/2023-</u>
10	research and research with vulnerable populations	 <u>Required Readings:</u> What is vulnerability? [read] https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6 Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217 <i>Getting started</i>. [skim] 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 <i>Consent guidelines</i>. [skim] Guidelines from the Human Research Protection Office (HRPO) at Washington University beginning p. 53 https://bpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/2/3030/files/2023/03/2023-03-15-HRPO-Research-Guide-V50.pdf
10	research and research with vulnerable populations	 <u>Required Readings:</u> <u>What is vulnerability?</u> [read] <u>https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-016-0164-6</u> Tools to reduce ethical breaches in research involving vulnerable groups. [read]. González-Duarte, et al. Bioethics in Clinical Research: The Research Ethics Involving Vulnerable Groups. Rev. invest. Clín. 2019; 71(4) <u>https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S0034-83762019000400217</u> <i>Getting started</i>. [skim] List of considerations for research with children. Note: this list offers important considerations for research with other vulnerable groups as well. <u>https://childethics.com/wp-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-only.pdf</u> <i>Consent guidelines</i>. [skim] Guidelines from the Human Research Protection Office (HRPO) at Washington University beginning p. 53 <u>https://bpb-us-w2.wpmucdn.com/sites.wustl.edu/dist/2/3030/files/2023/03/2023-</u>

		 Definitions and roles and responsibilities. Example, prisoners: <u>https://humansubjects.nih.gov/prisoners</u> Note: see bottom left corner of page for links to other vulnerable populations. Certificates of confidentiality (CoC) to protect the privacy of research participants. <u>https://humansubjects.nih.gov/coc/index</u> Consent. Emanuel E, Grady C, Menikoff J on informed consent. Is longer always better? <u>http://muse.jhu.edu/journals/hastings_center_report/v038/38.3.articl e.pdf</u>
Class 11 Mar 31	Societal impact of research and research misconduct (Hunleth)	 <u>Required Reading(s):</u> <i>Environmental impact of research/researchers.</i> [read] Cluzel et al. Reflecting on the environmental impact of research activities: an exploratory study. Procidia CIRP. 2020; 90:754-758 <u>https://www.sciencedirect.com/science/article/pii/S22128271203030</u> 73?via%3Dihub <i>Public input in (biospecimen) policy.</i> [read section on Eliciting and Using Public Opinion] Beskow, Laura M. Lessons from HeLa Cells: The Ethics and Policy of Biospecimens. Ann Rev Genomics Hum Genet 2016; 17:395-417 <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5072843/</u> <i>Decolonizing science.</i> [read] Liboiron, M. Decolonizing geoscience requires more than equity and inclusion. Nature Geoscience <u>https://www.nature.com/articles/s41561-021-00861-7</u> <i>Global health research ethics and colonialism.</i> [read] Pai, M. Global health still mimics colonial ways. <u>https://theconversation.com/global- health-still-mimics-colonial-ways-heres-how-to-break-the-pattern- 121951</u> <i>Full book on Henrietta Lacks.</i> Skloot, R. <i>The Immortal Life of Henrietta Lacks.</i> Broadway Books. 2010. <i>List of Global Health books</i> to inform more ethical global health research. https://naturemicrobiologycommunity.nature.com/posts/41300-if- you-had-to-read-one-book-on-global-health
Class 12 Apr 7	Student/Mentee and mentor relationships (Waters and Hunleth)	 <u>Required Readings:</u> 1. <i>Choosing a mentor.</i> [skim] https://www.training.nih.gov/mentors/developing-a-network-of- mentors-to-support-you/ 2. <i>Different types of mentoring relationships.</i> [skim] 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/ 3. <i>Understanding and dismantling privilege.</i> [read] Martinez-Cola, M. Collectors, Nightlights, and Allies, Oh My: White Mentors in the

	Academy https://www.wpcjournal.com/article/view/20275
<u>Op</u>	tional Readings and Recommended Resources:
•	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.
	http://www.nap.edu/openbook.php?record_id=5789
•	Are you a good protégé?
	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
•	Nature's guide for mentors: Lee, et al.
	https://www.nature.com/articles/447791a
•	Training for mentors.
	http://www.sciencemag.org/content/311/5760/473.summary?sid=99c
	2c85f-0d5e-4f8c-aac2-b6c447d2103c
•	Being a mentee: http://chronicle.com/blogs/onhiring/how-to-be-a-
	better-mentee/31973
•	Successful and failed mentoring relationships. [read] Strauss, et al.

 Successful and failed mentoring relationships. [read] Strauss, et al. Characteristics of Successful and Failed Mentoring Relationships. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/</u>

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 <u>MPHS Student</u> <u>Handbook</u>. 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 <u>MPHS Student Handbook</u>. 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 <u>WashU's academic integrity</u> 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 <u>MPHS Student Handbook</u>

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 <u>Disability Resources</u> 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: shi.www.shi.edu/MentalHealth.

SEXUAL ASSAULT RESOURCES

You can also speak confidentially and learn about available resources by contacting <u>Dr. Gladys Smith, PhD</u>, 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: <u>diversityinclusion.wustl.edu/brss/</u>.

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. <u>mddiversity.wustl.edu/</u>

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/