Ethics in Clinical and Population Health Research (M19-505)
Spring 2023 (1/23/23 – 4/10/23)
Mondays, 12:30 to 1:30pm
Location: Doll & Hill

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

Canvas
We will use Canvas to manage our class, access assignment instructions and media articles, 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
We recognize that we are holding this course in an ongoing pandemic. This semester the course will be held in-person, 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 as soon as possible. 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 active and thoughtful contributor 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 two times 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.

**Media Discussant (20 points) in Break Out group and for Full Group:** You will be required to serve as discussant two times 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 circulating it to your team and the instructors no later than the Thursday before the class session. We will not deduct points for late assignments this semester because we understand that the pandemic and what students must deal with because of the pandemic is unpredictable, but we encourage students to be respectful of each other’s schedules and turn in the news report on time.

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.
<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Readings</th>
</tr>
</thead>
</table>
| Class 1 | Jan 23 | Introduction to course and the responsible conduct of research (Hunleth and Waters) | **General References and Useful Web Pages:**
  - “Fostering integrity in Research” National Academies of Sciences, Engineering, and Medicine  
    [https://www.nap.edu/catalog/21896/fostering-integrity-in-research](https://www.nap.edu/catalog/21896/fostering-integrity-in-research)
  - NIH Investigator Manual for Human Subjects Research  
  - Hastings Center  
  - “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](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/](https://www.ascb.org/category/publications-columns/dear-labby/)

  **Other Ethics Resources and Sources for Finding Case Studies:**
  - NIH Office of Research Integrity  
    [https://ori.hhs.gov/general-resources-0](https://ori.hhs.gov/general-resources-0)
  - [https://ori.hhs.gov/research-misconduct-0](https://ori.hhs.gov/research-misconduct-0)
  - [https://ori.hhs.gov/newsletters](https://ori.hhs.gov/newsletters)
  - NIH Office of the Director  
  - Online Ethics Center for Engineering and Science at Case Western Reserve University  

  **Also:** Science Magazine ([http://www.sciencemag.org/](http://www.sciencemag.org/)) and the Chronicle of Higher Education ([www.chronicle.com](http://www.chronicle.com)) regularly publish commentaries and stories relevant to the responsible conduct of research. |
| Class 2 | Jan 30 | Research misconduct and policies for handling misconduct (Hunleth) | **Required:**
  1. *University policy. [skim]* Research Integrity Policy for Washington University  
    [https://research.wustl.edu/washington-university-research-integrity-policy/](https://research.wustl.edu/washington-university-research-integrity-policy/)
  2. *NIH on misconduct. [skim]* Brief NIH definition of misconduct and federal process for handling allegations  
    [https://grants.nih.gov/grants/research_integrity/research_misconduct.htm](https://grants.nih.gov/grants/research_integrity/research_misconduct.htm)
    [https://www.nature.com/articles/d41586-018-05145-6](https://www.nature.com/articles/d41586-018-05145-6)

  **Recommended Resources:**
  - *Handling misconduct.* Official Federal Policy on Misconduct and Handling of allegations  
Handling misconduct. NIH Office of Research Integrity, on handling misconduct.  
https://ori.hhs.gov/handling-misconduct

Class 3  
Feb 6  
Data acquisition and analysis, management, and sharing (Waters)  
Required:  
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]  
   - Allowable costs for data management and sharing [skim]  
   - Selecting a repository for data resulting from NIH-supported research [skim]  
   - [Also relevant for Class 5]  
3. **Data Management Plan Tool.** [explore for 5 mins] University of California.  
https://dmptool.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. You can also type in placeholder information in each section (e.g., “Test”) to see what it looks like when put all together.  
4. **Keeping records, from conceptualization through data analysis.** [read]  
How to keep a lab notebook.  
https://www.science.org/content/article/how-keep-lab-notebook  
5. **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.

Optional Readings and Recommended Resources:  
- **Open data.** Schiermeier Q. For the record: Making project data freely available is vital for open science. Nature 2018; 555:403-405.  
https://www.ncbi.nlm.nih.gov/pubmed/9741868

Class 4  
Feb 13  
Data exploration, interpretation, and presentation (Waters)  
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)


---

**Class 5**  
Feb 20  
Collaboration, data ownership, and resource sharing (Hunleth)

**Required:**

1. **Team science.** [read] 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)


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://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html](https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html)

**Recommended Resources:**

- **WU policy.** Washington University Policy on Intellectual Property  [https://wustl.edu/about/compliance-policies/intellectual-property-research-policies/intellectual-property/](https://wustl.edu/about/compliance-policies/intellectual-property-research-policies/intellectual-property/)

**Building Successful Research Teams.**  [https://www.facultydiversity.org/webinars/researchteams](https://www.facultydiversity.org/webinars/researchteams)

---

**Class 6**  
Feb 27  
Conflicts of interest – personal, professional, financial, and commitment (in allocating time, effort, and other resources) (Waters)

**Required Reading**

1. **Wash U policy.** [skim] Individual (Research) Conflicts of Interest Policy  [https://research.wustl.edu/research-conflicts-interest-policy-guidelines/](https://research.wustl.edu/research-conflicts-interest-policy-guidelines/)


3. **Reporting COIs.** [read] Mole B. Top cancer expert forgot to mention $3.5M
industry ties – he just resigned. Ars Technica.  

https://www.bmj.com/content/356/bmj.j176.long

Optional Readings and Recommended Resources:

- NIH Conflict of Interest Information Page.  
http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0104846
http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.1001770 Read only through the end of the discussion section – not the methods/materials

<table>
<thead>
<tr>
<th>Class 7 Mar 6</th>
<th>Safe laboratory practices and research environments (Waters)</th>
<th>Required Readings:</th>
</tr>
</thead>
</table>
https://hr.wustl.edu/items/discrimination-harassment-policy/|
|              | WUSTL policy. [read] Abusive conduct.                   | 2. WUSTL policy. [read] Abusive conduct.  
https://hr.wustl.edu/items/abusive-conduct-policy/|
|              | Workplace mistreatment. [skim] Prevalence of discrimination, abuse, and hardship in emergency medicine residency training in the US. Lall et al.  
AMA Netw Open. 2021;4(8):e2121706  
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783236|
|              | Physical safety. [read] Warning: This lab may cause injury or death.  
https://undark.org/2016/11/02/lab-safety-universities-oversight/|
|              | Reporting mistreatment of residents and fellows. [read]  | 4. Reporting mistreatment of residents and fellows. [read]  
https://bulletin.wustl.edu/medicine/policies/student-mistreatment/|

Optional Readings and Recommended Resources:

- Mistreatment of students  
https://bulletin.wustl.edu/medicine/policies/student-mistreatment/
- NIH pulls funding.  
https://www.science.org/content/article/nih-removed-more-70-lab-heads-grants-after-harassment-complaints
- 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-
Does science have a bullying problem?
https://www.nature.com/articles/d41586-018-07532-5

The Ethical Treatment of Research Assistants.

<table>
<thead>
<tr>
<th>Class 8</th>
<th>Mar 13</th>
<th>Animal research (Waters)</th>
<th>Required Readings:</th>
</tr>
</thead>
</table>

Optional Readings and Recommended Resources:
- WUSTL animal care and use policies. May require WUSTL login. https://research.wustl.edu/topics/animal-care-use/  
- 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.  
- NIH resources https://olaw.nih.gov/  

Class 9  Mar 20  Responsible authorship and publication, peer review confidentiality and security (Hunleth)  

<table>
<thead>
<tr>
<th>Required Readings:</th>
</tr>
</thead>
</table>
### Class 10  Mar 27

Human subjects research and research with vulnerable populations (Hunleth)

#### Required Readings:

1. **What is vulnerability?** [read]  


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.  

4. **Consent guidelines.** [skim] Guidelines from the Human Research Protection Office (HRPO) at Washington University p. 31-34  

#### Recommended Resources:

- **NIH guidance.** NIH on research involving vulnerable persons. Definitions and roles and responsibilities. Example, prisoners:  
  [https://humansubjects.nih.gov/prisoners](https://humansubjects.nih.gov/prisoners)  
  Note: see bottom left corner of page for links to other vulnerable populations.

- **Certificates of confidentiality** (CoC) to protect the privacy of research participants.  
  [https://humansubjects.nih.gov/coc/index](https://humansubjects.nih.gov/coc/index)

- **Consent.** 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)

### Class 11  Apr 3

Societal impact of research and research misconduct (Hunleth)

#### Required Reading(s):

1. **Environmental impact of research/researchers.** [read] Cluzel et al. Reflecting on the environmental impact of research activities: an exploratory study. Procida CIRP. 2020; 90:754-758  

2. **Public input in (biospecimen) policy.** [read section on Eliciting and Using Public Opinion] Beskow, Laura M. Lessons from HeLa Cells: The Ethics and

Recommended Resources:
- List of Global Health books 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 10
Student/Mentee and mentor relationships (Waters and Hunleth)

Required Readings:

Optional Readings and Recommended Resources:
- 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
- Training for mentors. http://www.sciencemag.org/content/311/5760/473.summary?sid=99c2c85f-0d5e-4f8c-aac2-b6c447d2103c
- Being a mentee: http://chronicle.com/blogs/ohniring/how-to-be-a-better-mentee/31973
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/