Ethics in Clinical and Population Health Research (M19-505)
Spring 2022 (1/18/22 – 4/11/2022)
Mondays, 12:30 to 1:30pm
Location: Zoom

INSTRUCTORS
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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 fulfill the National Institutes of Health requirements for training in responsible conduct of research.

This class is a seminar that will be held synchronously using Zoom. 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, thoughtful, and energetic 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. 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 a pandemic. The course will be held synchronously and will not be recorded to maintain confidentiality about the ethical issues disclosed and discussed. 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 part of your grade. More than two absences from class may result in a lowered grade.
• 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).
• Students who attend fewer than 8 Zoom sessions without creating an alternate plan with the instructors will not be certified as having completed the NIH responsible conduct of research requirements.

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. Note that using the chat box in the larger group discussion is encouraged and offers an opportunity to ask questions or get your thoughts heard given the short amount of time we are together.

Class format: The class format will be a mixture of full group and break out room discussions. We will utilize break out rooms 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 a break out room. Each team will have one Media Lead and one Media Discussant for each class session.

Media Lead (20 points) in Break Out Room: 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 Room 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>
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| Class 1 | Jan 24 | 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  
✓ Hastings Center http://www.thehastingscenter.org/  
✓ “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  

**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/research-misconduct-0  
✓ https://ori.hhs.gov/newsletters  
✓ Online Ethics Center for Engineering and Science at Case Western Reserve University http://onlineethics.org/  

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

| Class 2 | Jan 31 | 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/  
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://www.ncbi.nlm.nih.gov/books/NBK475962/  
**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](https://ori.hhs.gov/handling-misconduct)

**Required:**

1. **Practical data acquisition and management guidelines.** [read]

2. **NIH data sharing guidelines.** [mix of reading and skimming]
   - 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]

3. **Data Management Plan Tool.** [explore] University of California.
   [https://dmptool.org/](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.

**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.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)

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**Class 3**

Feb 7

Data acquisition, management, and sharing (Waters)

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**Class 4**

Feb 14

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.
- Open Science Framework https://osf.io/
- Foster Open Sciences https://www.fosteropenscience.eu/resources

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**Class 5  Feb 21**

Collaboration, data ownership, and resource sharing (Hunleth)

**Recommended Resources:**
- **WU policy.** Washington University Policy on Intellectual Property https://wustl.edu/about/compliance-policies/intellectual-property-research-policies/intellectual-property/

**Required Reading**
2. **Collaboration.** [listen; also for Class 9] McLaren. Drama-Free Collaborations: How to Develop and Sustain Healthy Partnerships with Co-Authors. NCFDD [join NCFDD using wustl membership] https://www.facultydiversity.org/webinars/healthy-collaboration
3. NIH list of data sharing policies – [skim the table to gain understanding of the scope of the issue.] https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html

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**Class 6  Feb 28**

Conflicts of interest – personal, professional, financial (Waters)

**Recommended Resources:**
- **Wash U policy.** [skim] Individual (Research) Conflicts of Interest Policy https://research.wustl.edu/research-conflicts-interest-policy-guidelines/
3. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2

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

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**Class 7 Mar 7**

**Safe laboratory and research practices and responsibilities as a PI (Waters)**

Required Readings:
1. **WUSTL policy.** [read] Discrimination and harassment. 
   https://hr.wustl.edu/items/discrimination-harassment-policy/
2. **Workplace mistreatment.** [skim] Prevalence of discrimination, abuse, and harassment 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
3. **Physical safety.** [read] Warning: This lab may cause injury or death. 
   https://undark.org/2016/11/02/lab-safety-universities-oversight/

Optional Readings and Recommended Resources:
- 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-science-promoting-a-culture-of-safety-in-academic-chemical
• Does science have a bullying problem?  
https://www.nature.com/articles/d41586-018-07532-5

• The Ethical Treatment of Research Assistants.  

Required Readings:
1. **NIH requirement to account for sex.** [read] Policy: NIH to balance sex in cell and animal studies.  

2. **General principles of animal research.** [read] The 3 Rs.  
https://www.nc3rs.org.uk/the-3rs.

Kilkenny et al., PLoS Biol 8(6): e1000412  
https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1000412


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.  

• 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.  

• NIH resources  
https://olaw.nih.gov/

• Nature collection on animal research.  
https://www.nature.com/collections/mnzcndqhts

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Class 8   Mar 14   Animal research (Waters)

Class 9   Mar 21   Responsible authorship and publication, peer review (Hunleth)

Required Readings:
http://www.wustl.edu/policies/authorship.html

2. **Defining the Role of Authors and Contributors.** [read]  

3. **Peer review.** [read] Lovejoy, Revenson, France. Reviewing manuscripts for peer-review journals: A primer for novice and seasoned reviewers. Annals of Behavioral Medicine  

4. **Co-authorship.** [remember, from Week 5] McLaren. Drama-Free Collaborations: How to Develop and Sustain Healthy Partnerships with Co-Authors. NCFDD  
https://www.facultydiversity.org/webinars/healthy-collaboration

Recommended Resources:


Required Readings:
2. 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-content/uploads/2013/10/ERIC-compendium-Getting-Started-section-only.pdf

Recommended Resources:
• NIH guidance. NIH on research involving vulnerable persons. Definitions and roles and responsibilities. Example, prisoners:  https://humansubjects.nih.gov/prisoners Note: see bottom left corner of page for links to other vulnerable populations.
• Certificates of confidentiality (CoC) to protect the privacy of research participants.  https://humansubjects.nih.gov/coc/index

Required Reading(s):

Recommended Resources:
• Full book on Henrietta Lacks. Skloot, R.  The Immortal Life of Henrietta Lacks


**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](https://naturemicrobiologycommunity.nature.com/posts/41300-if-you-had-to-read-one-book-on-global-health)

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**Required Readings:**

1. *Choosing a mentor.* [skim]
   [https://www.training.nih.gov/mentoring_guidelines](https://www.training.nih.gov/mentoring_guidelines)

   [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4811725/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4811725/)


**Optional Readings and Recommended Resources:**


- Thoughts on Choosing a Research Mentor. NIH Office of Intramural Research and Training.
  [https://www.training.nih.gov/mentoring_guidelines](https://www.training.nih.gov/mentoring_guidelines)

- Are you a good protégé?
  [http://chronicle.com/article/Are-You-a-Good-Prot-g/-45755/](http://chronicle.com/article/Are-You-a-Good-Prot-g/-45755/)

- Resources for Research Ethics Education’s website, with readings and discussion questions for mentors and mentees.
  [http://research-ethics.org/topics/mentoring/index2.php](http://research-ethics.org/topics/mentoring/index2.php)

  [https://www.nature.com/articles/447791a](https://www.nature.com/articles/447791a)

- Training for mentors.
  [http://www.sciencemag.org/content/311/5760/473.summary?sid=99c2c85f-0d5e-4f8c-aac2-b6c447d2103c](http://www.sciencemag.org/content/311/5760/473.summary?sid=99c2c85f-0d5e-4f8c-aac2-b6c447d2103c)


  [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3665769/)

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**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](https://wustl.edu/washu/integrity/) 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](https://wustl.edu/washu/disability/) 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](http://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)...
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/](http://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/](http://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/](http://mddiversity.wustl.edu/)

**The Diversity and Inclusion Student Council** promotes an inclusive campus environment for all School of Medicine students.
[sites.wustl.edu/disc/](http://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/](http://wumma.wustl.edu/)