

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

Spring 2018 (01/22/18 – 3/26/18)

Mondays, 12:30 to 1:30 pm

Location: Taylor Avenue Building 2nd floor, Richmond Room**INSTRUCTOR:**

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

TEACHING ASSISTANT:

Marquita Lewis, PhD, MPH, MS
Division of Public Health Sciences
Department of Surgery
mlewis25@wustl.edu
Phone: 314-747-0483
Office Hours: By appointment

COURSE DESCRIPTION & OBJECTIVES

This course will expose population and clinical health researchers to the various ethical issues and situations encountered in their research and clinical duties, with a focus on research-related issues and solutions. It will also familiarize them with principles of responsible conduct of research and available ethics and compliance resources. Case studies and scenario presentations will supplement discussion on topics such as informed consent and human subjects research, responsible conduct of research and allegations of misconduct, research with vulnerable populations, data management and presentation, publications and peer review, collaboration and sharing data, societal impact of research, and mentee-mentor relationships. This course meets the National Institutes of Health recommendations for training in responsible conduct of research.

COMPETENCIES

- 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

COURSE FORMAT & EXPECTATIONS

This class is a seminar. This is different from lecture courses in that it is primarily based on discussion and thus relies on the full participation of all students. Students must come to each session prepared to be active, thoughtful, and energetic participants. This requires thoughtful and careful reading of assigned course materials prior to each class session. Quizzes at the start of each class will evaluate the reading comprehension and retention.

Each student will be required to co-lead one class discussion. The student leaders will develop the discussion questions and additional readings in consultation with one of the instructors. Even though there are two leaders during each class

meeting, the discussion depends on everyone's participation and each student should come ready to discuss (and respectfully debate) the readings. The instructors will be available to students during and after class and by appointment, and provide clear, timely feedback on student performance. Depending on class size, the discussion will be for a whole class or part of a class.

STUDENT RESPONSIBILITIES

- ✓ Attend each class.
- ✓ Come to class on-time, prepared, and having read all required readings.
- ✓ Participate in class discussions.
- ✓ Complete assignments on time.
- ✓ Seek any necessary clarification regarding course expectations.

Any issues with attendance, deadlines, or completion of assignments should be discussed **before** the deadline/class with the instructor. Email is the best way to contact the instructor. Emails will be answered within two business days with the exception of weekends and holidays.

CLASSROOM ETIQUETTE

- ✓ Please turn all cellphones and pagers to silent or vibrate.
- ✓ If you need to answer a call or page, please leave the room quietly to do so.
- ✓ Do not use the internet, social media sites, BJC clinical sites, or check email during class time.
- ✓ Please be respectful of differences in viewpoints expressed during class discussion.
- ✓ Please keep any sensitive information that arises during discussion confidential.

EVALUATION AND GRADING

1. **Participation (10 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 arriving to class **on time** and being an **active and thoughtful contributor** to class discussions.
2. **Session lead (15 points):** You will be required to lead a session along with a group of your classmates. Size of the group presentation varies based on the class enrollment. This portion of the course grade is based on the extent to which you come prepared to lead the discussion of your assigned session, as evidenced by level of preparation, and discussion questions, and incorporation of recommended or other resources. **Your selected reading, slides, and discussion questions are due to the instructors by the WEDNESDAY before your class, by 5PM.** This allows time for the instructor to review materials and to get readings out to your classmates in a timely manner. You are welcome to meet with an instructor in person if you would like before your session.
3. **Quizzes (35 points):** Beginning with class 2, each session will begin with a short quiz on the course readings. The quizzes usually consist of multiple choice questions, fill-in-the-blank, or short answer and will cover fundamental issues in the readings. Only 7 quizzes count toward the final grade (i.e. the lowest grades will be dropped). **Quizzes are given at the start of class; you are expected to be on time or you will not be able to take the quiz. Illegible responses will be counted as incorrect.**

4. **Reflection papers (40 points):** Four reflection papers are required (2-3 double-spaced pages each, with 1-inch margins). Papers must relate to the topic and the readings covered in four different class sessions (excluding the introduction class). It is up to you to choose which class/readings you write about, but keep in mind that **papers are due at the beginning of the class they cover**. Reflection papers should cover the ideas and issues expressed in the readings, but they are not summaries of the readings. You may want to consider the following questions: What is the significance of the topic to research practice? What are the stakes involved for researchers, research participants, and institutions?

*Keeper/Query: In each reflection paper, you must offer one “keeper” and one “query.” A “keeper” is a key idea that you wish to carry with you as you move through your public health or medical career. It is something that you think is profound or significant. A “query” is a question about the material. This can be something that you did not understand OR a thoughtful prompt for discussion. Please make sure your keeper and query are clearly identifiable in your paper, or points may be deducted. **Come prepared to share your “keepers” and “queries” during class.** Any references used must be properly cited. Each paper is worth 10 points.

Grading:

Participation	10 points
Session lead	15 points
Quizzes	35 points (5 points each)
Reflection papers	40 points (10 points each)

Grading scale:

A:	90-100 points
B:	80-89 points
C:	70-79 points
F:	less than 69 points

POLICY ON CLASS ATTENDANCE AND DEADLINES

Class attendance and participation is critical. Participation (and therefore attendance) is part of your grade. More than two absences from class may result in a lowered grade. Do not enroll if you have more than two absences already planned. Students who are taking this class to fulfill NIH requirements for instruction in the responsible conduct of research must attend at least 8 sessions to meet the requirements.

There will be NO make-up opportunities for missed reflection papers or quizzes. Quizzes are administered promptly at the start of class. Reflection papers are due at the start of the class which they cover. You are expected to plan ahead with your reflection papers. The 2 lowest quiz grades will be dropped, so if you miss a class or are late, that can count as one of your dropped grades. Again, no make-up quizzes will be offered.

There are point penalties for late submissions. One point will be deducted per 24 hour period for assignments that are turned in late. For example, if your discussion questions/slides are due on Wednesday at 5pm, and are turned in after Wednesday 5:00pm but before 5:00pm on Thursday, you would lose one point from your session lead grade. Materials turned in on Thursday after 5:00 pm would lose 2 points. The same point deduction rubric will be used for reflection papers: they are due at the start of class and a point is deducted for every 24 hr period thereafter.

COURSE SCHEDULE

****The syllabus is subject to change at the discretion of the instructor. ****

Session	Date	Topic
1	Jan 22	Introduction to course and the Responsible conduct of research
2	Jan 29	Research misconduct and policies for handling misconduct
3	Feb 5	Data acquisition, management, and presentation
4	Feb 12	Resource sharing and collaboration
5	Feb 19	Conflicts of interest – personal, professional, financial
6	Feb 26	Responsible authorship and publication
7	Mar 5	Human subjects research and research with vulnerable populations
8	Mar 12	Safe laboratory and research practices and responsibilities as a PI
9	Mar 19	Student/Mentee and mentor relationships
10	Mar 26	Societal impact of research and research misconduct

READINGS AND RESOURCES

A schedule of required and recommended readings will be provided. Additional readings related to student presentations will be distributed a few days before each class. Below are some general resources related to our topic:

General References and Useful Web Pages:

- ✓ "The Lab: Avoiding Research Misconduct" is now available on the ORI web site. Interactive video simulation of decisions that affect the integrity of research. <http://ori.hhs.gov/TheLab/>
- ✓ "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>
- ✓ Hastings Center
<http://www.thehastingscenter.org/>
- ✓ *Dear Labby*, a monthly advice column in the American Society of Cell Biology newsletter, deals with practical issues in the science and career advancement.
<http://www.ascb.org/dear-labby-archive/>

Other Ethics Resources and Sources for Finding Case Studies:

- ✓ NIH Office of Research Integrity
<https://ori.hhs.gov/general-resources-0> and <https://ori.hhs.gov/research-misconduct-0>
- ✓ NIH Office of the Director
<https://www.nih.gov/institutes-nih/nih-office-director>
- ✓ Poynter Center for the Study of Ethics, at Indiana University
<https://provost.indiana.edu/poynter-center/>
- ✓ Online Ethics Center for Engineering and Science at Case Western Reserve University
<http://onlineethics.org/>
- ✓ University of Minnesota Education in the Responsible Conduct of Research
<http://research.umn.edu/units/rco/training-education/responsible-conduct-research-rcr-core-curriculum>

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.

Session 2: Research misconduct and policies for handling misconduct

Required:

1. Research Integrity Policy for Washington University
<http://www.wustl.edu/policies/research.html>
2. Federal process for handling allegations
 - a. <https://nexus.od.nih.gov/all/2012/03/16/nih-and-research-misconduct/>
 - b. <https://ori.hhs.gov/handling-misconduct>
3. Ochsensbauer, C. Getting a Grip on Scientific Misconduct. *Science Magazine*.
http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2003_01_31/nodoi.10726169930246436819

Recommended:

- Federal Policy on Misconduct
- <http://ori.hhs.gov/federal-research-misconduct-policy>
- Office of Research Integrity (ORI) Case study <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-149.html>
- Disgraced cloner's ally is cleared of misconduct. *Nature* 439, 768-769 (16 February 2006)
<http://www.nature.com/nature/journal/v439/n7078/full/439768b.html>
- UC Davis neurosurgeons' experimental surgery. For a summary see:
<http://www.sacbee.com/news/investigations/ucd-neurosurgery/article2576229.html>

Session 3: Data Acquisition, Management, and Presentation

Required:

1. Wilcox. On Precision. <http://www.ncbi.nlm.nih.gov/pubmed/14712138>
2. Rossner M & Yamada KM. What's in a picture? Temptation of image manipulation. *J. Cell Biol* 2004; 166:11-15. <http://www.jcb.org/cgi/content/full/166/1/11>
3. Zweig. Does the Language Fit the Evidence? <http://www.healthnewsreview.org/toolkit/tips-for-understanding-studies/does-the-language-fit-the-evidence-association-versus-causation/>
4. Christian MC, McCabe M, Korn E, Abrams J, Kaplan R, & Friedman M. The NCI Audit of the National Surgical Breast and Bowel Project Protocol B-06. *NEJM* 1995; 333:1469-1475.
<http://www.nejm.org/doi/full/10.1056/NEJM199511303332206#t=articleBackground> (see related article on guidelines).

Recommended:

- Knatterud GL. Management and conduct of randomized controlled trials. *Epidemiol Rev* 2002; 24(1): 12-25.
<https://www.ncbi.nlm.nih.gov/pubmed/12119852>
- Knatterud, Rockhold, et al. Guidelines for quality assurance in multi-center trials: a position paper. *Control Clin Trials* 1998; 19(5): 477-493.
https://scholar.google.com/scholar?hl=en&as_sdt=0%2C26&q=Guidelines+for+quality+assurance+in+multi-center+trials%3A+a+position+paper.++&btnG=

Session 4: Resource Sharing and Collaboration

Required:

1. Washington University Policies and Procedures on Material Transfer
<https://otm.wustl.edu/for-inventors/material-transfer/material-transfer-agreement-faqs/>

2. Washington University Policy on Intellectual Property
<http://www.wustl.edu/policies/intelprop.html>
3. NIH Data Sharing Policy and Implementation Guidance.
http://www.grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#goals
4. Court Decides Tissue Samples Belong to the University.
<http://www.sciencemag.org/content/312/5772/346.full?sid=2156b53a-80a3-4676-a262-8ff8b47a7064>
5. Human Tissue Ownership and Use in Research. <http://www.clinchem.org/content/56/11/1675.full.pdf+html>

Note: The policies are long but it is important to get the highlights of them. The articles (#4 and #5) are quite short.

Recommended:

- For a different angle on data sharing and ownership, read about Henrietta Lacks (a short summary is found here: <http://www.smithsonianmag.com/science-nature/henrietta-lacks-immortal-cells-6421299/?no-ist>)
- This is a useful but lengthy resource on collaboration and working in teams: https://ccrod.cancer.gov/confluence/download/attachments/47284665/TeamScience_FieldGuide.pdf?version=2&modificationDate=1285330231523

Session 5: Conflicts of Interest: Personal, Professional, Financial

Required Reading

1. Individual (Research) Conflicts of Interest Policy
<http://research.wustl.edu/ComplianceAreas/COI/Policy/Pages/default.aspx>
2. Publication bias? There are three sides to the story: Industry sponsored studies are more favorable for statins, industry sponsored studies are less favorable statins, or there
 - a. van Lent M, Overbeke J, Out HJ Role of Editorial and Peer Review Processes in Publication Bias: Analysis of Drug Trials Submitted to Eight Medical Journals
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0104846>
 - b. Lundh A1, Lexchin J2, Mintzes B3, Schroll JB4, Bero L5. Industry sponsorship and research outcome.<http://onlinelibrary.wiley.com/doi/10.1002/14651858.MR000033.pub2/abstract;jsessionid=38A8389DBECB588400BC3BE261DCB646.f03t01>
 - c. Krauth D, Anglemyer A, Philipps R, Bero L. Nonindustry-Sponsored Preclinical Studies
<http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.1001770>

Recommended Resources:

- NIH Conflict of Interest Information Page. <http://grants2.nih.gov/grants/policy/coi/index.htm>
- American Association of Universities. Task Force on Research Accountability. Report on Individual and Institutional Conflict of Interest.
http://ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/misc/Ref/AAU_Col.pdf

Session 6: Responsible Authorship and Publication

Required Readings:

1. Wash U Authorship Policy. <http://www.wustl.edu/policies/authorship.html>
2. Guidelines for Avoiding and Resolving Authorship Disputes.
<http://research.wustl.edu/PoliciesGuidelines/Pages/authorshipdisputes.aspx>
3. Plagiarism in Grant Proposals. <http://chronicle.com/article/Plagiarism-in-Grant-Proposals/136161/>
4. Cleaning up the paper trail. <http://science.sciencemag.org/content/312/5770/38.full>
5. Self-plagiarism. <http://www.ajronline.org/doi/abs/10.2214/AJR.12.10327>
6. Bohannon, J. Who's afraid of peer review? Science. <http://www.sciencemag.org/content/342/6154/60.full>

Recommended:

- International Committee of Medical Journal Editors. Recommendations for Reporting and Publishing Scholarly Work: <http://www.icmje.org/icmje-recommendations.pdf>
- And specifically Defining the Role of Authors and Contributors: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

For information about peer review (suggested readings):

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

Session 7: Human Subjects Research and Research with Vulnerable Populations

Required Readings:

1. Consent guidelines for the Human Research Protection Office (HRPO) at Washington University p. 32-35 of <https://hrpo.wustl.edu/wp-content/uploads/2015/04/2015-04-20-WU-IRB-policies-and-procedures.pdf>
2. Emanuel E, Grady C, Menikoff J: Is Longer always Better? http://muse.jhu.edu/journals/hastings_center_report/v038/38.3.article.pdf
3. Trauma trials leaves ethicists uneasy. *Nature*.
<http://www.nature.com/nature/journal/v440/n7083/full/440390b.html>
4. TAMPTI trial at WUSTL: <http://www.tampiti.wustl.edu/> (just look at the website)

Recommended Resources:

- Heimer, C. 'Wicked' ethics: Compliance work and the practice of ethics in HIV research. *Social Science and Medicine*. <http://www.sciencedirect.com.libproxy.wustl.edu/science/article/pii/S0277953612008271>
- Gallagher, M, Haywood, S, Jones, M, Milne, S. Negotiating informed consent with children in school-based research: A critical review. <http://onlinelibrary.wiley.com/doi/10.1111/j.1099-0860.2009.00240.x/abstract>
- Young Lives case study on paying youth for participation in research. http://childethics.com/wp-content/uploads/2013/11/ERIC_Compodium_Case-Studies_Payment-and-Compensation_Virginia-Morrow.pdf
- Additional case studies on ethics research involving children. <http://childethics.com/resources/case-studies/>
- Regulating creativity: Research and survival in the IRB iron cage. *Northwestern Law Review*
<http://groups.psych.northwestern.edu/uttal/documents/Bledsoeetal2007.pdf>

Session 8: Safe Lab (and Research) Practices and the Responsibility of the PI or supervisor

Required Readings:

1. A Death in the Lab. <http://www.nature.com/news/2011/110418/full/472270a.html>
2. Professor Charged in Research Assistant's accident. <http://www.the-scientist.com/?articles.view/articleNo/35354/title/Chemist-to-Court-Over-Assistant-s-Death/>
3. Safety in Academic Field Research. Chemist to Court Over Assistant's Death:
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0102172>

Recommended Resources:

- Safe Science: Promoting a Culture of Safety in Academic Chemical Research

<http://www.nap.edu/catalog/18706/safe-science-promoting-a-culture-of-safety-in-academic-chemical>

- The Ethical Treatment of Research Assistants. <http://jrp.icaap.org/index.php/jrp/article/view/360>

Session 9: Student-mentor relationships

Required Readings:

1. Develop a Trusted Senior Colleague (TSC). <http://chronicle.com/article/How-to-Develop-a-TSC-Trusted/142107/>
2. Are you a good protégé? <http://chronicle.com/article/Are-You-a-Good-Prot-g-/45755/>
3. Be a better mentee <http://chronicle.com/blogs/onhiring/how-to-be-a-better-mentee/31973>
4. Two Former Grad Students Sue Over Alleged Misuse of Ideas. <http://www.sciencemag.org/cgi/content/full/284/5414/562>
5. The Merits of Training Mentors. <http://www.sciencemag.org/content/311/5760/473.summary?sid=99c2c85f-0d5e-4f8c-aac2-b6c447d2103c>

Good resource:

- 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

Session 10: Societal Impact of Research and the Impact of Research Misconduct

Required Reading(s):

1. Welcome, Freshman, DNA Swabs please. <http://chronicle.com/article/Welcome-Freshmen-DNA-Swabs/65729/>
2. Facebook study on Moods. <http://chronicle.com/blogs/ticker/journal-that-published-controversial-facebook-study-raises-ethics-concerns/81153>
3. Protecting communities in Biomedical Research <http://www.sciencemag.org/content/289/5482/1142.full?sid=39665c90-1e24-4639-a7f6-c5e8a15f02ac>
4. Williams RL, Willging CE, Quintero G, et al. Ethics of health research in communities: perspectives from the Southwestern United States. Annals of Family Medicine <http://www.annfammed.org/content/8/5/433.full.pdf+html>
5. Fairhead, J, Leach, M, Small, M. Where techno-science meets poverty: Medical research and the economy of blood in The Gambia, West Africa. Social Science and Medicine <http://linkinghub.elsevier.com/retrieve/pii/S0277953606001092>

Recommended Resources:

TBD