FA23: INTRO TO RESEARCH ETHICS: 22403

Course Syllabus

**INTRODUCTION TO RESEARCH ETHICS**

**G-504 (33207)/MHHS M-504 (33490)**

Course Director: Colin Halverson, PhD (chalver@iu.edu)

TA: Pierce Logan (pielogan@iu.edu)

Time: Thursdays 2-4:40 p.m.

Location: Nursing School NU221

Office Phone: 278-4038 (Bioethics)

Office hours: By appointment call 278-4038 (Bioethics)

Background

The course covers a range of key issues related to scientific integrity and the responsible conduct of research, including policies and procedures related to scientific misconduct, authorship and peer review, conflicts of interest, the use of humans and animals in biomedical research, international research and ethical issues related to genetic technology.  This course also satisfies NIH requirements for training in responsible conduct of research (RCR), which has been required for all pre-doctoral and postdoctoral trainees supported by training grants since 1996.

Purpose

The goals of this course are practical. While many people may think of broad, philosophical concerns when they hear the word “ethics,” our purpose is to learn about the regulations and standards of behavior that exist in contemporary healthcare research. We will develop skills for dealing with difficult, real-life problems that researchers face in their professional lives, and discover the groups and individuals available to help you when issues get thorny. There aren’t hard-and-fast rules to correspond to every unique and particular problem that researchers encounter in their daily work. Thus, in our course, students explore a wide range of topics in research ethics and learn to apply these insights creatively and expansively to their own lives. We will discuss how standards of conduct vary from community to community, discipline to discipline, and allowing students to cultivate an awareness of and dexterity with these different principles so that they can justify plans of action both to themselves and to others.

About the Course Director

Colin Halverson is an assistant professor of medicine and anthropology and IUPUI. He has a PhD in medical and linguistic anthropology from the University of Chicago and wrote his dissertation on ethics and communication issues in precision medicine at Mayo Clinic. He has completed two fellowships in medical ethics, including a postdoc at Vanderbilt University. His current research continues to center on ethics issues related to the return of results in medical genetics and the diagnostic odyssey experienced by patients with rare and undiagnosed diseases. His other academic interests include invertebrate research ethics, sociolinguistics and semiotics, and medical interpretation.

Course Goals

By the end of this course, students will be able to:

1. Demonstrate the skills needed to solve problems involving relevant topic areas of the responsible conduct of research.
2. Clearly articulate both verbally and in writing ethical and legally acceptable solutions to problems that arise in the conduct of science.
3. Propose and critically analyze solutions to problems in the context of relevant written codes and unwritten conventions.
4. Develop an interest in and a positive attitude toward lifelong learning in matters of scientific integrity and the responsible conduct of their chosen profession.

Course Objective

The primary objective of this course is to provide graduate students, postdoctoral students, and faculty with skills and resources key to their professional success.  These objectives include:

1. To refine and define expected standards of conduct.
2. To increase your confidence in dealing with difficult issues.
3. To meet current NIH requirements for formal training in research ethics.

Texts

Weekly readings will be provided via the Canvas course page. They are divided into required readings that are necessary for students to have read in order to participate in class and those that are optional for students with special interest in that week’s topic.

Exams

Both the midterm and the final exam will be take-home, open-book exams, which students will have 7 days to complete. The questions will be posted on Canvas and students will submit their answers on Canvas. The final exam is not cumulative; it will cover primarily the second half of the class. If you read this, please send Colin and Pierce a YouTube link to your favorite 90s music video for a bonus point.

If there is a problem handing in an exam on time, the TA or professor must be informed prior to the due date.  We know that you are all busy and will try to be flexible.  If, for some reason, you cannot hand in an assignment on time, without previous agreement to a later due date, one letter grade will be subtracted for each day that the assignment is late.

Plagiarism and Academic Dishonesty

Be sure you understand the school's policy on plagiarism (copying). Those guilty of plagiarism will be dealt with in accordance with the regulations spelled out in the code. Moreover, use of AI language models, even to assist in any assignments, is considered academic dishonestly, and you will receive no credit for assignments completed in this manner.

IRB Attendance

Attendance at one IRB meeting is required. The meeting will provide invaluable experience of a process in which you will engage during your research career. All meetings are now taking place over Zoom. Students need to schedule their visit date in advance with Megan Bettag (mbettag@iu.edu). Please email him (include TA: pielogan@iu.edu) with your requested date. Students will be required to sign and send back a Confidentiality Agreement with the correct date and time before the meeting. Students must enter the Zoom room a few minutes early so that they can be introduced.

Students are expected to take notes during the meeting and summarize the key issues in responsible conduct of research in a 1-page reflection paper about the ethical issues the IRB considers. This is due one week after the date of their IRB meeting and should be sent to both Colin and Pierce.

Grading

Class attendance and participation are key aspects of the course. Students are expected to complete required readings prior to class in order to be able to participate actively in class discussions. Participation will be counted as verbally responding to the presenter, asking questions or making comments, and/or engaging actively in group work. This requires also that students are present in a majority of class sessions. In order to receive an A in participation and attendance, students must attend at least 80% of class sessions and participate as described. In the event that a student is unable to attend a class, they must communicate this with the TA prior to the class session and arrange to make up the material on their own time.

Classes will meet in person. Students will be required to attend and participate in discussions as explained above.

Grading for the course is as follows:

1. **Attendance and Participation – 20%**Students are required to attend class and contribute meaningfully to discussion. In order to receive an A for Attendance and Participation, students must attend ≥80% of the classes and participate actively in the majority of these classes. Active participation includes speaking at least once during each session. Students are expected to enter the classroom prepared and on time and to stay for the entirety of the class. Students may request up to three excused absences in advance of the session; any sessions missed beyond those three will result in a docked grade and students will be required to write a response paper to the missed session.
2. **Writing assignments – 10%**
Students are required to attend one virtual IRB session. They must submit a one-page reflection paper on the experience, summarizing the cases, noting strengths and weaknesses of the studies they discussed.
3. **Midterm examination – 35%**Students must respond to all questions. In the “Short Answer” section, students may write two or three sentences. However, in the “Essay” section, responses must be much more extensive. In order to receive an A on these questions, students must respond in essay format: an introduction with thesis statement, body, and conclusion. They must use appropriate spelling and grammar. Students must reference readings and lectures from class as evidence for a clear argument, demonstrating an understanding of themes and concepts from the course. Any citations from outside the course reading list must be made available upon request for full credit. Use of false sources is a sign of the assistance of AI language models and their use is considered academic dishonesty.
*POSTED: October 5
DUE: October 12*
4. **Final examination – 35%**The final examination will take the same form as the midterm examination.
*POSTED: December 5
DUE: December 12*

Points will be added, and the grade will be calculated based on the following percentages:

|  |  |  |  |
| --- | --- | --- | --- |
| A+       | 97- 100% | C+  |  77-79%         |
| A   | 93-96%     | C   | 73-76% |
| A-   | 90-92%           | C-         | 70-72% |
| B+  | 87-89%     | D+  | 67-69% |
| B     | 83-86%    | D    | 63-66% |
| B-     | 80-82%  | D-   | 60-62%     |
|  |  | F  | ≤59% |

Syllabus Supplements

Additional information about IUPUI student policies and services is available on Canvas under the Campus Syllabus Supplement and SLA Syllabus Supplement tabs, which you will find at the bottom of this page after the course calendar. This information is important: these policies and services are intended to help students succeed at IUPUI and have the potential to affect a student’s grade in this course. Students are expected to read, and will be held accountable for, the information posted under the Syllabus Supplement. Information is available on the following topics:

CAMPUS SYLLABUS SUPPLEMENT

* IUPUI Policy on Disability Accommodations (AES Services)
* IUPUI Policy on Religious Holidays
* IUPUI Policy on Academic Integrity (Plagiarism)
* IUPUI Policy on Sexual Misconduct
* Education and Title VI
* Military Related Personnel Statement
* Two-Step Login (Duo)

SLA SYLLABUS SUPPLEMENT

* Withdrawal (including Administrative Withdrawal)
* Incompletes
* Honors credit
* Student Advocate Office
* Counseling and Psychological Services (CAPS)
* University Writing Center
* Diversity

Course Schedule\*

**\*Remember always to check the Module for the current week for updates to readings and case studies.\***

Week 1- August 24: Introduction and Principles

**TOPICS**: Human subjects, research misconduct, contemporary issues, the scientist in society

* Brief introduction of professor and students, overview of course – Colin Halverson
* Basic ethical principles and theories (Belmont Report and case) – Peter Schwartz

**REQUIRED READINGS:**

1. INTRODUCTION
	* 1. [None]
2. BASIC ETHICAL PRINCIPLES AND THEORIES
	* 1. To be handed out in class.

**OPTIONAL READINGS:**

1. INTRODUCTION
	1. [None]
2. BASIC ETHICAL PRINCIPLES AND THEORIES
	1. [Belmont Report(Links to an external site.)Links to an external site.](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html)

Week 2- August 31: History

**TOPICS**: Human subjects, research misconduct, contemporary issues, the scientist in society

*Introduction – Colin Halverson*

* History of Research with Human subjects – Steven Jay
* Cases in the History of Medical Ethics – Nic Oliver

**REQUIRED READINGS**:

1. HISTORY OF RESEARCH WITH HUMAN SUBJECTS
	1. Cavanaugh D, Walter Reed and the Scourge of Yellow Fever. UVA Today, Nov 13, 2019. [https://news.virginia.edu/content/walter-reed-and-scourge-yellow-fever(Links to an external site.)Links to an external site.](https://news.virginia.edu/content/walter-reed-and-scourge-yellow-fever)
2. CASES IN THE HISTORY OF ETHICS
	1. ASM Reading Pgs. 1206-1209

**OPTIONAL READINGS**:

1. HISTORY OF RESEARCH WITH HUMAN SUBJECTS
	1. Jay essay on Reed: “A Fever When Walter Came to Indianapolis”, Indianapolis Literary Club, Feb 3, 2014, [http://literaryclub.org/sitebuildercontent/sitebuilderfiles/sjjay.pdf(Links to an external site.)Links to an external site.](http://literaryclub.org/sitebuildercontent/sitebuilderfiles/sjjay.pdf)
	2. Kumar NK. Informed consent: Past and present. Perspect Clin Res 2013 Jan-Mar; 4(1):21-25. doi: 10.4103/2229-3485.106372. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601698/(Links to an external site.)Links to an external site.](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601698/)
	3. *Yellow Yack: How Yellow Fever Ravaged America and Walter Reed Discovered its deadly secrets*. Wiley & sons 2005
2. CASES IN THE HISTORY OF ETHICS
	1. Salk Field Trials
	2. Moore v. Regents

Week 3- September 7: Law, Policy, and Ethics

**TOPICS**: Human subjects, research misconduct, environmental/societal impacts, the scientist in society, contemporary issues

*Introduction – Colin Halverson*

* IU policies – Amy Waltz
* Law and Ethics – Jane Hartsock

**REQUIRED READINGS**:

1. IU POLICIES
	1. [None]
2. LAW AND ETHICS
	1. [None]

**OPTIONAL READINGS**:

1. IU POLICIES
	1. Federal Research Misconduct Policy: [https://ori.hhs.gov/federal-research-misconduct-policy(Links to an external site.)Links to an external site.](https://ori.hhs.gov/federal-research-misconduct-policy)
	2. IU Policy on Research Misconduct: [https://policies.iu.edu/policies/aca-30-research-misconduct/index.html(Links to an external site.)Links to an external site.](https://policies.iu.edu/policies/aca-30-research-misconduct/index.html)
2. LAW AND ETHICS
	1. [None]

Week 4- September 14:  Misconduct and Plagiarism

TOPICS: Human subjects, collaboration, contemporary issues, data management, research misconduct, the scientist in society

*Introduction – Colin Halverson*

* Misconduct – Sylk Sotto
* Plagiarism – Jane Hartsock

**REQUIRED READINGS**:

1. MISCONDUCT
	1. Goodyear “The stress test”
	2. [Timeline: When Bad Research Changes Public Health Strategy (Links to an external site.)Links to an external site.](https://www.the-scientist.com/infographics/timeline-when-bad-research-changes-public-health-strategy-67971)
2. PLAGIARISM
	1. ICMJE “[Defining the role of authors and contributors (Links to an external site.)Links to an external site.](http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)”
	2. McKarney “Peer-review techniques for novices"

**OPTIONAL READINGS**:

1. MISCONDUCT
	1. [Marcus et al “The top 10 retractions of 2019” (Links to an external site.)Links to an external site.](https://www.the-scientist.com/news-opinion/the-top-retractions-of-2019-66852)
	2. Fanelli “How many scientists fabricate and falsify research?” (2009)
	3. [8% of researchers in Dutch survey have falsified or fabricated data.(2021) (Links to an external site.)Links to an external site.](https://www.nature.com/articles/d41586-021-02035-2)
2. PLAGIARISM
	1. [None]

Week 5- September 21: Conflict of Interest & Collaboration

**TOPICS**: Conflict of interest, collaboration, the scientist in society

*Introduction – Colin Halverson*

* Collaboration with industry – Peter Schwartz
* Conflict of interest – Stephanie Jones

**REQUIRED READINGS**:

1. COLLABORATION WITH INDUSTRY
	1. Indiana University Conflict of Interest and Commitment Policy:[https://policies.iu.edu/policies/ua-17-conflicts-of-interest-commitment/index.html (Links to an external site.)Links to an external site.](https://policies.iu.edu/policies/ua-17-conflicts-of-interest-commitment/index.html)
	2. Indiana University School of Medicine “Industry Relations Policy.” Available at: [https://medicine.iu.edu/about/policies-guidelines/industry-relations/(Links to an external site.)Links to an external site.](https://medicine.iu.edu/about/policies-guidelines/industry-relations/)
	3. Rosenbaum, Lisa. Reconnecting the dots — reinterpreting industry–physician relations. NEJM 2015; 372(19): 1860-1864.
	4. Rosenbaum, Lisa. Understanding bias — the case for careful study. NEJM 2015; 372(20):1959- 1963.
	5. Steinbock R, Kassier JP, and Angell M, “Justifying conflicts of interest in medical journals: a very bad idea,” BMJ 2015; 350.
	6. Steinbock, Robert, “Chapter 10:  The Gelsinger Case,” pp. 110-120, from Emanuel, E. J., Grady, C. C., Crouch, R. A., Lie, R. K., Miller, F. G., & Wendler, D. D. (Eds.). (2008). The oxford textbook of clinical research ethics. ProQuest Ebook.
2. CONFLICT OF INTEREST
	1. [None]

**OPTIONAL READINGS**:

1. COLLABORATION WITH INDUSTRY
2. CONFLICT OF INTEREST
	1. [Indiana University conflict of interest and commitment policy(Links to an external site.)Links to an external site.](https://policies.iu.edu/policies/ua-17-conflicts-of-interest-commitment/index.html)
	2. [https://khn.org/news/article/national-academies-big-pharma-support-drug-waste-report/(Links to an external site.)Links to an external site.](https://khn.org/news/article/national-academies-big-pharma-support-drug-waste-report/)

Week 6- September 28: Alternative Medicine and the Role of the IRB

**TOPICS**: Conflict of interest, collaboration, peer review, data ownership, responsible authorship and publication, mentor/mentee relationship, research misconduct, the scientist in society

*Introduction – Colin Halverson*

* Researching Complementary and Alternative Medicine – Jennifer Stone
* Role of the IRB – Brian Stage

**REQUIRED READINGS**:

1. COMPLEMENTARY MEDICINE
	* 1. Read the abstract: [Integrative Medicine for Pain Management in Oncology: Society for Integrative Oncology–ASCO GuidelineLinks to an external site.](https://ascopubs.org/doi/pdf/10.1200/JCO.22.01357)
		2. [Covid-19: Vaccines journal retracts controversial paper after editorial board members quitLinks to an external site.](https://www.bmj.com/content/374/bmj.n1726)
		3. [Why do people believe medical misinformation?Links to an external site.](https://www.aamc.org/news/why-do-people-believe-medical-misinformation)
2. ROLE OF THE IRB
	1. Review the [Common Rule(Links to an external site.)Links to an external site.](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)
	2. Review the [Belmont Report(Links to an external site.)Links to an external site.](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html)

**OPTIONAL READINGS**:

1. COMPLEMENTARY MEDICINE
	1. [Integrative Medicine for Pain Management in Oncology: Society for Integrative Oncology–ASCO GuidelineLinks to an external site.](https://ascopubs.org/doi/pdf/10.1200/JCO.22.01357)
2. Torke AM, Alexander GC, Lantos J, Siegler M. The physician-surrogate relationship. Arch Intern Med. 2007 Jun 11;167(11):1117-21. doi: 10.1001/archinte.167.11.1117. PMID: 17563018.ROLE OF THE IRB
3. [FDA’s version of the Common Rule(Links to an external site.)Links to an external site.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)
4. [IU policies(Links to an external site.)Links to an external site.](https://research.iu.edu/policies/human-subjects-irb/index.html) (IRB review, informed consent, exempt research, recruitment, reportable events, adult individuals lacking consent capacity, children, pregnant women, prisoners, and students and use of education records)

Week 7- October 5: Children and Community Engagement

**\*TAKE-HOME MIDTERM EXAMINATION POSTED\***

TOPICS: Human subjects, the scientist in society, contemporary ethical issues, environmental/societal impacts, vulnerable populations, consent and assent

*Introduction – Colin Halverson*

* Children and adolescents in research – Mary Ott
* Community-engaged research – Mary Ott

**REQUIRED READINGS:**

1. CHILDREN
	1. Nuffield Council on Bioethics.  Be a Part of It: What Young People Think of Clinical Research: [https://www.youtube.com/watch?v=e2k6eA0dn9Q(Links to an external site.)Links to an external site.](https://www.youtube.com/watch?v=e2k6eA0dn9Q)
		1. What 2-3 things did you learn from the kids’ perspectives?  What was important to kids?  Who did they think should make research decisions?
	2. Hein IM, De Vries MC, Troost PW, Meynen G, Van Goudoever JB, Lindauer RJ. Informed consent instead of assent is appropriate in children from the age of twelve: Policy implications of new findings on children's competence to consent to clinical research. BMC Med Ethics. 2015;16(1):76.
		1. What are the implications of these data for our current approaches to consent? (Look at IU Research Policies on Research with Children)
	3. Sarah Jane Blakemore. TEDGlobal 2012 - The Mysterious Workings of the Adolescent Brain: [https://www.ted.com/talks/sarah\_jayne\_blakemore\_the\_mysterious\_workings\_of\_the\_adolescent\_brain?language=en (Links to an external site.)(Links to an external site.)Links to an external site.](https://www.ted.com/talks/sarah_jayne_blakemore_the_mysterious_workings_of_the_adolescent_brain?language=en)
		1. What are the implications of the social brain in adolescent capacity to consent to research?
	4. Child-centered Nuffield Council on Bioethics. Health research: making the right decision for me ([https://youtu.be/6yaKwLG\_vlE (Links to an external site.)(Links to an external site.)Links to an external site.](https://youtu.be/6yaKwLG_vlE)
		1. For this video created for children, ask yourself what they emphasize and why.
	5. Shenk, et al. (2014). Enrollment of Adolescents Aged 16–17 Years Old in Microbicide Trials: An Evidence-Based Approach. *Journal of Adolescent Health*. 54(6), 654- [https://reader.elsevier.com/reader/sd/pii/S1054139X14000597?token=E885CEFA75146D3FA2382D0C03BA4A75E3D4528887A1167E46908A1F1367069941B4083AE10534BD6E4324AF0ECFFF9A (Links to an external site.) (Links to an external site.)Links to an external site.](https://reader.elsevier.com/reader/sd/pii/S1054139X14000597?token=E885CEFA75146D3FA2382D0C03BA4A75E3D4528887A1167E46908A1F1367069941B4083AE10534BD6E4324AF0ECFFF9A)
	6. Ott, Mary A. (2014). Vulnerability in HIV Prevention Research with Adolescents, Reconsidered. *Journal of Adolescent Health*. 54(6), 629-630 [https://reader.elsevier.com/reader/sd/pii/S1054139X14001608?token=3F29F69B96D1D4445F210C09FB14C720193E42500C0A905D0F810B89AE388964AFE67AABF7C28D8C635DEF044E7B60D9 (Links to an external site.) (Links to an external site.)Links to an external site.](https://reader.elsevier.com/reader/sd/pii/S1054139X14001608?token=3F29F69B96D1D4445F210C09FB14C720193E42500C0A905D0F810B89AE388964AFE67AABF7C28D8C635DEF044E7B60D9)
		1. In what ways were these youth vulnerable?  How did the researchers address this vulnerability?
		2. Should the IRBs have allowed adolescents to provide their own consent?  Or should a parent or ombudsman help with the consent process?  Please consider arguments for and against minor self-consent.
	7. COMMUNITY-ENGAGED RESEARCH
		1. Nina Wallerstein.  CBPR – History, Principles and Definitions. [https://www.youtube.com/watch?v=8EcCjmZLp94(Links to an external site.)Links to an external site.](https://www.youtube.com/watch?v=8EcCjmZLp94)
		2. American Academy of Pediatrics Committee on Native American Child Health; American Academy of Pediatrics Committee on Community Health Services. (2004) Ethical considerations in research with socially identifiable populations. Pediatrics 113(1 Pt 1):148-51. PubMed PMID: 14702468.
		3. Making antenatal care youth-friendly: Starting from the Roots: Using Human Centered Design to Make an Adolescent Pregnancy Program Youth Friendly in Western Kenya.
			1. Who is the community?
			2. What are the benefits of this approach? The potential harms?
			3. What best practices in community ethics do you see?
			4. What else could they do?

**OPTIONAL READINGS:**

1. CHILDREN
	1. IU IRB Policies on research with children: ([https://research.iu.edu/policies/human-subjects-irb/children-in-research.html (Links to an external site.)(Links to an external site.)Links to an external site.](https://research.iu.edu/policies/human-subjects-irb/children-in-research.html))
	2. Santelli JS, Rogers A, Rosenfeld WD, DuRant RH, Dubler N, Morreale M, English A, Lyss S, Wimberly Y, Schissel A. (2003) Guidelines for adolescent health research: A position paper of the society for adolescent medicine.  J Adolesc Health 33:396-409. [Canvas Resources]
	3. Kipnis K. Seven vulnerabilities in the pediatric research subject. Theor Med Bioeth. 2003;24(2):107-20
2. COMMUNITY-ENGAGED RESEARCH
	1. Yale CARE: Community Alliance for Research and Engagement. Principles and Guidelines for Community-University Research Partnerships.
	2. McClosky, et al. Chapter 1: Community Engagement: Definitions and Organizing Concepts from the Literature. Centers for Disease Control and Prevention.  Last updated 2011.

**Unit 2 – Research with Protected Subjects**

Week 8- October 12: Return of Results, and Mock IRB

TOPICS: Human subjects, contemporary ethical issues, environmental/societal impacts, vulnerable populations, consent and assent, data management

*Introduction – Colin Halverson*

* Return of Results – Colin Halverson
* Mock IRB – Brian Stage

**\*TAKE-HOME MIDTERM SUBMISSION DUE\***

**REQUIRED READINGS**:

1. RETURN OF RESULTS
	1. [None]
2. MOCK IRB
	1. Amendment
	2. FYI UPIRTSO
	3. Noncompliance
	4. CC NS pain study
	5. NS tabled
	6. Renewals
	7. IU policies on IRB meetings and minutes
	8. IU policies on IRB membership
3. Review PowerPoint slides from Week

**OPTIONAL READINGS**:

1. RETURN OF RESULTS
	1. Makela NL, Birch PH, Friedman JM, Marra CA. (2009). Parental perceived value of a diagnosis for intellectual disability (ID): A qualitative comparison of families with and without a diagnosis for their child’s ID. Am J Med Genet Part A 149A:2393–2402.
	2. Clift (2015) Patients' views on incidental findings from clinical exome sequencing
2. MOCK IRB
	1. [None]

Week 9- October 19:  Informed Consent and Race in Research

TOPICS: Human subjects, the scientist in society, research misconduct

* Informed Consent – Colin Halverson
* Clinical Trials and Diversity – Lauren Nephew (hosted day before - Oct. 18th by Zoom)
* International research – Megan McHenry

**REQUIRED READINGS**:

1. INFORMED CONSENT
	1. [None]
2. DIVERSITY
	1. TBD
3. INTERNATIONAL RESEARCH
	1. [none]

**OPTIONAL READINGS**:

1. INFORMED CONSENT
	1. Faden et al. (2014). Informed consent, comparative effectiveness, and learning health care. NEJM, 370, 766-768.
	2. Grady, C. (2015). Enduring and emerging challenges of informed consent. NEJM, 372, 855-862.
2. DIVERSITY

1. Improving Representation in Clinical Trials and Research (chapters 2 and 5)

2. Lancet Article

3. INTERNATIONAL RESEARCH

* 1. EJ Emanuel (2004) “What makes clinical research in developing countries ethical?”
	2. [to skim:] [International ethical guidelines for health-related research involving humans(Links to an external site.)Links to an external site.](https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf)
	3. [Council for International Organizations of Medical Sciences Guidelines(Links to an external site.)Links to an external site.](https://cioms.ch/wp-content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf)

Week 10- October 26: Animals in Research

TOPICS: Animals in research, the scientist in society

* Research with Invertebrates – Colin Halverson
* Research with Nonhuman Vertebrates – Matthew Allen

**REQUIRED READINGS**:

1. INVERTEBRATES
	1. [none]
2. NONHUMAN VERTEBRATES
	1. [none]

**OPTIONAL READINGS**:

1. INVERTEBRATES
	1. Friedersdorf, C. (2013). Consider the Lobster Claw: Why a twist on an arcade classis delights and disturbs us. The Atlantic. [https://www.theatlantic.com/technology/archive/2013/03/consider-the-lobster-claw-why-a-twist-on-an-arcade-classic-delights-and-disturbs-us/273977/(Links to an external site.)Links to an external site.](https://www.theatlantic.com/technology/archive/2013/03/consider-the-lobster-claw-why-a-twist-on-an-arcade-classic-delights-and-disturbs-us/273977/)
	2. Elwood - 2012 - Evidence for pain in decapod crustaceans
2. NONHUMAN VERTEBRATES
	1. [none]

Week 11- November 2: Science and Society, and Self-Experimentation

**TOPICS**: Human subjects, collaboration, data management, research misconduct, the scientist in society

*Introduction – Colin Halverson*

* Return of Results - Colin Halverson
* Self-experimentation – Tom Doyle

**REQUIRED READINGS:**

1. Return of Results
	1. None
2. SELF-EXPERIMENTATION
	1. [Review of Scientific Self-Experimentation:Links to an external site.](https://www.liebertpub.com/doi/epdf/10.1089/rej.2018.2059)

**OPTIONAL READINGS:**

1. Return of Results

       1.  None

2. SELF-EXPERIMENTATION

* 1. None

Week 12- November 9: Incarcerated Persons and International Research

TOPICS: Human subjects, the scientist in society, contemporary issues, environmental/societal impacts, responsible authorship and publication

*Introduction – Colin Halverson*

* Research with incarcerated persons – Danielle Giltner
* Science and Society – Meg Gaffney

**REQUIRED READINGS:**

1. INCARCERATED PERSONS
	1. [Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects(Links to an external site.)Links to an external site.](https://www.ecfr.gov/cgi-bin/text-idx?SID=608364068aac51ec4b8f6d83064b92df&mc=true&node=sp45.1.46.c&rgn=div6)
2. SCIENCE AND SOCIETY
	1. Didier “Science and society”
	2. Lucas “The responsibility of scientists to society”
	3. Godwin “We will get regular body upgrades"
	4. NPR Article

**OPTIONAL READINGS:**

1. INCARCERATED PERSONS
	1. [none]
2. SCIENCE AND SOCIETY
	1. None

**Unit 3 – Research and Society**

Week 13- November 16: Public Health and Women in Research

TOPICS: Collaboration, the scientist in society, contemporary issues, environmental/societal impacts, human subjects, cognitive bias, public media

*Introduction – Colin Halverson*

* Public Health – Amy Martin
* Women in Research – Christian Kautzman

**REQUIRED READINGS:**

1. PUBLIC HEALTH
	1. [None]
2. WOMEN IN RESEARCH
	1. [https://www.openaccessjournals.com/articles/from-no-to-yes-the-history-and-ethics-of-including-pregnant-women-in-clinical-trials.pdf(Links to an external site.)Links to an external site.](https://www.openaccessjournals.com/articles/from-no-to-yes-the-history-and-ethics-of-including-pregnant-women-in-clinical-trials.pdf)

**OPTIONAL READINGS:**

1. PUBLIC HEALTH
	1. IU HRPP policy “Individuals lacking capacity”
	2. [Research involving individuals with questionable capacity to consent (Links to an external site.)Links to an external site.](https://grants.nih.gov/grants/policy/questionablecapacity.htm)
2. WOMEN IN RESEARCH
	1. [None]

*Week 14- November 23 THANKSGIVING- NO CLASS*

**Unit 4 – Data**

Week 15- November 30: Big Data & Learning Healthcare Systems

TOPICS: Human subjects, collaboration, data management, contemporary issues, the scientist in society, data ownership, privacy

*Introduction – TBD*

* Big data – Jane Hartsock
* Learning Healthcare Systems – Peter Schwartz

**REQUIRED READINGS:**

1. BIG DATA
	1. Harrell et al “Biobanking research and privacy laws in the US”
	2. Henderson et al “Characterizing biobank organizations in the US”
	3. McGregor et al “Inclusion of pediatric samples in an opt-out biorepository"
2. LEARNING HEALTHCARE SYSTEMS
	1. Faden, R., Beauchamp, T., Kass, N. (2014). Informed Consent, Comparative Effectiveness, and Learning Health Care. *The New England Journal of Medicine*. 370(8), 766-768.
	2. Faden, R., et al. (2013). An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics. *Ethical Oversight of Learning Health Care Systems, Hastings Center Report Special Report*43(1), S16-S27. DOI: 10.1002/hast.134

**OPTIONAL READINGS:**

1. BIG DATA
	* 1. [None]
2. LEARNING HEALTHCARE SYSTEMS
3. [None]

**\*TAKE-HOME FINAL EXAMINATION POSTED TUESDAY, DECEMBER 5\***

Week 16- December 7: Bias in Machine Learning

TOPICS: Data management, the scientist in society

*Introduction – Colin Halverson*

* Bias and the Ethics of Machine Learning – Erika Cheng

*Coda – Colin Halverson*

**REQUIRED READINGS:**

1. BIAS AND MACHINE LEARNING
	* 1. [None]

**OPTIONAL READINGS:**

1. BIAS AND MACHINE LEARNING
	* 1. [None]

**\*TAKE-HOME FINAL EXAMINATION DUE TUESDAY, DECEMBER 12\***