FA25: INTRO TO RESEARCH ETHICS: 21060/21223

Course Syllabus

INTRODUCTION TO RESEARCH ETHICS

G-504 (21060)/MHHS M-504 (21223)

Course Director: Colin Halverson, PhD (chalver@iu.edu) TA: Seamus Donahue (seadonah@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 allow 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 IUI. 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 a YouTube link to your favorite music video from between 2000-2009 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 dishonesty, and you will receive no credit for assignments completed in this manner. If AI use is suspected, we reserve the right to require a face-to-face discussion in which the student will be asked to explain the submission, its argument, and its supporting evidence.

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 Danielle Redkey (dredkey@iu.edu). Please email her (include TA: seadonah@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 the TA.

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:

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.

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.

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 2
DUE: October 9

Final examination – 35%
The final examination will take the same form as the midterm examination.
POSTED: December 9
DUE: December 16

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 28: Introduction and Principles

TOPICS: Research misconduct, scientific rigor, scientist in society, contemporary ethics issues

- 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. Evans, Parexel Misled Sick People (To be handed out in class)

OPTIONAL READINGS:

1. INTRODUCTION
    1. [None]

2. BASIC ETHICAL PRINCIPLES AND THEORIES
    1. Belmont ReportLinks to an external site.

Week 2- September 4: Law, Policy, and Ethics

TOPICS: Research misconduct, data management, civility and harassment, scientist in society, contemporary ethics issues

Introduction – Colin Halverson

- IU Process and Misconduct – 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. Links to an external site.Links to an external site.IU Policy on Research Misconduct: https://policies.iu.edu/policies/aca-30-research-misconduct/index.htmlLinks to an external site.
2. LAW AND ETHICS
    1. [None]

Week 3- September 11: Informed consent and the IRB

TOPICS: Research misconduct, authorship, peer review, mentor/mentee relationship, contemporary ethics issues

Introduction – Colin Halverson

- Informed consent – Colin Halverson
- Role of the IRB – Brian Stage

REQUIRED READINGS:

1. INFORMED CONSENT

1. [none]

1. ROLE OF THE IRB

    1. Review the Common RuleLinks to an external site.

    2. Review the Belmont ReportLinks to an external site.

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.

3. IRB

4. [None]

Week 4- September 18: History of Regulations & Historical Cases

TOPICS: Conflict of interest, collaborative science, scientist in society, contemporary ethics issues, research misconduct, challenges of informed consent

Introduction – Colin Halverson

- History of Regulations – Elizabeth Nelson
- Historical Cases – Nic Oliver

REQUIRED READINGS:

1. HISTORY OF REGULATIONS

    1. Rice TW. The historical, ethical, and legal background of human-subjects research. Respir Care. 2008 Oct;53(10):1325-9. PMID: 18811995.Links to an external site.

2. HISTORICAL CASES

1. Numbers RL. William Beaumont and the ethics of human experimentation. J Hist Biol. 1979 Spring;12(1):113-35. doi: 10.1007/BF00128137. PMID: 11645818. [PAGES 128-132 OPTIONAL]

OPTIONAL READINGS:

1. HISTORY OF REGULATIONS
    1. [None]
2. HISTORICAL CASES
    1. [None]

Week 5- September 25: Conflict of Interest and Plagiarism

TOPICS: Data management, scientific rigor, social and environmental impact

Introduction – Colin Halverson

- Conflict of Interest – Stephanie Jones
- Plagiarism – Jane Hartsock

REQUIRED READINGS:

1. CONFLICT OF INTEREST
    1. Indiana University conflict of interest and commitment policyLinks to an external site.
1.
    1. National Academies' Report Took Pharma-Friendly Stance After Millions in Gifts From DrugmakersLinks to an external site.
1. PLAGIARISM
    1. ICMJE "Defining the role of authors and contributors"Links to an external site.
    2. McKarney "Peer-review techniques for novices"

OPTIONAL READINGS:

1. CONFLICT OF INTEREST
    1. [None]
2. PLAGIARISM

1. [None]

Week 6- October 2: Return of Results and Mock IRB

TAKE-HOME MIDTERM EXAMINATION POSTED

TOPICS: Social and environmental impact, contemporary ethics issues

Introduction – Colin Halverson

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

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
    9. Review PowerPoint slides from Week 3

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

1. MOCK IRB
    1. [None]

Unit 2 – Research with Protected Subjects

Week 7- October 9: Collaboration with Industry & Clinical Trials and Diversity

TOPICS: Collaborative science, scientists in society, social and environmental impact, contemporary ethics issues

Introduction – Colin Halverson

- Collaboration with Industry – Peter Schwartz
- Clinical Trials and Diversity – Lauren Nephew

TAKE-HOME MIDTERM SUBMISSION DUE

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.
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.
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.

1. CLINICAL TRIALS AND DIVERSITY

1. Birhiray MN, Birhiray RE. Practical strategies for creating diversity, equity, inclusion, and access in cancer clinical research: DRIVE. Blood Adv. 2023 Apr 25;7(8):1507-1512. doi: 10.1182/bloodadvances.2022008220. PMID: 36005840; PMCID: PMC10139854.Links to an external site.

2. Nephew LD. Accountability in clinical trial diversity: The buck stops where? EClinicalMedicine. 2021 May 23;36:100906. doi: 10.1016/j.eclinm.2021.100906. PMID: 34041464; PMCID: PMC8144740.Links to an external site.

OPTIONAL READINGS:

1. COLLABORATION WITH INDUSTRY
    1. [None]

1. CLINICAL TRIALS AND DIVERSITY

1. Food and Drug Administration, Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry (2020)Links to an external site.

Week 8- October 16: Community-Engaged Research & Research with women, pregnant persons, and sexual/reproductive issues

TOPICS: Research misconduct, social and environmental impact, contemporary ethics issues

- Community-Engaged Research – Jimmy Carlucci
- Research with women, pregnant persons, and sexual/reproductive issues – Tavonna Kako

REQUIRED READINGS:

1. COMMUNITY-ENGAGED RESEARCH

1. Carlucci JG, Huntington T, Technau KG, Yotebieng M, Leroy V, Anderson K, Amorissani-Folquet M, Wools-Kaloustian K, Edmonds A. High Prevalence of Unconfirmed Positive HIV PCR Test Results among African Infants with HIV Exposure in the International epidemiology Databases to Evaluate AIDS (IeDEA) Consortium. Clin Infect Dis. 2024 May 14:ciae251. doi: 10.1093/cid/ciae251. Epub ahead of print. PMID: 38742844.

2. Nightingale KJ, Lowenthal ED, Gross MS. When Black and White Turns Gray: Navigating the Ethical Challenges of Implementing Shared Infant Feeding Decisions for Persons Living with Human Immunodeficiency Virus in the United States. Clinics in Perinatology. 2024. ISSN 0095-5108. doi: 10.1016/j.clp.2024.08.002.

1. RESEARCH WITH WOMEN
    1. Ethical Considerations for Increasing Inclusivity in Research Participants

OPTIONAL READINGS:

1. COMMUNITY-ENGAGED RESEARCH

1. WHO Guidelines on HIV Diagnosis and Antiretroviral Use in HIV-Exposed Infants [**ATTN to SECTION 3.1**] (https://iris.who.int/bitstream/handle/10665/273155/WHO-CDS-HIV-18.17-eng.pdf?sequence=1)Links to an external site.
2. DHHS Guidelines on Infant Feeding for Individuals With HIV in the United States (https://clinicalinfo.hiv.gov/en/guidelines/perinatal/infant-feeding-individuals-hiv-united-states?view=fullLinks to an external site.

1. RESEARCH WITH WOMEN
    1. [None]

Week 9- October 23: Animals in Research and Animal Ethics

TOPICS: Research misconduct, biosafety and animal research subjects, social and environmental impact, scientific rigor, scientists in society

- Animals and IACUC – Adrian Oblak
- Animal Ethics – Colin Halverson

REQUIRED READINGS:

1. ANIMALS AND IACUC
    1. NIH "Medical Research with Animals"
2. ANIMAL ETHICS
    1. TBD

OPTIONAL READINGS:

1. ANIMALS AND IACUC

1. [None]

2. ANIMAL ETHICS

    1. Friedersdorf, C. (2013). Consider the Lobster Claw: Why a twist on an arcade classis delights and disturbs us. Links to an external site.

2. Elwood - 2012 - Evidence for pain in decapod crustaceans

Week 10- Oct 30: Science & Society and Zombies

TOPICS: Research misconduct, scientific rigor, scientist in society, contemporary ethics issues

Introduction – Colin Halverson

- Science and Society – Meg Gaffney
- Zombies – Colin Halverson

REQUIRED READINGS:

1. SCIENCE AND SOCIETY

    1. Didier "Science and society"
    2. Lucas "The responsibility of scientists to society"
    3. Godwin "We will get regular body upgrades"

1. ZOMBIES

    1. [None]

OPTIONAL READINGS:

1. SCIENCE AND SOCIETY

    1. [None]

1. ZOMBIES

    1. [None]

Week 11- November 6: Incarcerated Persons and Pediatric Ethics

TOPICS: Research misconduct, scientific rigor, collaborative science, scientist in society, social and environmental impact

Introduction – Colin Halverson

- Pediatric Ethics – Brian Leland

REQUIRED READINGS:

1. PEDIATRIC ETHICS
    1. Gillam L. Fifty years of pediatric ethics. *J Paediatr Child Health*. 2015;51(1):8-11. doi:10.1111/jpc.12793Links to an external site.

OPTIONAL READINGS:

1. PEDIATRIC ETHICS
    1. [none]

Unit 3 – Research and Society

Week 12- November 13: Rare Disease

TOPICS: Data management, scientific rigor, collaborative science, scientist in society, social and environmental impact, contemporary ethics issues

Introduction – Colin Halverson

- Rare Disease – Tom Doyle
- Research with Incarcerated Persons - Ryan Ballard

REQUIRED READINGS:

1. RARE DISEASE RESEARCH
    1. [None]

OPTIONAL READINGS:

1. RARE DISEASE RESEARCH
    1. [None]

REQUIRED READINGS:

1. RESEARCH WITH INCARCERATED PERSONS
    1. [None]

OPTIONAL READINGS:

1. RESEARCH WITH INCARCERATED PERSONS

1. Common Rule Subpart C regulationsLinks to an external site.

Unit 4 – Data

Week 13- November 20: Big Data & Learning Healthcare Systems

TOPICS: Data management, scientific rigor, collaborative science, social and environmental impact, contemporary ethics issues

Introduction – Colin Halverson

- 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
    1. [None]

Week 14- November 27 THANKSGIVING- NO CLASS

Week 15- December 4: Bias in Machine Learning & Integrative Medicine

TOPICS: Data management, scientific rigor, contemporary ethics issues

Introduction – Colin Halverson

- Bias and the Ethics of Machine Learning – Erika Cheng

REQUIRED READINGS:

1. BIAS AND MACHINE LEARNING
    1. [None]

OPTIONAL READINGS:

1. BIAS AND MACHINE LEARNING
    1. [None]

Week 16- December 11: Ethics of Whistleblowing

Introduction – Colin Halverson

- Ethics of Whistleblowing – Colin Halverson

REQUIRED READINGS:

1. ETHICS OF WHISTLEBLOWING
    1. TBD

OPTIONAL READINGS:

1. ETHICS OF WHISTLEBLOWING
    1. TBD

TAKE-HOME FINAL EXAMINATION POSTED TUESDAY, DECEMBER 9

TAKE-HOME FINAL EXAMINATION DUE TUESDAY, DECEMBER 16