

**PHIL 20413: Research Ethics**

***Call me, beep me, if ya wanna reach me:***

Instructor: [Isabel Canfield](https://philosophy.nd.edu/people/graduate-students/isabel-canfield/)

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Office: 400 Malloy Hall

Classroom: DeBartolo Hall 223

Course Hours: MW 12:30 – 1:45

Office Hours: In person: Wednesdays 2:30 – 3:30 & By appointment

Zoom: By appointment

This course examines the ethical underpinnings of responsible human subjects research in both medicine and technology. We will utilize philosophical concepts and methods to wrestle with both contemporary cases and historical events that have shaped modern research ethics. To grapple with practical problems, we will consider and evaluate both well-established ethical research principles along with less common ethical frameworks. We will consider materials provided by philosophers, practitioners, and narratives that center research participants. Topics we will cover include: pediatric research, global research, research with vulnerable populations, pandemic research, and AI research.

**Course Format:** Class sessions will incorporate lectures, discussions, and case studies. Course discussions and writing assignments will be an opportunity for you to clarify the issues addressed in lectures and readings and to practice practical and critical thinking skills that will be required for your final project. This sort of course works best if there is considerable student participation and there are numerous ways for students to actively contribute to the class.

**Grading:**

30% Midterm Paper

15% Participation

15% Discussion Papers

40% Final Project

**Assignments and Assessments:**

**Participation:** I am looking for consistent contributions that productively move the group discussion forward and show engagement with reading assignments, lecture material and/or any case studies. Your grade is based on quality of your participation throughout the semester. Please note, it is difficult to productively contribute to the group without attending class. Whenever possible, let the instructor know if you will not be attending a class session.

*Pre-Class Emailed Comments (Optional):*

* I know that students differ in how they prefer to participate. To acknowledge different learning styles, I welcome emails from students with comments or questions on the week’s readings and lectures by 10pm on Sunday and Tuesday nights.
* These emails should be the sort of comments or questions that I could reference in the discussion. You may also be asked to read or expand on these comments in class.
* This is an optional form of participation. You can still receive full credit for participation without commenting ahead of discussion sections. Note that emailed comments do not replace attendance and you must be present for these emailed comments to factor into your participation grade.

**Discussion Papers:** Twice throughout the semester, from weeks 3-11, students will write a 500-word reflection on the class discussion. In these short discussion papers, you might present some light research answering a lingering question raised in the group discussion, comment on what you’ve learned, or pose a new question. These discussion papers must be posted to the course discussion board on Friday before 10pm. At least three times throughout the semester, you will comment on another student’s discussion post before the next week’s classes begin.

**Midterm Paper:** This paper is your main opportunity to work on your writing in this course. There are a few components of the paper assignment that will help you develop your writing along the way. All students are required to meet with the instructor to discuss paper outlines. Students will also trade paper drafts with a partner and give comments. These peer review comments will be worth 15% of the total midterm paper grade. The final version of the paper will be 2,500 words.

**Final IRB Project**: In lieu of a traditional final exam, students will participate in a mock institutional review board. This project includes both an oral and a written component.

**Resources:**

**Writing Resources:** Writing Center tutors work with writers during all stages of the writing process — from understanding an assignment and developing a thesis to organizing the paper and revising the final product**.** I strongly encourage all students in this class to utilize the Center. Visit:[**https://writing.nd.edu/writing-center/**](https://writing.nd.edu/writing-center/)

**Accessibility:** Any student who has a documented disability and is registered with Sara Bea Accessibility Services should speak with the instructor as soon as possible regarding accommodations. Students who have questions about Sara Bea Accessibility Services or who have, or think they may have, a disability are invited to contact Sara Bea Accessibility Services for a confidential discussion by emailing at sarabeacenter@nd.edu or by phone at 574-631-7157.

**Mental Health Resources:** Care and Wellness Consultants at Notre Dame provide support and resources to students who are experiencing stressful or difficult situations that may be interfering with academic progress. Through Care and Wellness Consultants, students can be referred to The University Counseling Center (for cost-free and confidential psychological and psychiatric services from licensed professionals), University Health Services (which provides primary care, psychiatric services, case management, and a pharmacy), and The McDonald Center for Student Well Being (for problems with sleep, stress, and substance use). Visit: [care.nd.edu](http://care.nd.edu/)

**Other Course Information:**

**Honor Code:** Notre Dame students are expected to abide by the Academic Code of Honor. All students should familiarize themselves with the honor code. All graded work for this class should be your own and you must clearly acknowledge the sources you have used in written work. We will discuss the use of AI technology before your first paper; all student writing is to be completed without the use of AI unless otherwise stated. If you have questions, ask me!

**Privacy**: As a group, we will be exploring and thinking through topics that may be emotionally and/or politically charged. Ideally, this class should be a place to begin and continue thinking about these topics together. To do this, I hope we can cultivate a community that encourages the sharing of nascent and sensitive ideas. Please do not record discussions or share class materials without explicit consent from your classmates and the instructor.

**Learning Environment**: I am committed to and strive to maintain a positive learning environment based on open communication, mutual respect, and non-discrimination. In this class we will not discriminate on the basis of race, gender, sex, age, economic class, disability, veteran status, religion, sexual orientation, color, or national origin. Any suggestions as to how to further such a positive and open environment will be appreciated and given serious consideration.

**Zoom**: In the event of an emergency situation or disruption to normal campus operations (weather, health emergency, etc.), our class will likely shift to remote instruction using Zoom, as well as other synchronous and asynchronous course materials. Class sessions will not typically be available via Zoom. Any changes will be communicated through email and/or Canvas.

***Class Schedule and Topics***

***Module One: Background: Ethics, History, & Guidelines/Regulations***

***Week 1***

*Introduction to the course*

Wednesday, August 23: Introduction

***Week 2***

*Introduction to normative ethical theories and research ethics themes*

Monday, August 28: Ethical Theories: An Overview

Wednesday, August 30:Research Ethics Themes as seen in Flowers for Algernon

*Reading: 1) Keyes, Daniel (1959). Flowers for Algernon*

*2) Emanuel, E. J., Wendler, D., & Grady, C. (2000). What Makes Clinical*

*Research Ethical?*

***Week 3***

*Basic research ethics principles and history*

Monday, September 4: Research Ethics: A Partial History

*Reading: 1) Emanuel, Ezekiel J, and others (eds), (2008) The Oxford Textbook of Clinical Research Ethics, Ch.10: A Selected History of Research With Humans.*

*Pick any 3 of the 10 cases to read.*

Wednesday, September 6: Research Ethics Principlism and Where We Are Now

*Reading: 1) Beecher, Henry K. (1966). Ethics and Clinical Research*

*2) Jones, D. S., Grady, C., & Lederer, S. E. (2016). “Ethics and Clinical Research” —*

*The 50th Anniversary of Beecher’s Bombshell.*

*3) The Nuremberg Code*

*4) WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving*

*Human Subjects*

*5) Nelson, Daniel K., and David Forster, 'Guidelines, Codes, and Regulations', in Ana S.*

*Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics*

***Module 2: Established Problems in Research Ethics***

***Week 4***

*Conducting research with vulnerable populations*

Monday, September 11: Common Rule & Vulnerable Populations

*Reading: 1) Macklin, Ruth. (2003). Bioethics, Vulnerability, and Protection.*

*2) Hurst, Samia A. (2008).* *Vulnerability in Research and Health Care; Describing the*

*Elephant in the Room?*

*Optional further reading:*

*Christopher, Paul P., 'Vulnerability in Research with Prisoners', in Ana S. Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics*

Wednesday, September 13: Military Research Ethics

*Reading: 1) McManus, John, et al. (2005) Informed Consent and Ethical Issues in Military*

*Medical Research.*

*2) Parasidis, Efthimios. (2015) Emerging Military Technologies: Balancing Medical*

*Ethics and National Security*

*Optional further reading:*

*Gross, Michael L., 'Military Medical Research Ethics: Investigational Drugs, Clinical Trials, and Enhancement', in Ana S. Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics*

***Week 5***

*Compensation, undue inducement, and benefits of research*

Monday, September 18: Potential Benefits of Research Participation

*Reading: REQUIRED:*

*1) Phillips, Trisha, 'Coercion, Exploitation, and Undue Inducement', in*

*Ana S. Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics*

*THEN PICK EITHER:*

1. Henrietta Lacks:
   1. Watch The Immortal Life of Henrietta Lacks an HBO film produced by Oprah. Available via Hesburgh online*.*
   2. *Optional Further Reading: Wertheimer, Alan (2010) Should We Worry about Money?*

*OR:*

1. Guinea-Pigging:
   1. *Elliott, Carl (2007), Guinea-Pigging*
   2. *Abadie, Roberto & Elliott,Carl (2008). Exploiting a Research Underclass in Phase 1 Clinical Trials*

Wednesday, September 20: Compensation & Undue Inducement

*Reading: 1) Specter, Michael (2021). How ACT UP Changed America*

*2) Anderson, Emily E., and Ryan Spellecy, 'Research That Engages Community and Patient Partners', in Ana S. Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics*

***Week 6****:*

*AI research ethics and midterm paper assignment*

Monday, September 25: ChatGPT and Midterm Paper Assignment

*Reading: 1) Denton, Emily et al. (2020) Bringing the People Back In: Contesting Benchmark*

*Machine Learning Datasets*

*Optional further reading:*

1. *Birhane,Abeba (2021) Algorithmic injustice: a relational ethics approach*
2. *Bender, Emily et al. (2021) On the Dangers of Stochastic Parrots: Can Language Models Be Too Big?*

Wednesday, September 27: AI and Moral Patiency

*Reading: 1) Sullins, John P. (2006) When is a Robot a Moral Agent?*

***Week 7***

NOTE: All students are required to meet with instructor on midterm paper outlines this week

*Pediatric Ethics*

Monday, October 2: Consent vs. Assent: Children, Parents, and Researchers

*Reading: 1) Ramsey, Paul (1976). The Enforcement of Morals: Nontherapeutic Research on*

*Children*

*2) Shah, Seema K., 'The Ethics of Pediatric Research', in Ana S. Iltis, and Douglas*

*MacKay (eds), The Oxford Handbook of Research Ethics*

Wednesday, October 4: Visiting Speaker – Jill Robinson (BCM Center for Ethics & Health Policy)

*Reading: 1) Robinson, Jill et al. (2014) Pediatric Data Sharing in Genomic Research: Attitudes*

*and Preferences of Parents*

*SEND QUESTIONS FOR JILL TO INSTRUCTOR BY MONDAY at 11:59*

Paper drafts due to your peer commentator today by 12:30

***Week 8***

Case 4: *Social science research*

Monday, October 9: Human Subjects Research from Afar

*Reading: 1) DuBois, James, and Emily Lisi, 'Current Issues in Behavioral and Social*

*Science Research Ethics', in Ana S. Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics*

Wednesday, October 11: Peer Feedback on papers -- NO CLASS

Meet and Exchange peer comments on midterm papers today by 12:30

***FALL BREAK***

***Week 9***

*International research ethics*

Monday, October 23: Justice in International Research and Historical Failures

*Reading: 1) Hawkins, Jennifer S. and Emanuel, Ezekiel J. (2008) Introduction: Why*

*Exploitation?". Exploitation and Developing Countries: The Ethics of Clinical Research.*

*AND*

*2) Case Primary Source Materials:*

1. *Angell, Marcia (1997) The Ethics of Clinical Research in the Third World.*
2. *French, Howard, W. (1997) AIDS Research in Africa: Juggling Risks and Hopes.*

*Optional further reading:*

1. *Kukla, Rebecca (2007) Resituating the Principle of Equipoise: Justice and Access to Care in Non-Ideal Conditions.*
2. *Charani, Esmita (2023) The use of imagery in global health: an analysis of infectious disease documents and a framework to guide practice.*

Midterm paper due today by 12:30

Wednesday, October 25: Collaboration and Limits of IRBs

*Reading: 1) Emanuel, Ezekiel J. et al. (2004) What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research*

*AND*

*2) Alex John London on International Research & Justice:*

1. *Watch this 20minute video of Professor Alex John London lecture on international research ethics (watch from 3:05 – 24:55):* [*https://youtu.be/dAyVHb5QKPE?si=oh\_CVSB4k6b20FVn&t=183*](https://youtu.be/dAyVHb5QKPE?si=oh_CVSB4k6b20FVn&t=183)

*OR*

1. *London, Alex John (2022). Justice and the Human Development Approach to International Research: For the Common Good. Alex John London, Oxford University Press.*

*Optional further reading:*

1. *Pratt, Bridget, 'International Health Research Ethics', in Ana S. Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics*
2. *Daniel Z Hodson, et al. (2023). Striving towards true equity in global health: A checklist for bilateral research partnerships.*

***Module Three: In-the-news-cases & Application***

***Week 10***

*Pandemic ethics: Covid-19 case study*

Monday, November 6: Adjusting Research Standards

*Reading: 1) Savulescu, Julian (2020) Is it right to cut corners in the search for a coronavirus*

*cure?*

*2) Eyal, Nir, 'Research during Pandemics and Epidemics', in Ana S. Iltis, and Douglas*

*MacKay (eds), The Oxford Handbook of Research Ethics*

Wednesday, November 8: Challenge Studies In-Class Debate

*Reading: 1) PRO: Eyal, Nir et al. (2020) Human Challenge Studies to Accelerate Coronavirus*

*Vaccine Licensure.*

*2) CON: Kahn, Jeff P. (2020) For now, it’s unethical to use human challenge studies*

*for SARS-CoV-2 vaccine development*

***Week 11***

*New and emerging genomic technology*

Monday, November 6: Genetic Exceptionalism and Biobanks

*Reading: 1) Garrison, Nanibaa’ A.**(2019). Genomic Contextualism: Shifting the Rhetoric*

*of Genetic Exceptionalism*

*Optional further reading:*

1. *Parker, Lisa S., 'Genetic and Genomic Research', in Ana S. Iltis, and Douglas MacKay (eds), The Oxford Handbook of Research Ethics.*
2. *Murray, Thomas, H. (2019) Is Genetic Exceptionalism Past Its Sell-By Date? On Genomic Diaries, Context, and Content.*
3. *McGuire, Amy et al. (2020) The road ahead in genetics and genomics.*

Wednesday, November 8: CRISPR Technology

*Reading: PICK EITHER:*

1. *Human Gene Editing: Goodyear, Dana (2023) The Transformative, Alarming Power of Gene Editing.*

*OR:*

1. Gene Drives*: Specter, Michael (2016) Rewriting the Code of Life.*

*Optional further reading:*

1. *Guerrini, Christi, J. et al. (2019) DIY CRISPR.*
2. *Yin, Steph (2016) Is DIY Kitchen CRISPR A Class Issue?*

***Week 12***

*In-the-News-Cases*

Monday, November 13: Psychedelics and Research Ethics

*Reading: 1) Pollan, Michael (2018) Prologue: How to Change Your Mind: What the New*

*Science of Psychedelics Teaches Us About Consciousness, Dying, Addiction, Depression, and Transcendence*

*Optional further reading:*

1. *Pollan, Michael (2015) The Trip Treatment*
2. *Edward Jacobs, David Bryce Yaden & Brian D. Earp (2023)*

*Toward a Broader Psychedelic Bioethics*

Wednesday, November 15: Environmental research ethics

***Module 4: Mock IRB Project***

***Week 13***

*Discussion of IRBs*

Monday: Practice Case: Research on the newly dead

Wednesday: Thanksgiving Break – NO CLASS

***Week 14***

*Student IRB research presentations:*

Monday, November 27: Topic 1: Placebo/Sham Surgery

Wednesday, November 29: Topic 2: Adaptive Deep Brain Stimulation

***Week 15***

*Student IRB research presentations:*

Monday, December 4: Topic 2: Adaptive Deep Brain Stimulation

Wednesday, December 6 (Last Day of Class): Topic 1: Placebo/Sham Surgery

***Week 16***

*Final exam period*

Tuesday, December 12: Final Exam Period

Reflection paper on IRB project/oral exam due today by 10 am