Course Syllabus

Edit

GRDM-G506 – RESPONSIBLE CONDUCT OF TRANSLATIONAL RESEARCH

Course Director:

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Director, IU Center for Bioethics

Professor of Philosophy, IU School of Liberal Arts, IUI.

Semester: Spring 2025

Wednesdays 1:30-3:00 p.m. In-Person. Nursing Room 221

Zoom: **https://iu.zoom.us/j/81996631761 (https://iu.zoom.us/j/81996631761)**

TA: Morgan Rich – mbrich@iu.edu

COURSE DESCRIPTION

Translational research brings breakthroughs “from the bench to the bedside,” i.e. harnessing scientific advances to improve individual healthcare and public health. The National Institutes of Health, through the National Center for Research Resources, supports 60 Clinical and Translational Science Awards (CTSAs) across the country, including the Indiana Clinical and Translational Sciences Institute (CTSI) since 2008. The Indiana CTSI provides funding for translational research projects, pre-graduate and post-graduate training, project development, research cores, and programs in community engagement, regulation, and bioethics and subject advocacy, at four campuses throughout the state (IUPUI, IUB, Purdue, Notre Dame).

The NIH defines responsible conduct of research (RCR) as “the practice of scientific investigation with integrity.” It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.” RCR is a requirement of all research, and special principles and issues arise when humans are being studied, as in translational and clinical research. NIH requirements include the following topics: conflicts of interest, policies on research with human subjects, mentor/mentee relationships, collaborative research including research with industry, peer review, data acquisition, research misconduct policies, issues in authorship and publication, and the role of science in society.

This one-credit course provides a basic introduction to RCR related to translational research and fulfills the NIH requirements for instruction in RCR for trainees and students in this area. The course is team taught by faculty members of the Bioethics and Subject Advocacy Program (BSAP) of the Indiana CTSI. We hope that students in this class will develop an interest in and a positive attitude toward lifelong learning in matters of scientific integrity and the responsible conduct of research or other profession.

NIH Suggested Topics for RCR Instruction:

In Feb. 2022, the NIH published updated guidance for instruction in Responsible Conduct of Research (Notice Number NOT-OD-22-055) (**https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.htmlLinks to an external site. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html)**), highlighting the following topics as central:

1. conflict of interest – personal, professional, and financial – and conflict of commitment, in allocating time, effort, or other research resources
2. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
3. mentor/mentee responsibilities and relationships
4. safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)
5. collaborative research, including collaborations with industry and investigators and institutions in other countries
6. peer review, including the responsibility for maintaining confidentiality and security in peer review
7. data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks
8. secure and ethical data use; data confidentiality, management, sharing, and ownership
9. research misconduct and policies for handling misconduct
10. responsible authorship and publication
11. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

The lectures in this course cover all these topics to at least some degree. For each lecture, the syllabus lists which topics are aimed to be covered (or at least considered to some extent).

COURSE ACTIVITIES

Class meetings/ structure

The class meets for 90 minutes per week for eight weeks: the first thirty minutes review key principles, and the next hour involves discussion and interpreting and applying those principles to real-life cases.

Course Goals

The goal of this course is to provide graduate students, postdoctoral students, and faculty with skills and resources valuable for conducting responsible, ethical, effective research. The goals include:

1. To define expected standards of conduct.
2. To increase the student's or trainee's confidence in dealing with difficult issues.
3. To meet current NIH requirements for formal training in responsible conduct of research.

Course Objectives

The goals are that at 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 translational science.
3. Propose and critically analyze solutions to problems in the context of relevant written codes and unwritten conventions.

Course Assessments

There are four factors that contribute to the final grade:

- Class preparation (including readings) and participation – This class is structured around student participation, and as such students must be properly prepared for class and must engage in discussion. This includes reading the assigned readings ahead of time, taking notes on the reading in order to garner key points, and offering up opinions and ideas in class during discussion time.
- Class attendance – As participation is a key component of class, class attendance will be taken. Additionally, in order to receive confirmation of fulfilling NIH training requirements, students are required to have at least 8 contact hours.
- Midterm exam – Students will have a take home midterm covering the first four class meetings. The midterm will be posted on Canvas at the end of the fourth class and will be due by the start of the following class period. Students should submit midterms via Canvas.
- Final exam – Students will have a take home final exam covering the final four class meetings. The final will be posted on Canvas following the last class and will be due a week later.

GRADING AND EVALUATION

Course Assessments and Grades:

- Class preparation (including readings), and participation (30%)
- Class attendance (10%)
- Take-home midterm (25%) – short answer and essay questions.
- Take-home final exam – comprehensive, including short answer and essay questions (35%).

All points will be added; 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%

Graduate programs or schools may not accept courses for credit towards a graduate degree if the student has earned a passing grade below a certain level, such as below B- or B. Please check with your graduate program or school to identify the minimum grade for your department to grant credit for your work in this course.

Syllabus Supplements

Additional information about IUPUI student policies and services is available on Canvas under the Campus Syllabus Supplement and SLA Syllabus Supplement tabs. 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)
- Withdrawal (including Administrative Withdrawal)
- Incompletes
- Honors credit
- Student Advocate Office
- Counseling and Psychological Services (CAPS)
- University Writing Center
- Diversity

SLA Syllabus Supplement: **https://liberalarts.indianapolis.iu.edu/faculty-staff/faculty-resources/syllabus-supplement.html (https://liberalarts.indianapolis.iu.edu/faculty-staff/faculty-resources/syllabus-supplement.html)**

COURSE PLAN AND READINGS

WEEK 1 – JANUARY 15: HUMAN SUBJECTS RESEARCH: A PHASE I TRIAL THAT WENT WRONG

Speaker: Peter H. Schwartz, MD, PhD

Readings:

The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavior Research. April 18, 1979.

- This is the founding document for the modern conception of research ethics and the regulatory framework enshrined in the Common Rule that governs almost all human subjects research in the United States and other areas of the world. And even better, just 10 pages!

Case: (There will be time during the class to read this short article if you have not had a chance beforehand.)

Evans, David. Parexel Misled Subjects Sickened in London Study, Ethicists Say. Bloomberg. Retrieved Aug 8, 2006.

- Popular press article about a research study where something went wrong (Evans, from Bloomberg News).
- Please read this article with the following question in mind: The ethicists and others interviewed in this article identify many different ethical lapses in this study where participants were injured. For each of the alleged lapses, please try to decide if they are actually ethical lapses or not (perhaps by thinking about the principles of the Belmont report.) If they were real lapses, please identify which were the most important ones.

NIH RCR Topics covered:

Main topic: b. policies regarding human subjects, …

Other potential topics:

1. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

WEEK 2 – JANUARY 22: SCIENTIFIC MISCONDUCT: DEFINITIONS, POLICIES AND PROCEDURES

Speaker: Amy Waltz, JD, CIP, Deputy Research Integrity Officer and Associate Director, Research Integrity Office, Indiana University Office of Research Compliance

Readings:

- Federal Research Misconduct Policy: **https://ori.hhs.gov/federal-research-misconduct-policy (Links to an external site.)Links to an external site.Links to an external site.Links to an external site.** **(https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fori.hhs.gov%2Ffederal-research-misconduct-policy&data=05%7C01%7Cacthurst%40iu.edu%7C67af171e5fcd470de2de08da814fcd5c%7C1113be34aed14d00ab4bcdd02510be91%7C0%7C0%7C637964476986**

- 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.Links to an external site.Links to an external site.** **(https://policies.iu.edu/policies/aca-30-research-misconduct/index.html)**
- Habermann B, Broome M, Pryor ER, Ziner KW. Research coordinators' experiences with scientific misconduct and research integrity. Nurs Res. 2010 Jan-Feb;59(1):51-7. doi: 10.1097/NNR.0b013e3181c3b9f2. PMID: 20010045; PMCID: PMC2877381. Attached and available at **https://pubmed.ncbi.nlm.nih.gov/20010045/ Links to an external site.Links to an external site.Links to an external site.** **(https://pubmed.ncbi.nlm.nih.gov/20010045/)** .

NIH RCR Topics Covered:

Main topic: i. research misconduct and policies for handling misconduct

Other potential topics:

1. data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks
2. secure and ethical data use; data confidentiality, management, sharing, and ownership

WEEK 3 – JANUARY 29: AUTHORSHIP AND PLAGIARISM

Speaker: Jane Hartsock, JD, System Director of Clinical and Organizational Ethics, IU Health,

Readings:

- International Committee of Medical Journal Editors. **Defining the Role of Authors and Contributors Links to an external site.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)** . Available at: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
- McKarney L. (2001) **Peer Review Techniques for Novices Links to an external site.Links to an external site.Links to an external site.** **(https://www.sciencemag.org/careers/2001/04/peer-review-techniques-novices)** . Science Magazine April 20, 2001. Available at: **https://www.sciencemag.org/careers/2001/04/peer-review-techniques-novicesLinks to an external site.Links to an external site.Links to an external site.** **(https://www.sciencemag.org/careers/2001/04/peer-review-techniques-novices)**

NIH RCR Topics Covered:

Main topics:

1. responsible authorship and publication
2. peer review, including the responsibility for maintaining confidentiality and security in peer review

Other potential topics:

3. mentor/ mentee responsibilities and relationships

WEEK 4 – FEB. 5: CONFLICTS OF INTEREST

Speakers: Stephanie Jones, Associate Director for Research Compliance, IU Office of Research Compliance, and Peter Schwartz, M.D., Ph. D.

Readings:

- Indiana University Conflict of Interest and Commitment Policy: **https://policies.iu.edu/policies/ua-17-conflicts-of-interest-commitment/index.htmlLinks to an external site.** **(https://policies.iu.edu/policies/ua-17-conflicts-of-interest-commitment/index.html)**

- 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.Links to an external site.** **(https://medicine.iu.edu/about/policies-guidelines/industry-relations/)**
- Rosenbaum, Lisa. Reconnecting the dots — reinterpreting industry–physician relations. NEJM 2015; 372(19): 1860-1864.
- Rosenbaum, Lisa. Understanding bias — the case for careful study. NEJM 2015; 372(20):1959- 1963.

Case Study:

- 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.

NIH RCR Topics Covered:

Main topics:

1. conflict of interest – personal, professional, and financial – and conflict of commitment, in allocating time, effort, or other research resources
2. collaborative research, including collaborations with industry …

Other potential topics:

1. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

MIDTERM ASSIGNED FEBRUARY 6 (NOON) AND DUE BY FEBRUARY 13th AT 11:30 P.M

WEEK 5 – FEB. 12 – RESEARCH ENVIRONMENT AND RESPECT

Speaker : Erika Cheng, PhD, Associate Professor of Pediatrics, IUSM and Executive Director, Health Equity Advancing through Learning Health Systems Research (HEAL-R) Collaborative

Readings: NONE

NIH RCR Topics Covered:

Main topics:

1. safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)

Other potential topics:

1. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

WEEK 6 – FEBRUARY 19: RESEARCH ON DIGITAL DATA: Ethical Challenges of Remote Monitoring

Speaker: Andrew Brightman, Ph.D, Professor of Engineering Practice, Weldon School of Biomedical Engineering, Purdue University,

Required Reading:

- Muurling, M., Pasmooij, A. M., Koychev, I., Roik, D., Froelich, L., Schwertner, E., ... & RADAR-AD Consortium. (2023). Ethical challenges of using remote monitoring technologies for clinical research: A case study of the role of local research ethics committees in the RADAR-AD study. *Plos one*, *18*(7), e0285807.

Case Study:

- Please SKIM - Muurling, M., de Boer, C., Vairavan, S., Harms, R. L., Chadha, A. S., Tarnanas, I., ... & Brem, A. K. (2023). Augmented reality versus standard tests to assess cognition and function in early Alzheimer’s disease. *NPJ digital medicine*, *6*(1), 234.

Optional Readings:

- de Jong, A. J., Shahid, N., Zuidgeest, M. G., Santa-Ana-Tellez, Y., Hogervorst, M., Goettsch, W., ... & Trials@ Home Consortium. (2023). Opportunities and challenges for decentralized clinical trial approaches: European health technology assessment perspective. *Value in Health*.
- Owens, A. P., Hinds, C., Manyakov, N. V., Stavropoulos, T. G., Lavelle, G., Gove, D., ... & Aarsland, D. (2020). Selecting remote measurement technologies to optimize assessment of function in early Alzheimer's disease: a case study. *Frontiers in Psychiatry*, *11*, 582207.

WEEK 7 – FEBRUARY 26: INTERNATIONAL RESEARCH

Speaker: Megan McHenry, MD, MS, Associate Professor of Pediatrics, IUSM

Readings:

- Emanuel EJ, et al. What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *Journal of Infectious Diseases*. 2004:189 (1 March), p930-937
- Adhikari B, Pell C, Cheah PY. Community engagement and ethical global health research. *Glob Bioeth*. 2019;31(1):1-12. Published 2019 Dec 20. doi:10.1080/11287462.2019.1703504
- Familiarize yourself with the guidelines in the following document, skimming or looking more into any areas of interest (do NOT read entire document): International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.

OPTIONAL:

Case Study (Optional):

- Documenting the health conditions of an indigenous community – From Casebook on Ethical Issues in International Health Research. World Health Organization. 2009. **https://apps.who.int/iris/bitstream/handle/10665/44118/9789241547727_eng.pdf;jsessioniLinks to an external site.Links to an external site.Links to an external site.** **(https://apps.who.int/iris/bitstream/handle/10665/44118/9789241547727_eng.pdf;jsessioni)** d=5A449B3D5BE0649B52790ED4D1DC4CD2?sequence=4

NIH RCR Topics covered:

Main topics:

1. collaborative research, including … investigators and institutions in other countries
2. policies regarding human subjects, …
3. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

WEEK 8 – MARCH 5: ANIMALS IN RESEARCH

Speaker: Matthew Allen, Ph.D., Professor of Anatomy, Cell Biology and Physiology, IUSM.

Readings: NONE

NIH RCR Topics Covered:

Main topics:

1. Policies regarding… live vertebrate animal subjects in research, and safe laboratory practices

NIH RCR Topics covered:

Main topics:

1. policies regarding human subjects, …

2. data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); record keeping practices, including methods such as electronic laboratory notebooks

3. secure and ethical data use; data confidentiality, management, sharing, and ownership

FINAL EXAM ASSIGNED MARCH 7 AND DUE MARCH 14TH AT 5:00 P.M.

▶ Syllabus Supplement for Spring 2025

Course Summary:

Date	Details	Due
Thu Feb 13, 2025	**Midterm** **(https://iu.instructure.com/courses/2298070/assignments/17117975)**	due by 11:30pm
Mon Mar 17, 2025	**Final Exam** **(https://iu.instructure.com/courses/2298070/assignments/17117976)**	due by 11:59pm