**GRDM-G506 – Responsible Conduct of Translational Research**

Course Director: Peter Schwartz, M.D., Ph.D.

Semester: Spring 2023

Wednesdays 2-3:30 p.m. In-Person. Nursing Room 221

Zoom:  [https://iu.zoom.us/j/82130041130Links to an external site.](https://iu.zoom.us/j/82130041130)

TA: Pierce Logan – pielogan@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.

**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 of interpreting and applying those principles to a case of research.

**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.iupui.edu/faculty-staff/faculty-resources/syllabus- Links to an external site.](https://liberalarts.iupui.edu/faculty-staff/faculty-resources/syllabus-)supplement.html

**COURSE PLAN AND READINGS**

**Week 1 – January 11: Scientific Misconduct: Definitions, Policies and Procedures**

Speaker: Amy Waltz, JD

Readings:

* Federal Research Misconduct Policy: [https://ori.hhs.gov/federal-research-misconduct-policy (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%7C637964476986863936%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=OqUJIKdu0A%2FpSEGClLNmS%2FJCjrfD%2BDB2Yg35aV4F3iI%3D&reserved=0)
* 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)
* 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.](https://pubmed.ncbi.nlm.nih.gov/20010045/).

Topics Covered:

* Research misconduct and policies for handling misconduct
* Mentor/mentee responsibilities and relationships
* Peer review
* Data acquisition and laboratory tools; management, sharing and ownership
* Conflict of interest (personal)

**Week 2 – January 18: Authorship and Plagiarism**

Speaker: Jane Hartsock, JD

Readings:

* International Committee of Medical Journal Editors. [Defining the Role of Authors and Contributors 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.](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.](https://www.sciencemag.org/careers/2001/04/peer-review-techniques-novices)

**Week 3 – January 25: 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.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.](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.

Topics Covered:

* Conflict of interest (professional and financial)
* Collaborative research including collaborations with industry
* Data management, sharing, and ownership

**Week 4 – February 1: Research with Children**

Speaker: Mary Ott, M.D.

Readings:

* Nuffield Council on Bioethics. Health research: making the right decision for me. [https://youtu.be/6yaKwLG\_vlELinks to an external site.](https://youtu.be/6yaKwLG_vlE)
* 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\_adLinks to an external site.](https://www.ted.com/talks/sarah_jayne_blakemore_the_mysterious_workings_of_the_ad)olescent\_brain?language=en
* IU IRB Policies on research with children: [https://research.iu.edu/policies/human-subjects-irb/children-in-research.htmlLinks to an external site.](https://research.iu.edu/policies/human-subjects-irb/children-in-research.html)
* Iltis AS (2009) Vulnerability in biomedical research. J Law Med Ethics 37(1)6-11.

Optional Readings:

* Santatelli et al. (2003) Guidelines for Adolescent Health Research. J Adolesc Health 33 (5): 396-409.
* Kipnis S. (2003) Seven vulnerabilities in the pediatric research subject. Theor Med Bioeth24(2):107-120.
* 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.
* Nuffield Council on Bioethics. Involving children and young people in health research – getting it right. ([http://nuffieldbioethics.org/wp-content/uploads/Children-and-clinical- Links to an external site.](http://nuffieldbioethics.org/wp-content/uploads/Children-and-clinical-)research-magazine-version1.pdf)

Case Study:

* Shenk, et al. Enrollment of Adolescents Aged 16–17 Years Old in Microbicide Trials: An Evidence-Based Approach. J Adolesc Health 2014, 54(6): 654-662. https://reader.elsevier.com/reader/sd/pii/S1054139X14000597?token=E885CEFA75146D3FA2382D0C03BA4A75E3D4528887A1167E46908A1F136069941B4083AE10534 BD6E4324AF0ECFFF9A
* Editorial on adolescent vulnerability and consent: https://reader.elsevier.com/reader/sd/pii/S1054139X14001608?token=3F29F69B96D1D4445F210C09FB14C720193E42500C0A905D0F810B89AE38964AFE67AABF7C28D8C635DEF044E7B60D9

Questions to Consider for Case Study:

* In what ways were these youth vulnerable? How did the researchers address this vulnerability?
* Should the IRBs have allowed adolescents to provide their own consent? Or should a parent or ombudsman have helped with the consent process? Please consider arguments for and against minor self-consent.

Topics Covered:

* Policies regarding human subjects
* The scientist as a responsible member of society
* Contemporary ethical issues in biomedical research
* The environmental and societal impacts of scientific research
* Vulnerable populations
* Consent and assent in pediatric research

**Midterm assigned February 1st and DUE by February 8th at 2:00 P.M**

**Week 5 – February 8: Return of Research Results in Genetics**

Speaker: Colin Halverson, Ph.D.

Readings:

* Ossario P (2012) Taking aims seriously: Repository research and limits on the duty to return individual research findings. *Genetics in Medicine*14:461- 466.
* Jarvik GP, Amendola LM, Berg JS, et al. (2014). Return of genomic results to research participants: The floor, the ceiling and the choices in between. The American Journal of Human Genetics 94:818-826.

Case Study:

* Jennifer Couzin-Frankel – Unexpected revelations for study volunteer. Science 352:754- 755.

Topics Covered

* Policies regarding human subjects
* The scientist as a responsible member of society
* Contemporary ethical issues in biomedical research
* Informed consent

**Week 6 – February 15: Animals in Research**

Speaker: Matthew Allen, Ph.D.

Readings: NONE

**Week 7 – February 22: International Research**

Speaker: Megan McHenry, MD, MS, FAAP

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.](https://apps.who.int/iris/bitstream/handle/10665/44118/9789241547727_eng.pdf;jsessioni)d=5A449B3D5BE0649B52790ED4D1DC4CD2?sequence=4

Topics covered:

* The scientist as a responsible member of society
* Contemporary ethical issues in biomedical research
* Environmental and societal impacts of scientific research
* Policies regarding human subjects
* Research misconduct and policies for handling misconduct

**Week 8 – March 1: Research on Devices: Home COVID Tests**

Speaker: Andrew Brightman, Ph.D

 Readings:

* London, A. J., & Kimmelman, J. (2020). Against pandemic research exceptionalism. *Science*, *368*(6490), 476-477.
* Roback, J. D., Tyburski, E. A., Alter, D., Asakrah, S., Chahroudi, A., Esper, A., ... & Lam, W. A. (2021). The need for new test verification and regulatory support for innovative diagnostics. *Nature Biotechnology*, *39*(9), 1060-1062.  [https://www.nature.com/articles/s41587-021-01047-7Links to an external site.](https://www.nature.com/articles/s41587-021-01047-7)

Optional Readings:

* Vandenberg, O., Martiny, D., Rochas, O., van Belkum, A., & Kozlakidis, Z. (2021). Considerations for diagnostic COVID-19 tests. *Nature Reviews Microbiology*, *19*(3), 171-183. [https://www.nature.com/articles/s41579-020-00461-z Links to an external site.](https://www.nature.com/articles/s41579-020-00461-z)([**https://rdcu.be/cBs5b** Links to an external site.](https://rdcu.be/cBs5b)**)**

Case Study:

* Kalokairinou, L., Zettler, P. J., Nagappan, A., Kyweluk, M. A., & Wexler, A. (2020). The promise of direct-to-consumer COVID-19 testing: ethical and regulatory issues. *Journal of Law and the Biosciences*, *7*(1), lsaa069.

Topics covered:

* The scientist as a responsible member of society
* Contemporary ethical issues in biomedical research
* Policies on research with human subjects
* Privacy and confidentiality
* Collaborative research including collaborations with industry
* Interacting with public media
* Data integrity and accuracy

**Final exam assigned March 2nd and DUE by March 9th at 5:00 P.M.**