GRDM-G506 – Responsible Conduct of Translational Research

Course Director: Sylk Sotto, Ed.D., MBA, M.S.
Spring 2020 Semester
Wednesdays 2-3:30 p.m.
Nursing School (NU) 210
TA: Heather Anderson – helander@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 assessments points toward 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 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%)
- Take-home final exam – comprehensive, including short answer and essay questions (35%).

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%

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)

SLA Syllabus Supplement https://liberalarts.iupui.edu/faculty-staff/faculty-resources/syllabus-supplement.html

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

COURSE PLAN/ READINGS

Week 1 – January 15: Authorship and Plagiarism
Speaker: Jane Hartsock, J.D.

Readings:

- International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors. Available at: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
- Benson PJ (2015) Eyes wide open: reader and author responsibility in understanding the limits of peer review. The Annals of The Royal College of Surgeons of England. 97(7):487-489. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5210144/
- McKarney L. (2001) Peer Review Techniques for Novices. Science Magazine April 20, 2001. Available at: http://www.sciencemag.org/careers/2001/04/peer-review-techniques- novices

Week 2 – January 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
- 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.

Case Study:

- 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;jsessionid=5A449B3D5BE0649B52790ED4D1DC4CD2?sequence=4

Case Study: 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 3 – January 29: Scientific Misconduct: Definitions, Policies and Procedures
Speaker: Sylk Sotto, EdD., MBA, MPS
Readings:

- Young JK and Janz N (2015) What social science can learn from the LaCour scandal. Chronicle of Higher Education: Commentary June 3, 2015.
- Marcus A, McCook A, and Oransky I. (2015) The top 10 retractions of 2015. December 23, 2015, The Scientist Magazine.
- Fanelli D (2009) How many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data. PLoS, May 2009, Vol.4, Issue 5 e5738.
- Ingold, J. (2017) CU professor engaged in research misconduct, investigative committee finds. The Denver Post. June 21, 2017. http://www.denverpost.com/2017/06/21/university-colorado-anschutz-professor-research- misconduct/

Case Study:

- Dana Goodyear: The Stress Test: Competition and intrigue in stem-cell research.The New Yorker, February 29, 2016.

Topics Covered:

- Research misconduct and policies for handling misconduct
- Mentor/mentee responsibilities and relationships
- Peer review
- Policies regarding live vertebrate animal subjects in research
- Data acquisition and laboratory tools; management, sharing and ownership
- Conflict of interest – Personal

Week 4 – February 5th: Collaborative Research with Industry
Speaker: Peter Schwartz, MD

Readings:

- Indiana University School of Medicine "Industry Relations Policy." Available at: https://medicine.iu.edu/about/policies-guidelines/industry-relations/
- Rosenbaum, Lisa.
    - Reconnecting the dots — reinterpreting industry–physician relations. NEJM 2015; 372(19): 1860-1864.
    - Understanding bias — the case for careful study. NEJM 2015; 372(20: 1959- 1963.
- Steinbock R, Kassier JP, and Angell M, "Justifying conflicts of interest in medical journals: a very bad idea," BMJ 2015; 350:

Case Study:

- Kearns C, Schmidt L, and Glantz S. Sugar industry and coronary heart disease research: A historical analysis of internal industry documents. *JAMA Internal Medicine* 2016; 176(11): 1680-1685.
- Johns DM and Oppenheimer GM. Was there ever really a 'sugar conspiracy'? *Science* 2018; 359(6377): 747-750.

- Kearns C, Schmidt L, Apollonio D, and Glantz S. Letter to the Editor: The sugar industry's influence on policy. *Science* 2018; 360 (6388): 501.
- Johns DM and Oppenheimer GM. Letter to the Editor: Response. *Science* 2018; 360 (6388): 501-2.

Topics Covered:

- Conflict of interest – Professional and Financial
- Collaborative research including collaborations with industry
- Data management, sharing and ownership

Midterm assigned February 5th and DUE by February 12th at 2:00 P.M.

Week 5 – February 12th: 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_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_adolescent_brain?language=en
- IU IRB Policies on research with children: 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-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=E885CEFA75146D3FA2382D0C03BA4A75E3D4528887A1167E46908A1F1367069941B4083AE10534BD6E4324AF0ECFFF9A

- Editorial on adolescent vulnerability and consent: https://reader.elsevier.com/reader/sd/pii/S1054139X14001608?token=3F29F69B96D1D4445F210C09FB14C720193E42500C0A905D0F810B89AE388964AFE67AABF7C28D8C635DEF044E7B60D9

Questions to consider for case study

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 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

Week 6 – February 19th: Biobanks and Big Data

Speakers: TJ Kasperbauer, Ph.D

- Caulfield T, Burningham S, Joly Y, et al. A review of key issues associated with the commercialization of biobanks. Journal of Law and the Biosciences 2014; 94-110.
- Price, W. N. & Cohen, I. G. (2019). Privacy in the age of medical big data. Nature Medicine, 25, 37-43.
- [Only read the Introduction and Background]: Laura M. Beskow & Kevin P. Weinfurt (2019). Exploring understanding of "understanding": The paradigm case of biobank consent comprehension. American Journal of Bioethics, 19:5, 6-18.

Optional Readings

- Master Z, Nelson E, Murdoch B, Caulfield T. Biobanks, consent and claims of consensus. Nature Methods 2012; 9(9): 885-888.
- Lee, S.-J. et al. (2019). "I don't want to be Henrietta Lacks": diverse patient perspectives on donating biospecimens for precision medicine research. Genetics in Medicine, 21, 107-113.

Case Study:

Havasupai Tribe vs. Arizona State University

- Harmon A. Indian tribe wins fight to limit research of its DNA. New York Times, April 21, 2010

Topics covered

- Policies regarding human subject research

- Scientist as a responsible member of society
- Contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research
- Privacy and confidentiality
- Community engagement

Week 7 – February 26th: Return of Research Results in Genetics
Speaker: Peter H. Schwartz, M.D., 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 8 – March 4th: Community Engaged Research
Speaker: Mary Ott, M.D.
Readings:

- CBPR (Intro) – ChrisFlipp. https://www.youtube.com/watch?v=AePC97aKOJA
- 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.
- Yale CARE: Community Alliance for Research and Engagement. Principles and Guidelines for Community-University Research Partnerships. Available at: https://depts.washington.edu/ccph/pdf_files/Principles_for_U-CPs_09-05-11_-_FINAL.pdf

Optional Readings:

- McClosky, et al. Chapter 1: Community Engagement: Definitions and Organizing Concepts from the Literature. Centers for Disease Control and Prevention. Last updated 2011. Available at:

https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_Chapter_1_SHEF.pdf

Case Study:

- Making antenatal care youth-friendly: Starting from the Roots: Using Human Centered Design to Make an Adolescent Pregnancy Program Youth Friendly in Western Kenya.

Questions to Consider for Case Study:

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?

Topics covered:

- Policies regarding human subjects
- Collaborative research including collaborations with industry
- The scientist as a responsible member of society
- Contemporary ethical issues in biomedical research
- The environmental and societal impacts of scientific research
- Cognitive bias
- Interacting with public media

Final exam assigned March 4th and DUE by March 11th at 5:00 P.M.