

GRDM-G504 - INTRODUCTION TO RESEARCH ETHICS

Sections: 23070/23371

Fall 2020 Semester

Course Director: Colin Halverson, PhD

TAs: Heather Anderson and Katie Randall

Email: helander@iu.edu and katerand@iu.edu

Time: Thursdays 2-4:40 p.m.

Location: Zoom Meeting ID 996 5785 9401 Passcode 177515

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Office hours: By appointment call 278-4038 (Bioethics)

Cross-listed as: MHHS M504 3065

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 allowing 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 IUPUI. He has a PhD in 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

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 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 valuable for survival. The primary objectives of this course are:

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 Canvas course page.

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 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

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.

Grading

This is a 3-credit course. Class attendance and participation are key aspects of the course. Students are expected to complete assigned 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, posting a question/comment in the chat, or responding to polls. 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 synchronously via Zoom. Students will be required to attend and participate in discussions as explained above. Zoom tools, such as breakout rooms, may be used to facilitate discussions between students and faculty. If students are not able to attend the in real time or experience technical difficulties, the sessions will be recorded and made available via Canvas.

Grading for the course is as follows:

1. 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 $\geq 80\%$ of the classes and participate actively in the majority of these classes. Active participation includes speaking or posting in the chat at least once during each session. Students are expected to enter the virtual classroom prepared and on time and to stay for the entirety of the class. They will be docked points for each unexcused absence. Students are encouraged but not required to have their cameras on throughout the class.

2. Writing assignments – 10%

Students are required to attend one virtual IRB session. They must submit a 500-word reflection paper on the experience, summarizing the cases, noting strengths and weaknesses of the studies they discussed. A second 500-word reflection paper must be submitted in response to the in-class mock IRB session within three days of the class period.

3. 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.

POSTED: October 8, 2020

DUE: October 15, 2020

4. Final examination – 35%

The final examination will take the same form as the midterm examination.

POSTED: December 8, 2020

DUE: December 15, 2020

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. 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

SLA SYLLABUS SUPPLEMENT

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

Course Schedule

Unit 1: History and Foundations

Week 1- August 27: Introduction and Principles (TA: Heather)

TOPICS: Human subjects, research misconduct, contemporary issues, the scientist in society

- Brief introduction of professor and students, overview of course – Colin Halverson
- Basic ethical principles and theories (Belmont Report and case) – Peter Schwartz

READINGS:

1. The Belmont Report (1979), i.e. “Ethical Principles and Guidelines for Research Involving Human Subjects,” by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
2. Evans (2006), “Parexel Misled People Sickened by Test, Ethicists Say,” Bloomberg News, April 10, 2006.

CASE STUDY:

- None to read ahead of time; will be incorporated into lecture.

Week 2- September 3: History (TA: Katie)

TOPICS: Human subjects, research misconduct, contemporary issues, the scientist in society

Introduction – Colin Halverson

- History of science and misconduct – William H. Schneider
- History of Research with Human subjects – Steven Jay

READINGS:

History of misconduct:

1. “The Establishment of Institutional Review Boards in the U.S.: Background History”. Available at: <file:///Users/admin/Downloads/irbhist-1.html>
2. Brandt AM (1978) Racism and Research: The case of the Tuskegee Syphilis Study. *The Hastings Center* 8:21-29. Also available from: <http://www.jstor.org/stable/3561468>
3. Vonderlehr RA, Clark T, Wenger OC and Heller JR (1936) Untreated syphilis in the male negro. *Venereal Disease Information* 17:260-265.
4. Pesare PJ, Bauer TJ, Gleeson GA (1950) Untreated syphilis in the male negro: Observation of abnormalities over sixteen years. *American Journal of Syphilis, Gonorrhoea, and Venereal Diseases*. 34:201-213.

History with human subjects:

1. Jay, S. (2014). A Fever When Walter Came to Indianapolis. *Indianapolis Literary Club 2013-2014*. literaryclub.org <http://literaryclub.org/id5.html>.

2. Kumar N. K. (2013). Informed consent: Past and present. *Perspectives in clinical research*, 4(1), 21–25. <https://doi.org/10.4103/2229-3485.106372>.
3. OPTIONAL. Jay, S. (2010). Ravenscrag Revisited. *Indianapolis Literary Club 2009-2010*. <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwin0Yz577vrAhWJXMOKHVpfDusQFjAAegQIAhAB&url=http%3A%2F%2Fwww.literaryclub.org%2Fsitebuildercontent%2Fsitebuilderfiles%2Fravenscrag.pdf&usg=AOvVaw2bRkGYARQQq-95S1pCJb6>

CASE STUDY:

History of misconduct:

- None to read ahead of time; will be incorporated into lecture.

History with human subjects:

- None to read ahead of time; will be incorporated into lecture.

Week 3- September 10: Misconduct (TA: Heather)

TOPICS: Human subjects, research misconduct, environmental/societal impacts, the scientist in society, contemporary issues

Introduction – Colin Halverson

- Misconduct, IU policies, definition – Sylk Sotto

READINGS:

1. Marcus A, McCook A, and Oransky I. (2015) The top 10 retractions of 2015. December 23, 2015, The Scientist Magazine.
2. 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.

CASE STUDY:

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

Week 4- September 17: Authorship (TA: Katie)

Late start (3:20 PM)

TOPICS: Conflict of interest, collaboration, peer review, data ownership, responsible authorship and publication, mentor/mentee relationship, research misconduct, the scientist in society

Introduction – Colin Halverson

- Authorship and Plagiarism – Jane Hartsock

READINGS:

1. ICMJE. (2020). Defining the Role of Authors and Contributors. <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>
2. McKarney, L. (2001) Peer-Review Techniques for Novices. *Science*.

CASE STUDY:

- None to read ahead of time; will be incorporated into lecture.

Week 5- September 24: Collaboration & Conflict of Interest (TA: Heather)

TOPICS: Conflict of interest, collaboration, the scientist in society

Introduction – Colin Halverson

- Conflict of interest – Stephanie Jones
- Collaboration with industry – Peter Schwartz

READINGS:

Conflict of Interest:

1. Indiana University Conflict of Interest and Commitment Policy:

<https://policies.iu.edu/policies/ua-17-conflicts-of-interest-commitment/index.html>

Collaboration:

1. Indiana University School of Medicine Industry Relations Policy:
<https://medicine.iu.edu/about/policies-guidelines/industry-relations/>
2. Rosenbaum, L. Reconnecting the dots — reinterpreting industry–physician relations. *NEJM* 2015; 372(19): 1860-1864.
3. Rosenbaum, L. Understanding bias — the case for careful study. *NEJM* 2015; 372(20): 1959-1963.
4. *OPTIONAL* Steinbrook R, Kassier JP, and Angell M, “Justifying conflicts of interest in medical journals: a very bad idea,” *BMJ* 2015; 350.

CASE STUDY:

Conflict of Interest:

- None to read ahead of time; will be incorporated into lecture.

Collaboration:

- 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.
- *OPTIONAL* 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.
- *OPTIONAL* Johns DM and Oppenheimer GM. Letter to the Editor: Response. *Science* 2018; 360 (6388): 501-2.

Week 6- October 1: Consent and the Role of the IRB (TA: Katie)

TOPICS: Human subjects, collaboration, contemporary issues, data management, research misconduct, the scientist in society

Introduction – Colin Halverson

- Informed Consent – T.J. Kasperbauer
- Role of IRB – Brian Stage

READINGS:

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.

Role of IRB:

1. The Belmont Report (1979), i.e. “Ethical Principles and Guidelines for Research Involving Human Subjects,” by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
2. Common Rule (45 CFR 46) (skim)
3. FDA’s version of the Common Rule (21 CFR 50 and 56) (skim)
4. IU Policies <https://research.iu.edu/policies/human-subjects-irb/index.html>
 - a. IRB Review Process
 - b. Informed Consent
 - c. Exempt Research
 - d. Recruitment of Human Subjects
 - e. Reportable Events
 - f. Adult Individuals Lacking Consent Capacity
 - g. Children in Research
 - h. Pregnant Women, Fetuses, and Neonates in Research
 - i. Prisoners in Research
 - j. Students and Use of Education Records in Research

CASE STUDY:

- None to read ahead of time; will be incorporated into lecture.

Week 7- October 8: Return of Results and Mock IRB (TA: Heather)

TOPICS: Human subjects, collaboration, data management

TAKE-HOME MIDTERM EXAMINATION POSTED

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

READINGS:

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.

Mock IRB: (documents in Canvas)

1. Mock IRB- Amendment
2. Mock IRB- FYI UPIRTSO
3. Mock IRB- Noncompliance CC
4. Mock IRB- NS Pain Study
5. Mock IRB- NS Tabled
6. Mock IRB- Renewals
7. IU Policies on IRB Meetings and Minutes <https://research.iu.edu/policies/human-subjects-irb/irb-meetings-and-minutes.html>
8. IU Policies on IRB Membership <https://research.iu.edu/policies/human-subjects-irb/irb-membership.html>

CASE STUDY:

Return of Results

- None to read ahead of time; will be incorporated into lecture.

Unit 2 – Research with Protected Subjects

Week 8- October 15: Research with Protected Subjects (TA: Katie)

TOPICS: Human subjects, the scientist in society, contemporary ethical issues, environmental/societal impacts, vulnerable populations, consent and assent

Introduction – Colin Halverson

- Cognitively Impaired /Mentally Ill Persons /Persons with Dementia – Amber Comer
- Children and Adolescents – Mary Ott

TAKE-HOME MIDTERM SUBMISSION DUE

READINGS:

Cognitively Impaired:

1. IU HRPP Policy – Individuals Lacking Capacity. <https://research.iu.edu/policies/human-subjects-irb/adult-individuals-lacking-consent-capacity.html>
2. NIH – Research Involving Individuals with Questionable Capacity to Consent: Points to Consider. <https://grants.nih.gov/grants/policy/questionablecapacity.htm>

Children & Adolescents:

1. Nuffield Council on Bioethics. Health research: making the right decision for me (https://youtu.be/6yaKwLG_vlE)
2. 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
3. IU IRB Policies on research with children: (<https://research.iu.edu/policies/human-subjects-irb/children-in-research.html>)

Optional Readings

1. Santelli JS, Rogers A, Rosenfeld WD, DuRant RH, Dubler N, Morreale M, English A, Lyss S, Wimberly Y, Schissel A. (2003) Guidelines for adolescent health research: A position paper of the society for adolescent medicine. *J Adolesc Health* 33:396-409. [Canvas Resources]
2. Kipnis K. Seven vulnerabilities in the pediatric research subject. *Theor Med Bioeth.* 2003;24(2):107-20.
3. 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.
4. 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:

Cognitively Impaired:

- None to read ahead of time; will be incorporated into lecture.

Children & Adolescents:

- Shenk, et al. (2014). Enrollment of Adolescents Aged 16–17 Years Old in Microbicide Trials: An Evidence-Based Approach. *Journal of Adolescent Health.* 54(6), 654-662. <https://reader.elsevier.com/reader/sd/pii/S1054139X14000597?token=E885CEFA75146D3FA2382D0C03BA4A75E3D4528887A1167E46908A1F1367069941B4083AE10534BD6E4324AF0ECFFF9A>
- Ott, Mary A. (2014). Vulnerability in HIV Prevention Research with Adolescents, Reconsidered. *Journal of Adolescent Health.* 54(6), 629-630
<https://reader.elsevier.com/reader/sd/pii/S1054139X14001608?token=3F29F69B96D1D444>

[5F210C09FB14C720193E42500C0A905D0F810B89AE388964AFE67AABF7C28D8C635
DEF044E7B60D9](https://doi.org/10.1002/9781118134461.ch28)

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

Week 9- October 22: Prisoners & Women in Research (TA: Heather)

TOPICS: Human subjects, the scientist in society

- Research with Prisoners – Elizabeth Nelson
- Women in Research – David Haas

READINGS:

Research with Prisoners:

1. Huang, E., Cauley, J., and Wagner, J. (2017). Barred from better medicine? Reexamining regulatory barriers to the inclusion of prisoners in research. *Journal of Law and the Biosciences*, 159-174.
2. Osagie, O.K., Keramet, R.A. (2011). Human Subjects Research with Prisoners: Putting the Ethical Questions in Context. *Bioethics*, 25(1), 55-56.

Women in Research:

3. NICDH PRGLAC Report to Congress. Section 2.
https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf

CASE STUDY:

Research with Prisoners & Women in Research:

- None to read ahead of time; will be incorporated into lecture.

Week 10- October 29: Animals in Research (TA: Katie)

TOPICS: Animals in research, the scientist in society

- Research with Invertebrates – Colin Halverson
- Research with Nonhuman Vertebrates – Nancy Johnston

READINGS:

Research with invertebrates:

1. Friedersdorf, C. (2013). Consider the Lobster Claw: Why a twist on an arcade classic delights and disturbs us. *The Atlantic*.
<https://www.theatlantic.com/technology/archive/2013/03/consider-the-lobster-claw-why-a-twist-on-an-arcade-classic-delights-and-disturbs-us/273977/>

Research with animals:

1. Fuchs, B and Macrina, F. Use of Animals in Biomedical Experimentation. Chapter 6.
2. Rollin, B. (2002). An Ethicist's Commentary on Animal Rights versus Welfare. *Canadian Veterinary Journal*, 43, 913.
3. Goodman, J., Chandna, A., and Roe, K. (2015). Trends in Animal Use at US Research Facilities. *Journal of Medical Ethics*, 41, 567-569.
4. Bailoo, J., Reichlin, T., and Würbel, H. (2014). Refinement of Experimental Design and Conduct in Laboratory Animal Research. *ILAR Journal*, 55(3), 383-391.
5. ARRIVE guidelines at <https://www.nc3rs.org.uk/arrive-guidelines>
6. Skim the NCR3 homepage: <https://www.nc3rs.org.uk/>

CASE STUDY:

Research with invertebrates:

- None to read ahead of time; will be incorporated into lecture.

Research with animals:

- McGreevy, J., et al. (2015). Animal Models of Duchenne Muscular Dystrophy: from basic mechanisms to gene therapy. *Disease Models & Mechanisms*, 8, 195-213.

Unit 3 – Research and Society

Week 11- November 5: Pandemics (TA: Heather)

TOPICS: Collaboration, peer review, research misconduct, responsible authorship

Introduction – Colin Halverson

- Challenge trials – Peter Schwartz
- Virtual research and junk science, special case of COVID – Jody Madeira

READINGS:

Challenge trials:

1. Eyal, N. (2020). Why Challenge Trials of SARS-CoV-2 Vaccines Could Be Ethical Despite Risk of Severe Adverse Events. *Ethics & Human Research*. 42, 1-11
2. Macklin, R. (2020). Human Challenge Studies for Covid-19 Vaccine: Questions about benefits and risks.[Blog Post] *The Hastings Center*, <https://www.thehastingscenter.org/human-challenge-studies-for-covid-19-vaccine-questions-about-benefits-and-risks/>
3. Spinola, S., Zimet, G., Ott, M., Katz, B. (2020). Human Challenge Studies Are Unlikely to Accelerate Coronavirus Vaccine Licensure Due to Ethical and Practical Issues. *The Journal of Infectious Diseases*, <https://doi.org/10.1093/infdis/jiaa457>

4. Eyal, N., Lipsitch, M., and Smith, P. (2020). Human Challenge Studies to Accelerate Coronavirus Vaccine Licensure. *The Journal of Infectious Diseases*, DOI: 10.1093/infdis/jiaa152

Virtual research:

1. RETRACTED. Mehra, M.R., Desai, S.S., Ruschitzka, F., Patel, A.N. (2020). Hydroxychloroquine or Chloroquine with or without a Macrolide for Treatment of COVID-19: a multinational registry analysis. *The Lancet*. [https://doi.org/10.1016/S0140-6736\(20\)31180-6](https://doi.org/10.1016/S0140-6736(20)31180-6)
2. Open letter to MR Mehra, SS Desai, F Ruschitzka, and AN Patel, authors of “Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis”. *Lancet*. 2020 May 22:S0140-6736(20)31180-6. doi: 10.1016/S0140-6736(20)31180-6. PMID: 32450107 and to Richard Horton (editor of The Lancet) Concerns regarding the statistical analysis and data integrity
3. The Lancet Editorial Group. (2020). Learning from a Retraction. *The Lancet*. Published Online September 17, 2020 [https://doi.org/10.1016/S0140-6736\(20\)31958-9](https://doi.org/10.1016/S0140-6736(20)31958-9)
4. Ledford, H. & Van Noorden, R. (2020). High-profile Coronavirus Retractions Raise Concerns About Data Oversight. *Nature*. Published Online June 5, 2020

CASE STUDY:

Challenge trials & Virtual research:

- None to read ahead of time; will be incorporated into lecture.

Week 12- November 12: Culture and Cultural Difference (TA: Katie)

TOPICS: Human subjects, collaboration, research misconduct, the scientist in society, contemporary issues, environmental/societal impacts, responsible authorship and publication, human subjects

Introduction – Colin Halverson

- Cultural Competency in Research – Sylk Sotto
- International research – Megan McHenry

READINGS:

Cultural competency:

1. Betancourt et al. Defining Cultural Competence: A Practical Framework for Addressing Racial/Ethnic Disparities in Health and Health Care.
2. Wilson D, Neville S. (2009). Culturally safe research with vulnerable populations. *Contemp Nurse*.,33 (1),69-79.
3. Dein S. (2006). Race, culture and ethnicity in minority research: a critical discussion. *J Cult Divers*.,13 (2): 68-75.
4. Gil EF, Bob S. (1999). Culturally competent research: an ethical perspective. *Clin Psychol Rev*.,19(1),45-55.

International research:

1. 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
2. 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:

Cultural competency:

- None to read ahead of time; will be incorporated into lecture.

International research:

5. Documenting the health conditions of an indigenous community – From Casebook on Ethical Issues in International Health Research. World Health Organization. 2009.

Week 13- November 19: Citizen Science (TA: Heather)

TOPICS: Collaboration, the scientist in society, contemporary issues, environmental/societal impacts, human subjects, cognitive bias, public media

Introduction – Colin Halverson

- Scientist as Member of Society – Meg Gaffney
- Community Based Research – Mary Ott

READINGS:

Scientist in society:

1. Didier, Elizabeth. “Science and Society – The Scientist as a Responsible Member of Society.” *RCR Fall 2011 Seminar Series*. Tulane University. September 29, 2011.
2. Lucas, Stephen. “The Responsibility of Scientists to Society.” www.ucl.ac.uk/.../The%20responsibility%20of%20scientists%20to%20society.pdf
3. Godwin, R. (2018). We Will Get Regular Body Upgrades: What will humans look like in 100 years? *The Guardian*. <https://www.theguardian.com/lifeandstyle/2018/sep/22/regular-body-upgrades-what-will-humans-look-like-in-100-years>

Community based research:

1. CBPR (Intro) – Chris Flipp. <https://www.youtube.com/watch?v=AePC97aKOJA> (accessed 16 Aug 2019)
2. 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.

3. Yale CARE: Community Alliance for Research and Engagement. Principles and Guidelines for Community-University Research Partnerships.

OPTIONAL READING:

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

CASE STUDY:

Scientist in society:

6. None to read ahead of time; will be incorporated into lecture.

Community based research:

7. Making antenatal care youth-friendly: Starting from the Roots: Using Human Centered Design to Make an Adolescent Pregnancy Program Youth Friendly in Western Kenya.
8. Questions to consider for case study:
 - a. Who is the community?
 - b. What are the benefits of this approach? The potential harms?
 - c. What best practices in community ethics do you see?
 - d. What else could they do?

Week 14- November 26 THANKSGIVING- NO CLASS

Unit 4 – Data

Week 15- December 3: Big Data & Biobanks (TA: Heather)

TOPICS: Human subjects, collaboration, data management, contemporary issues, the scientist in society, data ownership, privacy

Introduction – Colin Halverson

- Big data – Jane Hartsock
- Biobanks – T.J. Kasperbauer

READINGS:

Big data:

1. Harrell, Heather L and Rothstein, Mark A. “Biobanking Research and Privacy Laws in the United States.” *The Journal of Law, Medicine and Ethics*, 44(2016): 126-127.
2. Henderson G et al. “Characterizing biobank organizations in the U.S.: results from a national survey.” *Genome Medicine*, 2013, 5:3.

3. McGregor et al. "Inclusion of Pediatric Samples in an Opt-Out Biorepository Linking DNA to De-Identified Medical Records: Pediatric BioVU." *Clinical Pharmacology and Therapeutics*, February 2013, 93:2.

Biobanks:

1. Price, W. N. & Cohen, I. G. (2019). Privacy in the age of medical big data. *Nature Medicine*, 25, 37-43.
2. Fox, K. 2020. The Illusion of Inclusion — The "All of Us" Research Program and Indigenous Peoples' DNA. *NEJM*, 383, 411-413.
3. Kasperbauer, T.J., Schmidt, K., Thomas, A., Perkins, S., & Schwartz, P. H. (in press). Incorporating biobank consent into a healthcare setting: Challenges for patient understanding. *AJOB Empirical Bioethics*

CASE STUDY:

Big data:

- None to read ahead of time; will be incorporated into lecture.

Biobanks:

- Havasupai Tribe vs. Arizona State University. Harmon A. Indian tribe wins fight to limit research of its DNA. *New York Times*, April 21, 2010

TAKE-HOME FINAL EXAMINATION POSTED TUESDAY, DECEMBER 8

[Week 16- December 10: Learning Healthcare Systems & Data Management \(TA: Katie\)](#)

TOPICS: Data management, the scientist in society

Introduction – Colin Halverson

- Learning Healthcare Systems – Peter Schwartz
- Bias and the Ethics of Machine Learning – Erika Cheng

Coda – Colin Halverson

READINGS:

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

Bias and machine learning:

1. Piano, S. (2020). Ethical Principles in Machine Learning and Artificial Intelligence: cases from the field and possible ways forward. *Humanities & Social Sciences Communications*. <https://doi.org/10.1057/s41599-020-0501-9>
2. O'Reilly-Shah, V. et al. (2020). Bias and Ethical Considerations in Machine Learning and the Automation of Perioperative Risk Assessment. *British Journal of Anaesthesia*. doi: [10.1016/j.bja.2020.07.040](https://doi.org/10.1016/j.bja.2020.07.040)

CASE STUDY:

Learning healthcare systems & Bias and machine learning:

- None to read ahead of time; will be incorporated into lecture.

TAKE-HOME FINAL EXAMINATION DUE TUESDAY, DECEMBER 15