

EPI 828

Responsible Conduct of Research

Fall Semester 2020

Instructor	Dr. David Barondess Associate Professor, Dept. of Epidemiology and Biostatistics, College of Human Medicine
Office	Room 654, West Fee Hall E-mail: barondes@msu.edu
Room	This class is being offered in a fully remote, synchronous format.
Day & Time	Tuesday (4:10-5:00 p.m.)
Office Hours	Ongoing and scheduled as needed.

READINGS

No textbook is required. All required readings are on the Course Syllabus portion of this document – you can simply click on a hyperlink or copy/paste each reading into your browser of choice. For a given week, please read the articles in the order presented, as we will most often discuss the readings in that same order.

OBJECTIVES

This seminar addresses select topics within the broad scope of Responsible Conduct of Research. Our emphasis will be on scientific conduct/misconduct and the protection of human subjects.

D2L Course Name: "FS-20-EPI-828-001"

From time-to-time, I may add a reading(s) that I find interesting and timely. If I do, I will do my best to alert you a week ahead of time.

GRADING

Grades are based on the following:

- (1) Weekly class participation (40%)
- (2) Weekly writing assignments based on required readings (40%)
- (3) Final writing assignment (20%)

All students are expected to come ready to participate in a vigorous discussion concerning the weekly reading assignments. Near the end of this document are additional readings that you may want to access during the semester, or explore during your graduate studies more broadly, and beyond.

MISSED CLASSES

Please advise me ahead of time, as is reasonable, that you will be missing class.

RELIGIOUS OBSERVANCE

Students are able to miss class to observe ANY religious occasion. However, it is your responsibility to catch up the notes on those days you are not in class. I am happy to assist you under these circumstances.

CLASS ETIQUETTE

Lectures are based on critical thinking and engaged participation. Please ensure your cell phone and/or pager is switched to the 'quiet' mode while you are in the Zoom environment. Better yet, shut them off.

ACADEMIC HONESTY

The Department of Epidemiology adheres to the policies on academic honesty as specified in *General Student Regulations 1.0*, *Protection of Scholarship and Grades*, and in the *all-University Policy on Integrity of Scholarship and Grades*, which are included in *Spartan Life: 1998 Student and Handbook and Resource Guide*, and on the MSU Web site.

Please also see the “Spartan Code of Honor -- Academic Pledge Campaign” (bottom of syllabus).

PLAGIARISM

Plagiarism is presenting another person's work or ideas as one's own. You are expected to do your work on all assignments. Students who plagiarize will receive a 0.0 grade on the writing assignment, or even fail the entire course at my discretion.

ACCOMMODATIONS FOR DISABILITIES

If you are a student with a disability who requires reasonable accommodations, please call the OPHS Disability Resource center at 353-9642 (voice) or 355-1293 (TTY). In addition, if a professional has diagnosed you to have a learning disability, please submit your diagnosis and the type of assistance you require *in writing* to me during the first week of classes.

I respectfully acknowledge the historical contributions of Drs. Terry May and Phil Reed to this course offering.

Course Syllabus

September 8: Introduction: Course Mechanics and Expectations

Readings:

Steneck, NH. Fostering Integrity in Research: Definitions, Current Knowledge, and Future Directions. *Science and Engineering Ethics*. 2006. 12(1):53-74.

Martinson, BC., Anderson MS, de Vries, R. Scientists Behaving Badly. *Nature* (Commentary). 2005. 435:737-738.

Ioannidis, JPA. Why Most Published Research Findings Are False. *PLoS Medicine*. 2005. 2(8):0696-0701.

No Writing Assignment due this week.

September 15 & 22 (JP): Protection of Human Subjects

Readings:

Steinbrook, R. Protecting Research Subjects — The Crisis at Johns Hopkins. *N Engl J Med*. 2002 Feb 28; 346(9):716-20.

Levine, CL, Faden R, *et al*. The Limitations of “Vulnerability” as a Protection for Human Research Participants. *Amer J of Bioethics*. 2004. 4(3): 44-49.

Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. *World Medical Association*. Serial on the Internet. Accessed Aug 2017 Aug; 9 pgs.

Declaration of Helsinki: Recommendations Guiding Doctors in Clinical Research. *Bulletin World Health Organization*. 2008. 86(8):652. [Shorter version of above WMA entry]

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, *DHEW Publication No. (OS) 78-0012* (1978).

[Cassell EJ. The Principles of the Belmont Report Revisited: How Have Respect for Persons, Beneficence, and Justice Been Applied to Clinical Medicine. *Hastings Center Report*. 2000. 30\(4\):12-21.](#)

(JP) Tiokhin, L. The First Rule of Appealing Editor's Publication Decisions: Nobody Talks About Appealing Editors' Publication Decisions. July 3, 2020. http://www.the100.ci/2020/07/03/the-first-rule-of-appealing-editors-publication-decisions-nobody-talks-about-appealing-editors-publication-decisions/?fbclid=IwAR1qXAUSed5_3xW6_5OIJIZvjgDI9wi57n0RfU-b_w7T_97NfnSqlFMXWg

Writing Assignment:

Based on the assigned readings, please provide brief answers to the following questions.

Steinbock article:

Describe what went wrong at Johns Hopkins and what might have prevented it.

Levine *et al.* article:

What is a "vulnerable population(s)? How and why do epidemiologists need to pay special attention to them when generating/testing hypotheses and in the context of conceptualizing research designs?

Declaration of Helsinki:

What is the purpose of the Declaration of Helsinki?

Belmont Report:

Explain two distinct reasons (described in the Belmont Report) that could lead to the conclusion that an informed consent process may be flawed.

September 29 & October 6: Protection of Human Subjects -- Informed Consent

Readings:

Flory, J., Emanuel, E. Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review. *JAMA*. 2004. 292(13):1593-1601.

<https://jamanetwork.com/journals/jama/fullarticle/199537>

Committee on Bioethics. Informed Consent, Parental Permission, and Assent in Pediatric Practice. *Pediatrics*. 1995. 95(2):314-317.

<http://pediatrics.aappublications.org/content/pediatrics/95/2/314.full.pdf>

Hoeyer, K., Olofsson, B-E., Mjorndal, T., Lynoe, N. Informed consent and biobanks: a population-based study of attitudes towards tissue donation for genetic research. *Scand J Public Health*. 2004. 32: 224-229.

<https://doi.org/10.1080%2F14034940310019506>

Writing Assignment:

Please provide about 1 typed page addressing the following:

Flory or Hoeyer *et al.* article:

What have you learned about informed consent (in the context of the article you have chosen) that you did not already know? How do you think the article improves a research participant's understanding of informed consent?

Protection of Human Subjects -- Privacy

Readings:

[Rothstein, MA. Is Deidentification Sufficient to Protect Health Privacy in Research? *Amer J Bioethics*. 2010. 10\(9\):3-11.](#)

[Below "summary" is just FYI]

[Summary of the HIPPA Privacy Rule. US Department of Health & Human Resources. Accessed August 2017 \[Last Revised 05/03\]; 23 pgs. https://www.hhs.gov/sites/default/files/privacysummary.pdf](https://www.hhs.gov/sites/default/files/privacysummary.pdf)

Writing Assignment:

Please provide about 1 typed page addressing the following:

Rothstein article:

- a. What is meant by "deidentification?"
- b. What is meant by "reidentification?"
- c. How might problems arise between deidentified records and their commercial exploitation?

October 13 & 20: *Scientific Misconduct*

Readings:

Wakefield AJ. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet*. 1998. Feb 28; 351(9103):637-41.

[Article handed out to class]

[Deer B. MMR Scare. How the Case Against the MMR Vaccine was Fixed. *BMJ*. 2011 Jan 5; 342:c5347. Pp. 77-82. http://www.bmj.com/content/342/bmj.c5347](http://www.bmj.com/content/342/bmj.c5347)

[Deer B. Secrets of the MMR Scare. How the Vaccine Crisis was Meant to Make Money. *BMJ*. 2011 Jan 11; 342:c5258. Pp. 136-142. http://www.bmj.com/content/342/bmj.c5258](http://www.bmj.com/content/342/bmj.c5258)

[Deer B. Secrets of the MMR Scare. The Lancet's Two Days to Bury Bad News. *BMJ*. 2011 Jan 18; 342:c7001. Pp. 200-204. http://www.bmj.com/content/342/bmj.c7001](http://www.bmj.com/content/342/bmj.c7001)

Writing Assignment:

Please provide 1.5-3 typed pages addressing the following:

Wakefield and Deer articles:

What have been the short and long-term consequences for the general public as a result of the Wakefield research paper? How might these consequences have been avoided?

October 27 & Nov 3: *Conflict of Interest*

Readings:

Bekelman, JE, Li Y., Gross, GP. Scope and Impact of Financial Conflict of Interest in Biomedical Research. *JAMA*. 2003. 289(4):454-465.

<https://jamanetwork.com/journals/jama/fullarticle/195843>

Brody H. Clarifying Conflict of Interest. *Am J Bioeth*. 2011. Jan; 11(1):23-8.

<https://www.tandfonline.com/doi/abs/10.1080/15265161.2010.534530>

Rochon, P. *et al*. Financial Conflicts of Interest Checklist 2010 for Clinical Research Studies. *Open Medicine*. 2010. Mar: 4(1):1:E69-E91. [Please read pages E69-E74; glance at the remaining pages.]

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3116675>

Writing Assignment:

1-2 typed pages should be sufficient.

What do you think Bekelman *et al.* and Brody would think of what Rochon *et al.* have to say?
Do you think a comprehensive program to manage conflict of interest at a research institution is necessary?
Why or why not?

November 10 & 17: Plagiarism and Authorship

Readings:

Park, C. In other (People's) Words: Plagiarism by University Students – Literature and Lessons. *Assessment & Evaluation in Higher Education*. 2003. Vol. 28(5): 471-488.

<https://srhe.tandfonline.com/doi/abs/10.1080/02602930301677#.W2HkQkm0VaQ>

Loui, Michael C. Seven Ways to Plagiarize: Handling Real Allegations of Research Misconduct. *Science and Engineering Ethics*. 2002. Vol 8 (4): 529-539.

<https://link.springer.com/article/10.1007/s11948-002-0005-6>

Bird, Stephanie J. Self-Plagiarism and Dual and Redundant Publications: What Is the Problem? Commentary on 'Seven Ways to Plagiarize: Handling Real Allegations of Research Misconduct' (M. C. Loui). *Science and Engineering Ethics*. 2002. Vol 8 (4): 543-544.

<https://link.springer.com/article/10.1007%2Fs11948-002-0007-4?LI=true>

Writing Assignment:

About 2 typed pages should be sufficient.

What do you think about the concept of self-plagiarism? Do you think one can “ethically” self-plagiarize?
What would you say (to him) if C. Park asked you to comment on his article?

November 24 & Dec. 1: Research in International Settings

Readings:

Connor EM, *et al.* Reduction of Maternal-infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment for the Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. *N Engl J Med*. 1994. 331:1173-1180.

<https://www.nejm.org/doi/full/10.1056/nejm199411033311801>

Hoffman CA & Munson, Ronald. Ethical Issues in the Use of Zidovudine to Reduce Vertical Transmission of HIV. *N Engl J Med*. 1995. 332:891-892.

https://www.nejm.org/doi/10.1056/NEJM199503303321314?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

Lurie, Peter & Wolfe, Sidney M. Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries. *N Engl J Med*. 1997. 337:853-856.

https://www.researchgate.net/profile/Peter_Lurie/publication/13926523

Angell, Marcia. The Ethics of Clinical Research in the Third World. *N Engl J Med*. 1997. 337:847-849.

<http://za2uf4ps7f.search.serialssolutions.com/?sid=google&aunit=M&aurlast=Angell&atitle=The+ethics+of+clinical+research+in+the+Third+World&title=The+New+England+journal+of+medicine&volume=337&issue=12&date=1997&spage=847&issn=0028-4793>

Quinn, Thomas C. *et al.* Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1. *N Engl J Med*. 2000. 342:921-929.

<https://www.nejm.org/doi/full/10.1056/NEJM200003303421303>

Angell, Marcia. Investigators' Responsibilities for Human Subjects in Developing Countries. *N Engl J Med*. 2000. 342:967-969.

<https://www.nejm.org/doi/pdf/10.1056/NEJM200003303421309>

Fry, Craig L. Ethical Issues in Obesity Interventions for Populations. *NSW Public Health Bulletin*. 2012. 23(5-6):116-119.

<http://www.publish.csiro.au/nb/pdf/NB12062>

Writing Assignment:

1-2 typed pages should be sufficient.

1. Outline at least two ethical considerations that should be taken into account when using international sites for clinical trials that aim to evaluate the efficacy of pharmaceuticals.

Note: December 1st will be the last class meeting. Between that date and December 8th is the time for you to work on your final writing assignment.

December 8: Final Writing Assignment Due

Details to follow later in the semester.

This assignment must be e-mailed to me by 5:00 p.m. on this date.

Relevant Literature for Those Interested in Reading Beyond the Course Requirements You May Wish to Add to this List as You Read on Your Own Throughout Your Graduate Program

Bechtel, Kendra and Geschwind, MD. [Ethics in Prion Disease](#). 2013. *Progress in Neurobiology*. 110:29-34.

Bohannon, John. [Epidemiology: Author of Iraqi Deaths Study Sanctioned](#). 2009. *Science*. 323:1278.

[Brothers, KB. & Wilfond, Benjamin S. Research Consent at the Age of Majority: Preferable But Not Obligatory](#). 2018. *Pediatrics*. 142:2.

Buchanan, David and Miller, Franklin. [Justice and Fairness in the Kennedy Krieger Institute Lead Paint Study: the Ethics of Public Health Research on Less Expensive, Less Effective Interventions](#). 2006. *American Journal of Public Health*. 96:5.

Clayton, Ellen W. *et al.* [Confronting Real Time Ethical, Legal, and Social Issues in the eMERGE \(Electronic Medical Records and Genomics\) Consortium](#). 2010. *Genet Med*. 12(10):616-620.

Ellerin, Bruce E. *et al.* [Ethical, Legal, and Social Issues Related to Genomics and Cancer Research: The Impending Crisis](#). 2005. *American College of Radiology*. 2:919-926.

Fang, Ferric C. *et al.* [Misconduct accounts for the majority of retracted scientific publications](#). 2012. *PNAS*. 109(42):17028-17033.

Franzen Martina, *et al.* [Fraud: causes and culprits as perceived by science and the media](#). 2007. *European Molecular Biology Organization*. 8(1):3-7.

Greenland, Philip and Fontanarosa, Phil. [Ending Honorary Authorship](#). 2012. *Science*. 337.

Gross, Charles. [Disgrace: On Marc Hauser](#). 2012. *The Nation*.

Kakuk, Peter. [The Legacy of the Hwang Case: Research Misconduct in Biosciences](#). 2009. Springer. 15:545-562.

Karon, Jeff. [A Positive Solution for Plagiarism](#). 2012. *The Chronical of Higher Education*.

Long, Tara *et al.* [Scientific Integrity: Responding to Possible Plagiarism](#). 2009. *Science*. 323:1293-1294.

Staff, Reuters. [Amid Vaccination Debate, U.S. House Leaders Support Inoculations](#). 2015. *Medscape*.

Teixeira da Salva, JA and Dobranski J. Highly Cited Retracted Papers. 2017. *Scientometrics*. 110:1653-1661.

Titus, Sandra L. *et al.* Repairing Research Integrity. 2008. *Macmillan Publishers Limited*. 435(19).

Tubbs-Cooley, Heather L. *et al.* Issues in Research Integrity: Deciding What Is Mine, Yours, and Ours. 2012. *Journal of Pediatric Health Care*. 26(5).

Vahakangas, Kirsi. Research Ethics in the Post-Genomic Era. 2013. *Wiley Periodicals, Inc.* 54:599-610.

(Tuskegee Experiment--The Deadly Deception. Boston. WGBH, 1993) <https://youtu.be/qNa8CnC4sSU>.

MICHIGAN STATE UNIVERSITY

To: Advisors, Deans, Directors, and Chairs
From: Lorenzo Santavicca, ASMSU President (president@asmsu.msu.edu)
Date: August 25, 2017
RE: Spartan Code of Honor – Academic Pledge Campaign

Student leaders have recognized the challenging task of discouraging plagiarism from the academic community. The Associated Students of Michigan State University (ASMSU) is proud to be continuing awareness of the Spartan Code of Honor academic pledge, focused on valuing academic integrity and honest work ethics at Michigan State University. The pledge reads as follows:

"As a Spartan, I will strive to uphold values of the highest ethical standard. I will practice honesty in my work, foster honesty in my peers, and take pride in knowing that honor is worth more than grades. I will carry these values beyond my time as a student at Michigan State University, continuing the endeavor to build personal integrity in all that I do."

The Spartan Code of Honor academic pledge embodies the principles of integrity that every Spartan is required to uphold in their time as a student, and beyond. The academic pledge was crafted with inspiration of existing individual college honor codes, establishing an overarching statement for the entire university. It was formally adopted by ASMSU on March 3, 2016, endorsed by Academic Governance on March 22, 2016, and recognized by the Provost, President, and Board of Trustees on April 15, 2016.

Student conduct that is inconsistent with the academic pledge is addressed through existing policies, regulations, and ordinances governing academic honesty and integrity: Integrity of Scholarship and Grades, Student Rights and Responsibilities, and General Student Regulations.

While the Spartan Code of Honor has been a student-led effort, I continue to ask for faculty support across the MSU community to aid ASMSU in educating our undergraduate students on the importance of this campaign and its efforts.

I encourage you to visit our website at honorcode.msu.edu to learn more about how the Spartan Code of Honor academic pledge is critical to share with your staff and their students. On the website, students are urged to take the pledge, where they can publicly display their commitment to academic honesty with fellow Spartans. Testimonials and resources are also available to both faculty and students, along with locations to improve work ethics, study resources, as well as information related to the Ombudsperson's office and much more.

Lastly, I encourage faculty to include the Spartan Code of Honor academic pledge in syllabi this year. By including the pledge in course syllabi with other notes regarding no-tolerance for academic dishonesty, our MSU community will more closely realize the collective effort to educate our students about the detrimental effects these actions have on our reputation as a world-class institution.

Together, *Spartans Will* remain committed to honesty and integrity in our work – inside, and outside of the classroom.



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