

BEHP 405: Research Ethics
SUMMER 2017

Course Instructor:

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Course Description:

This interactive seminar will explore the responsible conduct of science with a focus on ethical issues in clinical research involving human participants. We will review federal research policies related to investigator responsibilities and institutional review board (IRB) function. Students will become familiar with the history, terminology, and resources of research ethics as well as key debates that have occurred/are occurring in the research ethics literature. Material covered in this course will be relevant for clinical investigators, IRB members, and ethicists.

Course Objectives:

At the end of this course, participants should be able to:

- Discuss the history of human research that lead to current federal policies
- Identify the ethical principles that undergird these policies
- Examine concepts central to research integrity and the responsible, ethical conduct of research
- Analyze dilemmas in specific cases applying ethical and regulatory frameworks for clinical research

Required Text:

Ezekiel J. Emanuel et al., *The Oxford Textbook of Clinical Research Ethics*, 2008

This book is available free through the library with an unlimited number of users (see "Library Texts" tab in Sakai). The textbook is also available on Amazon.com in paperback (fairly inexpensive, but large) and as an e-book.

Note: Other assigned articles or websites will be linked directly from the syllabus.

Grading:

| Assignment | # points | Due Date (your time zone) |
|--|-------------------|----------------------------|
| Weekly participation | 25 points | ---- |
| Completion of CITI training (end of Week 2) | 10 points | Sunday, June 18 (midnight) |
| Short writing assignment (end of Week 5) | 15 points | Sunday, July 9 (midnight) |
| IRB protocol review (end of Week 7) | 25 points | Sunday, July 23 (midnight) |
| Final Exam (end of Week 8/last day of class) | 25 points | Friday, July 28 (noon) |
| TOTAL | 100 points | |

Course Structure/Week by Week Format (Please read carefully)

- Log into the course through Sakai. Check any announcements as you enter the course.
- Look at the **Syllabus** to see the topic and readings for the week.
Note due dates for assignments.
- In **Weekly Lecture Material**: View or read the lecture for the week. Lectures will always be posted by Friday (for the next week starting Monday), usually sooner. Lectures include some notes/thoughts from me on reading materials as well as supplementary videos on the week's topics. Any additional readings not in textbook will also be posted here (they are also hyperlinked to the syllabus).
- The primary activity during the week will take place on the **Discussion Boards**.

Participation in Weekly Discussion (25 points)

- **Discussion each week starts Monday morning and ends Saturday night. Let's all use Sunday to get an early start on the next week. Discussion will be locked and no "make up" posts will be allowed.**
- I will often divide you up into smaller discussion groups each week. Look at the titles of each thread to determine which group you are in based on your last name.
- You are expected to post **at least 3 times and no more than 5 times** during each week. Your first post should be no later than Wednesday midnight. At least one of your posts should engage something another person has said in the discussion. If there are 2 questions for a given week (2 threads), you need to respond at least once in each thread.
- Posts should be between 100 and 250 words. Don't ramble or go off on a tangent. Don't regurgitate class readings. Don't try to impress us with your eloquence. You'll find that other students are more eager to engage with you if you are clear, concise, and to the point. Do say something interesting or provocative, raise a question about something someone (me, a classmate, and author) has said, or respond to a question with a thoughtful, concise solution. Be respectful (this should go without saying.) Share how the reading applies (or not) to your own experiences as researchers, IRB members, or research participants.
- If you go over the maximum number of 5 postings per week, post really long posts, do not post by Wednesday midnight, or do not engage other students' posts, you will lose points.
- *Don't feel like you have to complete all the assigned readings before your first post.* Make sure you've read/watched/listened to something to orient you to the discussion. But you need not have covered everything before posting in order to participate intelligibly.
- I will monitor the Discussion Board (checking in at least daily) but may not always participate in the discussion right away – I want you all to take the lead.
- There will also be a separate "Technical Issues and Housekeeping" discussion thread where you can post questions – chances are your fellow students will have better or quicker answers than me!
- There will also be a "Research Ethics in the News" thread where anyone can post anything related to research ethics (e.g., current news items, etc.). (No one is required to read or post anything here.)
- **You can miss 1 week of discussion (i.e., everyone gets one "free" week).** No need to ask permission or let me know in advance. This is for those little emergencies that come up.

Completion of CITI online training (10 points) DUE midnight SUNDAY JUNE 18 (end of Week 2)

CITI (www.citiprogram.org) is a human subjects protection and research integrity training program. This is by far the most popular and comprehensive training program in human subjects protection. Completion of this program required for researchers and IRB members at most institutions. CITI is free to all members of the Loyola community. Completing CITI will take approximately 3-6 hours (which is why there is no reading or lecture in Week 2 – but there is discussion). You can stop, exit, and re-enter as many times as you'd like. Remember to save your ID and password. **Proof of completion must be uploaded to Sakai. See the Assignments tab for specific instructions (public health students have additional requirements).** If you have completed CITI training within the last 2 years, you can upload proof of prior completion and receive full points. Completing CITI provides a nice overview of human research ethics and a common knowledge base/vocabulary as we continue discussion in future weeks.

Short Writing Assignment (15 points) (DUE midnight SUNDAY JULY 9 (end of Week 5)

This will be an essay of approximately 1200-1500 words, answering a targeted question using course readings and concepts (e.g., NOT an original research paper). **See the Assignments tab for specific instructions.**

IRB Protocol Review Assignment (25 points) DUE midnight SUNDAY JULY 23

You will be required to complete a written review of a mock IRB protocol, applying the concepts you have learned throughout the course. **See the Assignments tab for specific instructions.**

FINAL EXAM (25points) DUE by NOON FRIDAY JULY 28

The open book, timed final exam will consist of 25 questions, each worth 1 point (some will give partial points). You will have 2 hours to complete the exam – once you open the exam, you must complete it. The exam will open on Monday July 24 around noon CST and close at noon CST on Friday July 28.

Optional Live Adobe Connect Sessions

There will be **4 live Adobe Connect sessions** held throughout the semester. Students are encouraged but not required to participate in these calls. These will last about 1 hour and will be held at varying times. All calls will be archived. **All times are Central Time.**

Week 1 – Introduction to class: Monday June 5, 4:30 – 5:30 pm CST (probably won't last full hour)

Week 3 – Federal Regulations: Monday June 19, 12:00 – 1:00 pm CST

Week 6 – Vulnerability: Thursday July 13, 5:00 – 6:00 pm CST

Week 7 – Final Exam Review – Wednesday July 19, 6:00 – 7:00 pm CST

WEEKLY READING ASSIGNMENTS AND DUE DATES

Week 1: What is Research?/The Research Imperative/Frameworks

Monday June 5 – Sunday June 11

Textbook Chapters

- 21: Nature, Scope, & Justification of Clinical Research (Levine)
- 22: Four Paradigms of Clinical Research and Research Oversight (Emanuel and Grady)
- 11: An Ethical Framework for Biomedical Research (Emanuel et al)

Is Research a Moral Obligation? (Chapter 3)

https://bioethicsarchive.georgetown.edu/pcbe/background/callahan_paper.html

“Lies, Damned Lies, and Medical Science”

<http://www.theatlantic.com/magazine/archive/2010/11/lies-damned-lies-and-medical-science/308269/>

Adobe Connect Live Session – Introduction to class, Monday June 5, 4:30-5:30 pm CST

Week 2: CITI Training Modules

Monday June 12 – Sunday June 18

NO ASSIGNED READINGS – there IS DISCUSSION this week

Proof of completion of CITI online training due by midnight, Sunday June 18 (5 points)

See Assignments Tab for specific instructions

Note: CITI training covers much of the history of abuse of research participants. Your textbook chapters 1-10 cover specific incidents, and I encourage anyone who is interested to read more.

Week 3: Research Ethics History/Codes of Ethics for Research/Federal Regulations

Monday June 19 - Sunday June 25

Textbook Chapters

- 12: The Nuremberg Code (Optional)
- 14: The Belmont Report (Optional)
- 15: Regulations for Protection of Humans in Research in US: Common Rule (Porter and Koski)

Nuremberg Code: <http://www.ushmm.org/information/exhibitions/online-features/special-focus/doctors-trial/nuremberg-code>

Belmont Report: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

CIOMS Guidelines: <http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-EthicalGuidelines.pdf>

The Code of Federal Regulations, 45 CFR 46 (The Common Rule):

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Adobe Connect Live Session – Federal Regulations, Monday June 19, 12:00 - 1:00 CST

Week 4: Informed Consent

Monday June 26– Sunday July 2

Textbook Chapters

- 55: A History of Informed Consent in Clinical Research (Blacksher & Moreno)
- 56: Philosophical Justifications of Informed Consent in Research (Brock)
- 57: Legal and Regulatory Standards of Informed Consent in Research (Capron)
- 58: The Therapeutic Misconception
- 59: Empirical Issues in Informed Consent for Research

Note: For those who are interested in reading more: Chapters 27 (emergency research), 30 (deception), 36 (incentives), 41 (decision making capacity), and 60 (assent/pediatric research) cover other important informed consent-related topics.

Week 5: Institutional Review Boards and Risks and Benefits in Research (Fourth of July Holiday)

Wednesday July 5 – Sunday July 9

DISCUSSION STARTS WEDNESDAY; ONLY 2 POSTINGS REQUIRED

Textbook Chapters

- 50: The Origins and Policies that Govern Institutional Review Boards (McCarthy)
- 51: Models of Institutional Review Board Function (Bowen)
- 47: Risk-Benefit Analysis and the Net Risks Test (Wendler and Miller)
- 48: Assessing and Comparing Potential Benefits and Risks of Harm (King and Churchill)

Short Writing Assignment Due midnight Sunday, July 9

Week 6: Fair Selection, Vulnerability, and Justice

Monday July 10 – Sunday July 16

Textbook Chapters

- 35: What Is Fair Participant Selection? (Meltzer and Childress)

Vulnerability in Research Subjects: A Bioethical Taxonomy, pp. G1-G13

<http://bioethics.georgetown.edu/nbac/human/overvol2.pdf>

“Special Scrutiny”: A Targeted Form of Research Protocol Review (Levine et al)

<http://www.knepk.litbang.depkes.go.id/knepk/kegiatan/basic/readings/ethicsreview/levine.pdf>

Note: Chapters 38-46 cover specific special populations. I encourage further reading in a population of interest. BEHP 431 Advanced Topics covers ethical issues related to various special populations in research for those who are interested in taking another research ethics course!

Adobe Connect Live Session – Vulnerability, Thursday July 13, 5:00 – 6:00 pm CST

Week 7: Equipoise and Randomization/Placebo Controlled Trials

Monday July 17 – Sunday July 23

Textbook Chapter

24: Equipoise and Randomization (Joffe and Truog)

25: The Ethics of Placebo-Controlled Trials (Miller)

Adobe Live Session – Review for Final Exam – Wednesday July 19, 6:00 –7:00 pm CST

IRB Review Assignment due midnight Sunday July 23

Week 8: Research with Human Tissue Samples

Monday July 24 – Friday July 28

Textbook Chapters

28: Research with Biological Samples (Wendler)

“Taking the Least of You,” Rebecca Skloot

http://www.nytimes.com/2006/04/16/magazine/16tissue.html?_r=0

Final Exam Due by noon Friday July 28