

Course: MED255, the Responsible Conduct of Research

Time & Location: Variable; for current information on upcoming discussion sections please see: <http://med.stanford.edu/bioethics/education/rcr/Med255Schedule.html>

Instructors:

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The Responsible Conduct of Research class helps students think about how to identify and approach ethical dilemmas that commonly arise in biomedical research. The course covers issues in the practice of research such as peer review, authorship practices, and scientific publications; data acquisition, ownership, sharing, management, and interpretation; rigor and reproducibility; research involving human participants/subjects; the use of laboratory animals in scientific research; conflicts of interest; intellectual property; the role of scientists in society; and collaborative research and partnerships with industry. Satisfactory completion fulfills NIH/ADAMHA requirement for instruction in the ethical conduct of research.

Prerequisite: research experience recommended. This is a single day, 8-hour course.

Expectations & Grading:

Students will be expected to complete the pre-class assignment (the Study Guide) by watching all required videos at <http://med.stanford.edu/bioethics/education/rcr/med-255-videos.html>. The Study Guide is due before the discussion section of the class. Each hour/session of the discussion section is guided by 9 real-world cases. The cases revisit and ground group discussion on each of the topics introduced in the pre-class videos and reflection exercise. Students are expected to participate fully and contribute meaningfully to class discussions to satisfactorily complete course requirements. Students are also encouraged to bring up ethical challenges that they have heard about or experienced themselves in research.

The Honor Code

Violating the Honor Code is a serious offense, even when the violation is unintentional. The Honor Code is available at:

<http://www.stanford.edu/dept/vpsa/judicialaffairs/guiding/honorcode.htm>

You are responsible for understanding the University rules regarding academic integrity; you should familiarize yourself with the code if you have not already done so. In brief, conduct prohibited by the Honor Code includes all forms of academic dishonesty, among them copying from another's exam, unpermitted collaboration, and representing as one's own work the work of another. If you have any questions about these matters, see your lecturer during office hours.

FERPA: Student Record Privacy Policy

<http://studentaffairs.stanford.edu/registrar/students/ferpa>

Students with Disabilities

Students with Documented Disabilities

Students who may need an academic accommodation based on the impact of a disability must initiate the request with the Office of Accessible Education (OAE). Professional staff will evaluate the request with required documentation, recommend reasonable accommodations, and prepare an Accommodation Letter for faculty dated in the current quarter in which the request is being made. Students should contact the OAE as soon as possible since timely notice is needed to coordinate accommodations. The OAE is located at 563 Salvatierra Walk (Phone: 723-1066, URL: <http://oae.stanford.edu>).

RCR Optional Reference Readings

Session 1: Authorship, Publication and Inventorship

- Committee on Publication Ethics (COPE): How to handle authorship disputes: a guide for new researchers.
- COPE: What Constitutes Authorship? COPE Discussion Document
- ICMJE guidelines for Authors and Contributors: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>
- Stanford Policies:
 - Academic Authorship: <https://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/academic-authorship>
 - Multi-Authored Research Papers: <https://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/multi-authored-research-papers>

Session 2: Integrity and Information

- Resnick DB. What is ethics in research & Why is it important? 2015. NIH. <https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm>

Session 3: Safe Research Environment

- Bennett, L. M., Gadlin, H., & Marchand, C. (2010). *Collaboration and Team Science Field Guide*. 139.
- Dewsbury, B., & Seidel, S. (2020). Reflections and Actions for Creating an Inclusive Research Environment. *Current Protocols Essential Laboratory Techniques*, 21(1), e43. <https://doi.org/10.1002/cpet.43>
- The Lab: Avoiding Research Misconduct: <https://oric.research.wvu.edu/services/responsible-conduct/education-training/-the-lab-interactive-learning-simulation>

Session 4: Conflicts of Interest

- Stanford University Conflict of Interest Documents: <https://doresearch.stanford.edu/research-scholarship/conflicts-interest>
- Stanford School of Medicine Conflict of Interest Policy: <http://med.stanford.edu/coi/overview.html>
- NIH Financial Conflict of Interest Policy: <https://grants.nih.gov/grants/policy/coi/index.htm>
- NSF Conflict of Interest Policy: <https://www.nsf.gov/policies/conflicts.jsp>

Session 5: Regulatory Basics

- **Animal**
 - Stanford University Research Compliance Office: Administrative Panel on Laboratory Animal Care (Aplac): <https://labanimals.stanford.edu/>
 - NIH: <https://grants.nih.gov/grants/olaw/olaw.htm>
 - International Animal Research Regulations: Impact on Neuroscience Research: Workshop Summary, Chapter 8
- **Human**
 - Belmont Report: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
 - Stanford University Research Compliance Office: Human Subjects and IRB http://humansubjects.stanford.edu/new/policies_regulations/index.html
 - Office for Human Research Protections (OHRP): Regulations and Policy: <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>
 - Office of Research Integrity (ORI), Health and Human Services (HHS). Chapter 2: Research in Humans: <https://ori.hhs.gov/education/products/ucla/chapter2/default.htm>

Session 6: Collaborative Research

- Korenman, S. History of Rules About Research in Humans. Teaching the Responsible Conduct of Research in Humans. : <https://ori.hhs.gov/education/products/ucla/chapter2/page00.htm>
- Policy Regarding Human Subject Research in the Sociobehavioral Sciences. The Penbrook. University of Pennsylvania. (2009).
- Regulatory Changes in ANPRM. United States Department of Health and Human Services. Office for Human Research Protections.: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-changes-in-anprm/index.html>
- US Department of Health & Human Services FAQs on Human Research: <http://www.hhs.gov/ohrp/policy/faq/>

Session 7: Human Biological Materials

- Taking the Least of You by Rebeca Skloot, NY Times Magazine, April 16, 2006.
- Moore v. Regents of the University of California: <https://www.casebriefs.com/blog/law/property/property-law-keyed-to-cribnet/non-traditional-objects-and-classifications-of-property/moore-v-regents-of-the-university-of-california-2/>
- Greenberg v. Miami Children’s Hospital Research Institute: <https://www.casebriefs.com/blog/law/health-law/health-law-keyed-to-furrow/regulation-of-research-involving-human-subjects/greenberg-v-miami-childrens-hospital-research-institute/>

Session 8: Societal Responsibility

- Beckwith, J., & Huang, F. (2005). Should we make a fuss? A case for social responsibility in science. *Nature Biotechnology*, 23(12), Article 12. <https://doi.org/10.1038/nbt1205-1479>
- Bird SJ. Socially responsible science is more than just “Good Science.” 2014. *J Microbio Biol Educ.* 2014;15(2):169-172.
- Resnik, D. B., & Elliott, K. C. (2016). The Ethical Challenges of Socially Responsible Science. *Accountability in Research*, 23(1), 31–46. <https://doi.org/10.1080/08989621.2014.1002608>

- Sweeney, L. (2010). Privacy Issues Overlooked. *Modern Healthcare*, Sept. 9, 2010.

Session 9: Data Acquisition and Analysis, Laboratory Tools, and Recordkeeping Practices

- Data Curation Network CURATED Training Modules: <https://datacurationnetwork.github.io/CURATED/>
- National Institute of Health DMP resources: <https://sharing.nih.gov/data-management-and-sharing-policy/data-management>
- NIH DMP sample plans (13 plans/templates): <https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#sample-plans>
- OECD. (2018). *Storage and retention of records and materials* (pp. 153–160). OECD. <https://doi.org/10.1787/9789264304796-15-en>