Introduction to Ethics in Research

- Why are ethical norms important in research?
Ethical norms are important because they:

1. advance the aims of research, such as knowledge, truth, and avoidance of error (Domain 1);
2. promote accountability to the public (Domain 2);
3. promote fairness and accountability in collaborative work (Domain 3); and
4. advocate for moral and social values, such as social responsibility and protection of research subjects (Domain 4) (Resnik, 2011).
Student Learning Outcomes, Domain 1

- Students will be able to:
  - Describe the importance of ethical standards in research to promote knowledge, truth, and avoidance of error in research.
  - Evaluate a professional code of ethics to identify research-related standards.

Critical Dialogue: Activity 1

- Working in groups of 2-3 students, develop a list of ethics considerations necessary for research to:
  - produce knowledge,
  - maintain truth,
  - and avoid error.
Critical Dialogue: Activity 2

- Use a code of ethics developed for practitioners in your field of study to inform your work. Be prepared to discuss the list of key ethics considerations you develop. Also, be prepared to reflect on how your respective codes of ethics affect various areas of practice.

Readings/Source Materials:

Ethics to Promote Accountability to the Public

Student Learning Outcomes, Domain 2

- List at least five guidelines to promote scientific integrity in funded research.
- Discuss strategies to address key threats to scientific integrity.
- Evaluate potential impacts on individuals and populations served by the profession when ethical standards of research are not upheld.
- Critique the peer review process.
Nicklas, Kamally, and O’Neill (2011)

1. What are major funding sources for research?
2. What is “white hat bias”?
   ▶ Is it always related to industry funding?
3. What are some examples of ethical violations?
   ▶ From what is scientific misconduct thought to stem?
4. How would you summarize the ten guidelines for ethical industry-funded research presented in the article?
Ten Guidelines for Industry-Funded Research

1. Require a signed full disclosure of funding sources and financial interests in publications, conference presentations, and media releases.
2. Ensure that there is no conflict with the confidentiality agreement signed by the Principal Investigator and the funding agency.
3. Establish up-front control and ownership of the data by the Principal Investigator but provide accessibility to the data and statistical analyses to the funding agency and other appropriate entities.
4. Plan the research so that it is designed objectively and scientifically sound in its approach and analytical plan.
5. Generate clearly stated a priori research questions or hypotheses rather than those generated a posteriori or using a preconceived conclusion.

6. Ensure that the Principal Investigator maintains control of all aspects of the study and has the final authority on the design or conduct of the study; the collection, management, analysis, or interpretation of the data; and the preparation and approval of the peer-reviewed manuscript.
7. Make certain that publications do not favor a particular outcome or that unfavorable findings are not withheld from the scientific community. The Principal Investigator must retain full rights to publish all results, including those unfavorable to the client.
8. Invite the client to submit comments on a sponsored article under the strict stipulation that the Principal Investigator has the ultimate control of content.
9. Maintain objectivity in the interpretation of the results so that they are not biased and that a balanced discussion is presented based on the available science.
10. Ensure that all presentations are developed fully and media releases are endorsed by the Principal Investigator.
1. What are some examples of conflicts of interest?
   - Principle #12, AND Code of Ethics
     - The dietetics practitioner is alert to situations that might cause a conflict of interest or have the appearance of a conflict. The dietetics practitioner provides full disclosure when a real or potential conflict of interest arises.
     - What sorts of policies are in place to minimize potential conflicts of interest?


3. How does research related to new products potentially impact beneficence and nonmaleficence?

4. Why are manufacturer-funded studies more likely to result in favorable outcomes?

5. What federal policy exists related to conflicts of interest in research? (NIH)

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Conflict of Interest, defined

- “The term individual financial conflict of interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research. The bias such conflicts may conceivably impart not only affects collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.”

- Association of American Medical Colleges, 1990
Rowe et al. (2009)

1. What is the role of industry funding in research?
2. What are some examples of scientific and publication bias?
   - What are some checks in place to reduce bias?
3. How do the ILSI guidelines presented in this article compare to the AND guidelines (slides 13-14)?

Rowe et al. (2009)

In the conduct of public/private research relationships, all relevant parties shall:

1. Conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome;
2. Require control of both study design and research itself to remain with scientific investigators;
3. Not offer or accept remuneration geared to the outcome of a research project;
4. Ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame;
Rowe et al. (2009)

5. require, in publications and conference presentations, full signed disclosure of all financial interests;
6. not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;
7. guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers; and
8. require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.

International Life Sciences Institute, North American Group on Working Principles

Domain 2, Summary

1. What are example strategies to address key threats to scientific integrity at each of the following phases?
   - Design
   - Execution
   - Reporting (including interpretation)
   - Publishing
2. How can individuals and populations be affected when ethical standards of research are not upheld?
3. What is the role of the peer review process in promoting accountability to the public?
Readings/Source Materials:


Reaction Paper: Threats to Scientific Integrity (15 minutes)

- You have learned about threats to scientific integrity, and how ethics standards can help diminish the impacts of these threats. Thinking of threats to scientific integrity we discussed, choose two threats that are most concerning to you. Indicate why these threats concern you. How can strategies discussed in class work to limit the threats?
Ethics to Promote Fair Collaborations

Student Learning Outcomes, Domain 3

- Describe key considerations in research to promote collaboration while protecting intellectual property.
- Discuss guidelines for authorship in place by respected professional journals in a given field.
What are the benefits of collaboration?
What kinds of standards are necessary to foster fair collaborations?

Homer & Minifie (2011)

1. What are the characteristics of a good research mentor? In what capacity do you see yourself mentoring future practitioners? What skills will you need to develop to improve your mentoring capacity?
2. What sorts of ethics considerations are introduced by an environment of increasing collaboration?
3. What is peer review intended to accomplish? What are the limits of peer review?
4. What is meant by the following statement, “Statistically speaking, science suffers from an excess of significance.” (Ioannidi & Hotz, 2007)
Ritter-Gooder, Lewis, & Delserone (2011)

1. Take a look at author rights described on the website of a journal in your field. Be able to describe author rights to your classmates for the selected journal.
2. Discuss the scenarios 1-3 described in the article. Select one to share with the class and elicit feedback.

Washburn (2008)

1. What types of considerations should be made related to authorship policies?
2. How should authorship order be determined?
3. Discuss cases 1-4 in the article. Select one to share with the class, and elicit their feedback.
4. What can authorship policies accomplish? How can such policies promote fair collaboration?
Research Journal Authorship Guidelines

- Visit the site of a selected research journal in your field. Review guidelines for authorship (if present). Some journals require author roles in preparing the manuscript to be delineated.
- Do you think this is a good requirement? Why or why not?
- What are the author guidelines for your chosen journal? Could they be improved? If rules on authorship are not present, what do you think should be included?

Readings/Source Materials:

Student Learning Outcomes, Domain 4

- Describe basic ethical principles for research involving human subjects, including respect for persons, beneficence, and justice.
- Evaluate key ethical considerations related to subject selection.
- Develop a list of risks and benefits to human subjects related to a given research design.
- Develop an informed consent form using an Institutional Review Board template.
Treatment of Subjects

- WW II Nazi trials: forced prisoners into “medical torture” resulting in dismemberment or death (no consent)

- Tuskegee Syphilis Study (1930s-70s): black, rural residents of Alabama were studied for “bad blood” (researchers wanted to study syphilis progression) and were not treated though treatment was available (treatment withheld)

- Milgram Obedience Studies (Yale, 1961): “fake” shock given to an “actor” by the “subject” to see how high the subject would make the shock (debrief issue, stress to subject)

Major Acts of Legislation

1. National Research Act (Public Law 93-348, 1974)
   - Human subjects review committee
   - Subjects must be informed and give consent
   - Must be approved
   - National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
     - Belmont Report (1979)

   - “Buckley Amendment”
   - Provides confidentiality of student records

3. HIPAA (Public Law 104-191, 1996)
   - Health Information Portability and Accountability Act
   - Protection of medical information
Belmont Report: Respect for Persons

- Acknowledges autonomy (i.e., individuals should be treated as autonomous agents)
- Protects those with diminished autonomy (i.e., people with diminished autonomy are entitled to protection)
- Requires voluntary and informed participation

Belmont Report: Beneficence

- Do no harm
- Maximize benefits and reduce risks
Belmont Report: Justice

- Who ought to bear the burden of research? Who ought to reap the benefits of research?

What do these principles achieve?
What do these principles achieve?

- Voluntary participation/informed consent
- Research that balances risks and benefits
- Fairness in subject selection (as well as distributing benefits)

Case 1: Orphans and Speech

- “An Experimental Study of the Effect of Evaluative Labeling on Speech Fluency,” 1939
  - Evaluated the diagnosogenic theory of stuttering
  - Subjects:
    - 22 orphans, 10 stutterers at baseline, 12 normal speakers
    - Labeled half in each group as stutterers and evaluated effects

- Discuss ethical considerations of this study design related to voluntary participation, balance of risks and benefits, and subject selection.
Case 2: Body Image in College Students

Imagine you are developing a survey to implement with introductory nutrition students at CSULB to assess body image and its relationship to demographic characteristics. You plan to offer extra credit to study participants.

Discuss this study in light of the three ethical principles outlined in the Belmont Report (respect for persons, beneficence, and justice).

Work in teams to develop language for your assigned section of the informed consent document. Use the template on the CSULB IRB website:

http://web.csulb.edu/divisions/aa/research/compliance/humans/

Case 2: Teams

1. Purpose
2. Procedures
3. Potential Risks and Discomforts
4. Benefits to Subjects and/or Society
5. Confidentiality
Readings/Source Materials:


Additional Resources:

Scientists should continue to do research. But if a human being is ever used in the experiments, the scientists must make a moral commitment never to violate a person’s human rights and dignity. The scientist must respect the wishes of the subjects. The scientists of the world must remember that the research is done for the sake of mankind and not for the sake of science; scientists must never detach themselves from the humans they serve.”

Eva Mozes-Kor (1992)