Ethical Considerations in Research

Clinical Translational Research Fellowship Program
Curriculum Core

Clinical and Translational Science Institute / CTSI
Bringing better health to more people more quickly!
Objectives

- Increase awareness of ethical considerations in the conduct of research.
  - What are ethics?
  - What are common ethical dilemmas in the conduct of research:
    - Informed consent
    - Research misconduct
    - Conflicts of interest
    - Authorship
  - Resources
Ethics

- Method, procedure, or perspective for deciding how to act and for analyzing complex problems and issues

Basic Ethical Principles in Human Research

- The Belmont Report (1974) summarizes three basic ethical principles relevant to research involving human subjects.
  - Respect for persons
  - Beneficence
  - Justice
Respect for Persons

• Individuals should be treated as autonomous agents
  – The investigator must ensure that the subject has received a full disclosure of the nature of the study, the risks, benefits and alternatives, with an extended opportunity to ask questions.

• Persons with diminished autonomy are entitled to protection
  – Persons with diminished autonomy (e.g., prisoners, students, children, etc) should not be coerced to participate in a research
Beneficence

• Maximize possible benefits and minimize possible harms
  – The investigator should give forethought to the maximization of benefits and the reduction of risk that might occur from the research.
Justice

• Fairness in distribution
• Justice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly
• Equitable selection of participants
What are selected ethical dilemmas in research?

- Informed consent
- Misconduct in research
- Conflicts of interest
- Authorship

Case study: Informed consent

- You are studying an association between the Ares gene and Mars disease, a rare genetic disorder. Today you are recruiting a Martian subject and Martian people are known to carry a rare variant of the gene. When interviewing the subject, you discover the subject who speaks limited English seems to be interested in the study. Unfortunately, Martian translators are unavailable today and the subject does not seem to fully understand the study. Since your study does not have an invasive procedure and collects only mouth wash samples, you wonder if you can go ahead and enroll the subject.

- Case study adapted from: [http://www.actsi.org/areas/erks/ethics/index.html](http://www.actsi.org/areas/erks/ethics/index.html)
Guide to The Case

• The Martian subject is unlikely to fully understand the study due to the language barrier at this time. Enrolling this subject into the study violates one of the three basic ethical principles (i.e., respect for persons). Thus, the subject should not be enrolled until s/he fully understands the study with the help of a Martian translator.
Case study: Misconduct in research

• You are helping your close collaborator’s study in a lab. The study involves collecting blood over 6 hours in human subjects. You have made sure that you put correct labels on the blood collection tubes. When the study is over, your collaborator takes the tubes to store in a refrigerator. Two days later, you find that the labels on the tubes have been changed to make it appear that they were collected over a period of two weeks.

• Case study adapted from: [http://www.actsi.org/areas/erks/ethics/index.html](http://www.actsi.org/areas/erks/ethics/index.html)
Guide to The Case

• According to the U.S. Department of Health and Human Services Office of Research Integrity (ORI), research misconduct is defined as the “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”
Guide to The Case

• In addition, according to the *Guidelines for Responsible Conduct of Research issued by ORI*, reporting suspected research misconduct is a shared and serious responsibility of all members of the academic community. Any person who suspects research misconduct has an obligation to report the allegation to the dean of the unit in which the suspected misconduct occurred or to the Research Integrity Officer.
Guide to The Case

• In this case, your collaborator should be able to provide a reasonable explanation on the label change. If the explanation is not reasonable and/or data fabrication is highly suspected, it should be reported to the University Research Integrity Officer.

  – http://compliance.ucsf.edu/IntegrityOfResearchNotice.html
Case study: Conflicts of interest

• You have decided to submit your first abstract ever for a national conference. Preliminary data are very promising and likely to draw a lot of attention if the study is complete. Although the deadline of the abstract is just two weeks ahead, you still need 1 more healthy volunteer to complete the study. Hearing about your problem, your colleague suggests, “Why don’t you enroll yourself?”

• Case study adapted from: http://www.actsi.org/areas/erks/ethics/index.thml
Guide to The Case

• The investigator’s participation in his/her research may pose several problems.
  – Risks to his or herself if risks are unknown
  – Skew or bias his or her test results

• Due to these problems, it is generally recommended that the investigator should not participate as a research subject in his or her study.
Case study: Authorship

While you are uploading a paper to a journal’s website for submission, you get a phone call from one of your co-authors requesting to add two more names to the paper. The paper has been approved by all of your co-authors and these two people helped only enroll three more subjects in the study with 200 subjects. The requester is well-known in your field and you need his help with your post-graduate job search.

Case study adapted from: http://www.actsi.org/areas/erks/ethics/index.thml
Guide to The Case

- Misrepresentation of any form is wrong in scientific research
- Authorship requires “significant intellectual contribution”
Summary

Many resources are available at UCSF for the ethical conduct of research

• UCSF Human Research Protection Program
  – http://www.research.ucsf.edu/chr/About/chrAbout.asp

• UCSF Office of Ethics and Compliance:
  – http://compliance.ucsf.edu/IntegrityOfResearchNotice.html
Selected resources

  – [http://pediatrics.aappublications.org/content/125/4/850.full.pdf+html](http://pediatrics.aappublications.org/content/125/4/850.full.pdf+html)

• Atlanta Clinical & Translational Science Institute. (2008): Ethical dilemmas in scientific research and professional Integrity

• Resnik, DB. (2010). What is Ethics in Research & Why is It Important? NIEHS.
Additional resources

• The Belmont Report

• Lo, B. (2009). Ethical Issues in Clinical Research: A Practical Guide. Lippincott Williams & Wilkins
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