

“HOT TOPICS IN RESEARCH” : SUMMARY OF SOME BASIC ISSUES

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The following outline illustrates some basic legal and regulatory issues that may arise in research. It is intended to guide attendees through our presentation and does not constitute legal advice. If questions about these issues arise, the institution’s legal counsel should be consulted.

- I. Human Subjects Research
 - A. Fundamental issue: Protecting the rights of people who volunteer to participate in research
 - B. Resources:
 - 1. Department of Health and Human Services Office, for Human Research Protections (hhs.gov/ohrp)
 - 2. 45 CFR Part 46
 - 3. College/university policies
 - C. What “research” is covered?
 - 1. Federal definition: Systematic investigation designed to develop or contribute to generalizable knowledge (also check institutional definition)
 - 2. Federal regulations cover research supported with federal funding
 - 3. College/university policy may apply to all institutional research involving people (regardless of funding)
 - D. Levels of Institutional Review Board (IRB) review

1. Exempt
2. Expedited
3. Full board

E. Key concepts

1. Informed consent – understand the nature of voluntary participation in the research and the possible risks and benefits (construed broadly)
2. Voluntary – no coercion (real or perceived)
3. Risks – include physical, emotional, financial, reputational, legal
4. Benefits – to the individual and to the public

F. Social and behavioral research

1. Examples; Contrast with medical and bioscience protocols
2. General issues: research should be well-designed, participants should be selected to support meaningful research conclusion
3. Special populations – minors, prisoners, pregnant women and fetuses, mentally disabled, vulnerable
4. Certificates of confidentiality: Provide additional protection for participants in studies collecting information that, if disclosed, could have adverse consequences for participants, such as damage to their financial standing, employability, insurability, or reputation
 - a) Certificate states that researcher can't be compelled to turn over information about participants (e.g., for use in lawsuits)
 - b) Certificates are issued by NIH
 - c) Additional information is available at:
www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm
5. All changes to protocols, consent forms, other approved documents or practices must be approved by the IRB

G. Possible consequences of failing to follow regulations or poorly performed research

1. Harm to individuals
2. Misuse of resources
3. Credibility of research

II. Research Misconduct

- A. Fundamental issue: Protecting the integrity of research against misconduct that occurs in the conduct or reporting of research
- B. Resources
 1. Office of Research Integrity (ORI) (<http://ori.dhhs.gov/>)
 2. College/university policy
- C. What “research” is covered?
 1. Federal regulations apply to federally funded research
 2. Institutional policies may be broader
- D. Examples of misconduct: misrepresenting credentials, plagiarism, falsifying data (federal rules do not apply to authorship disputes unless plagiarism is alleged)
- E. Federal model policies and procedures anticipate 2 part process
 1. Inquiry Process to determine if sufficient allegations to merit full investigation
 2. Investigation Process is more detailed and comprehensive
- F. Process issues
 1. Allegations tend to be stigmatizing
 2. Confidentiality is important
 3. If no basis to pursue allegations or if allegations not supported, consider what steps need to be taken to remediate reputational harm to the researcher

III. Intellectual Property

- A. Fundamental issue: Providing an incentive for inventors and authors (including institutions) to create and disseminate new and creative work or discoveries
- B. Resources
 - 1. Federal law
 - a) Patents --U.S.C. Title 35
 - b) Copyrights -- U.S.C. Title 17
 - c) Trademarks -- Lanham Act, 15 U.S.C. §§ 1051 - 1127
 - 2. State law (trade names)
- C. College/university policies (may describe ownership of intellectual property and college/university marks and logos, revenue sharing, appeal rights)
- D. Educational uses may violate the intellectual property rights of third parties
 - 1. Must obtain a license for patented works
 - 2. Need permission to use copyrighted works or trademarks (unless an express legal exception permits use)
- E. General rule is that need written permission from the author/inventor/holder of rights before using the intellectual property of another person or entity
- F. Basic concepts
 - 1. Copyright
 - a) Protects original works of authorship that have been fixed in a tangible form
 - b) Arises automatically once work is "fixed"
 - c) Copyright notice is no longer required
 - d) Posting on the internet does not mean copying is permitted (always ok to link to the site)

- e) Fair Use Doctrine permits some use without permission, but depends on the amount of the work being copied, the nature of the portion being copied, the nature of the use and the effect of the use on the market for the work (educational use is NOT automatically fair use)
- f) Examples: articles, film/video, music, painting, sculpture, choreography

2. Patents

- a) Protects new, useful and non-obvious inventions
- b) Not automatic, so must not disclose until patent application is filed (discussion at a conference or publication prior to protection may result in loss of rights)

3. Trademarks

- a) Designates the source or origin of goods
- b) Must protect to avoid dilution and loss of rights (use in protected format and not allow unauthorized use)
- c) Registration is advisable
- d) Examples: college and university logos, mascots, commercial marks

IV. Ownership of Data and Research Materials

- A. Fundamental Issue: What are the rights of the college/university, the researcher, research participants and the research sponsor in materials used for research, donated for research, or developed in research?
- B. Resources
 - 1. College/university policies
 - 2. Sponsorship agreements, materials use agreements, treaties
 - 3. Consent forms, agreements with participants

C. Basic concepts

1. Rights to use data and materials – general rule is that the institution, not the researcher, will own the data and materials collected using institutional resources
2. Ownership of data and materials presumption may be varied by policy language and individual agreements