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Researching research seminar: ethical framework in research involving human participants

Martha F. Jones
Washington University School of Medicine in St. Louis

Researching Research Seminar
Ethical Framework in Research Involving Human Participants

Martha F. Jones, MA, CIP

Executive Director, Human Research Protection Office (HRPO)

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History of Ethical Regulations

- Nuremberg Code (1948)
  - Developed following Nuremberg Trials which judged human experimentation conducted by the Nazis
  - Identified basic ethical principles
    - Voluntary and informed consent
    - Favorable risk/benefit analysis
    - Right to withdraw without penalty

History of Ethical Regulations

- The Thalidomide Experiment (1962)
  - Investigational drug used in 1950s to treat variety of unpleasant symptoms in pregnancy
  - Not standard practice to inform patients of investigational treatment
  - Scientific correlation: birth defects in large percentage of women who took thalidomide
  - Public reaction (outrage)

History of Ethical Regulations

- The Thalidomide Experiment (1962)
  - FDA amendment requiring investigators to obtain informed consent from potential subjects before administering investigational medications
  - Legislative milestone in history of research regulation in U.S.
    - Federal agency authorized to establish and enforce specific ethical standards for the conduct of research

History of Ethical Regulations

- Other renowned studies
  - Willowbrook Hepatitis Studies (1950s)
  - Milgram Studies of Obedience to Authority (1960s)
  - San Antonio Contraception Study (early 1970s)
  - Tearoom Trade Study (early 1970s)
  - Tuskegee Syphilis Study (1932-1972)a
  - Havasupi Tribe (1989 – 2010)

History of Ethical Regulations

- 1973: Congressional Hearings on Quality of Health Care and Human Experimentation
  - National Research Act of 1974
    - Established modern IRB system for regulating research involving human participants
    - Established the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research
      - The Belmont Report (1978)

History of Ethical Regulations

- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
  - Respect for Persons (autonomy)
  - Beneficence
  - Justice

History of Ethical Regulations

- The Belmont Report
  - Respect for Persons
  - Moral requirements: autonomy
    - Individuals should be treated as autonomous agents
    - Individuals with reduced autonomy are entitled to protection
      - Voluntary participation
      - “Informed” consent
      - Privacy and confidentiality protected

History of Ethical Regulations

- The Belmont Report
  - Beneficence
  - Moral requirements: do unto others as you would have them do unto you
    - Risks are justified by potential benefits to individual/society
    - Risks must be minimized (do no harm – and beyond!)
    - Manage conflicts of interest

History of Ethical Regulations

- The Belmont Report
  - Justice
  - Moral requirements: equal distribution of risks among those who would reap benefits
    - Vulnerable subjects are not targeted
    - Those who will benefit are not systematically excluded

History of Ethical Regulations

- Federal Policy for Protection of Human Subjects (1981)
  - Codified by U.S. Department of Health and Human Services at Title 45, Part 46 (45 CFR 46)
  - Subpart A, basic provisions (Common Rule)
  - Subpart B, pregnant woman, fetuses and neonates
  - Subpart C, prisoners
  - Subpart D, children
- Based on FUNDING

History of Ethical Regulations

- Food and Drug Administration
  - Clinical investigations of drugs and devices
    - New drugs or devices
    - New use of approved drugs or devices
  - Define IRB responsibilities (21 CFR 56)
  - Define Investigator/Sponsor responsibilities (21 CFR 50)
- Based on OVERSIGHT AREA

Students as Researchers – the IRB

Institutional Review Board (Washington University Human Research Protection Office (HRPO)

- Independent committee comprised of at least 5 members from relevant academic disciplines and at least one non-affiliated member
- Role: protect research participants
- Authority: approve, require changes to study procedures, or disapprove proposed research
- Autonomy: decisions are final. University officials cannot approve a project that has been disapproved, suspected, or terminated by HRPO.

Students as Researchers – the IRB

- Must have necessary experience and expertise to evaluate proposed research projects.
- Must be diverse in terms of race, gender, cultural backgrounds, and include members from the local community.
- Charge: review all research involving human participants for compliance with institutional policies; state, local, and federal laws; ethical principles in Belmont Report
- Part of bigger system, *Human Research Protection Program* : Chancellor, Vice Chancellor for Research, Deans, Department Heads, all investigators, grants & contacts offices, other research compliance committees

Students as Researchers – the IRB

If you are conducting research involving human participants,

you must have IRB approval to do so

before you begin to collect data.

Students as Researchers

- Conducting or assisting in research projects involving human participants
  - Working in a lab (directed research)
  - Independent research (Senior Honors Thesis)
    - Must have Faculty Sponsor familiar with research topic or methods

Students as Research Participants

- Academic setting
  - WU Mission: promotion of learning by students and faculty
  - Teaching: transmission of knowledge
  - Research: creation of new knowledge
  - Students are integral in transmission and creation of knowledge
  - Recruitment flyers on campus; Research Participant Registry
  - Student Pools (Psychology, Business)

Students as Research Participants

- IRB responsibility to student participants
  - Ensure voluntary participation: protect against coercion and undue influence
    - Coercion – will it affect my grade if I do not participate?
    - Undue influence – will I get a better grade if I participate?

Students as Research Participants

- Pools (Psychology Dept and Olin School)
  - Written policies on their websites
  - Links on HRPO website
  - Reviewed by HRPO according to ethical principles and regulatory requirements
  - Include safeguards to ensure voluntary participation
  - Equity; alternatives
- Faculty research
  - Discourage involvement of own students as participants
  - Allowed in past when participation is anonymous

Students as Research Participants

- What you should expect when asked to participate in research
  - Informed consent
    - May be oral or written
    - Explain purpose, what you will be asked to do, time commitment, compensation (if any)
    - Describe risks (if any)
    - Describe benefits (to you, to society)
    - How your privacy will be protected
    - How confidentiality of data (information you provide) will be maintained
    - Who to contact with questions, concerns

Resources for Student Researchers and/or Student Participants

HRPO

http://hrpo.wustl.edu/

Resources for Student Researchers and/or Student Participants

- Faculty Sponsor
  - Familiar with ethical and regulatory requirements of human research
  - Discuss research ethics with students
  - Advise students conducting international studies on understanding local customs and ethics
  - Monitor student projects, provide oversight, be available for questions
  - Assure that any unexpected or adverse events are reported to the HRPO

Resources for Student Researchers and/or Student Participants

- Provost
  - Code of Conduct
  - http://provost.wustl.edu/code_of_conduct

- Vice Chancellor for Research
  - Institutional Official for human research
  - http://research.wustl.edu/Pages/default.aspx