Researching research seminar: ethical framework in research involving human participants

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Researching Research Seminar
Ethical Framework in Research Involving Human Participants

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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)
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](http://provost.wustl.edu/code_of_conduct)

- **Vice Chancellor for Research**
  - Institutional Official for human research
    - [http://research.wustl.edu/Pages/default.aspx](http://research.wustl.edu/Pages/default.aspx)