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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)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

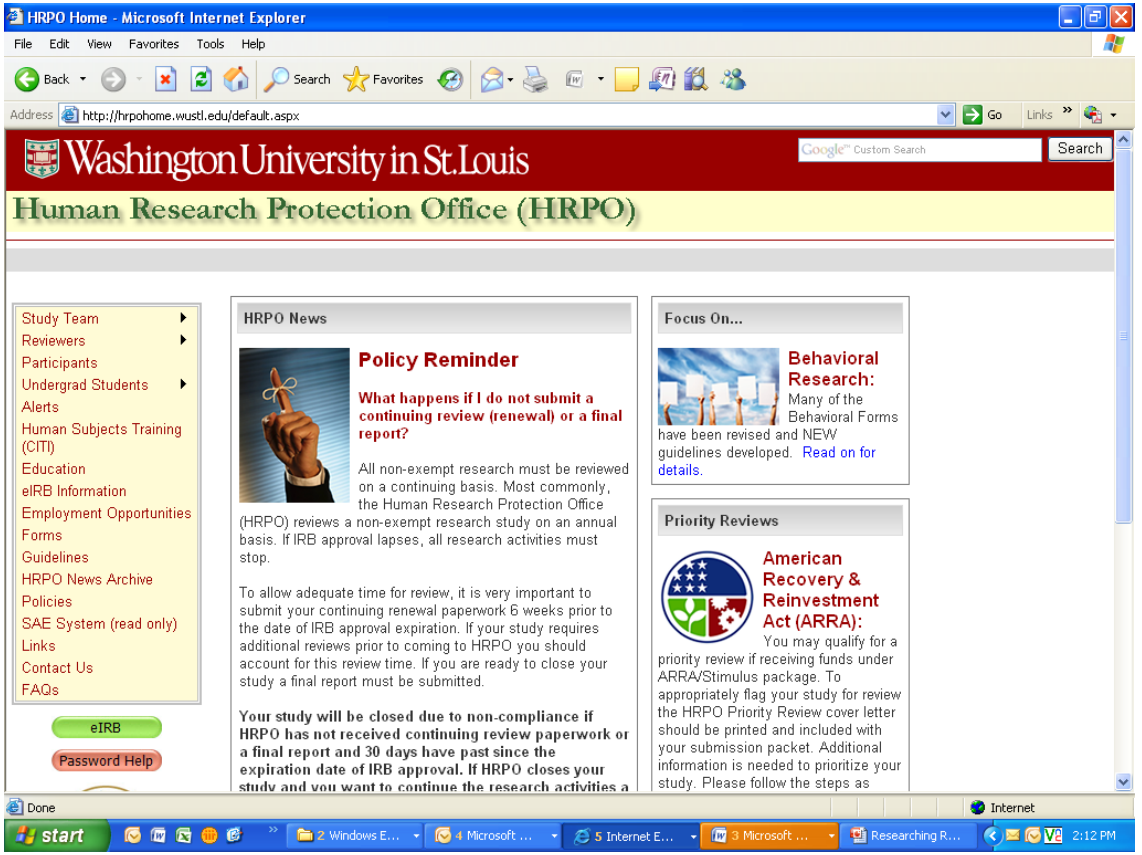
Students as Research Participants

- 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