

HUMAN RESEARCH PROTECTIONS AT EVERGREEN

Principles and Guidance

Human Subjects Review

The Evergreen State College

- Historical overview
- Risk of harm
- Principles of ethical research
- Research requiring review by an independent board (IRB)
- Review criteria
- Application processing procedures
- Case studies
- Online resources and references
- Q & A

Nazi Germany Medical Experiments

Nazi doctors and scientists conducted cruel, harmful, often lethal experiments on prisoners in war camps



Nazi Physicians at Auschwitz camp, between 1941 and 1944
-- Source: United States Holocaust Memorial Museum

Nuremberg Trials 1946



Nuremberg, Germany, 1946 -- Source: United States Holocaust Memorial Museum

- 16 of 23 defendant physicians convicted, 7 sentenced to death for “crimes against humanity”
- “Permissible Medical Experiments” used as standards for judgment, became known as the “Nuremberg Code” (1948)

Thalidomide

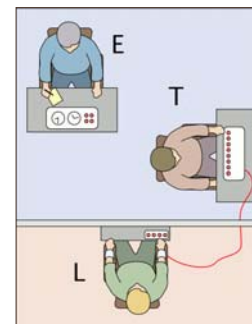
Europe, Canada, US - late 1950s

- Pregnant women given thalidomide, an experimental drug prescribed to control nausea
- Expectant mothers not informed of related risks or that the drug was experimental
- Did not consent to participate in research
- Thalidomide caused severe birth defects in fetuses, resulting in 12,000 deformed and limbless infants



Controversial Social Science Studies

- **Wichita Jury Study - 1955**
 - Recorded deliberations of juries without disclosure
 - Threatened "sanctity" of the jury system
- **Tearoom Trade Study - 1960s**
 - Laud Humphreys studied subjects who engaged in clandestine homosexual behavior and without their knowledge
 - No informed consent
 - Deceived subjects in follow-up research
 - Some subjects inadvertently identified in reports
- **Stanley Milgram studies of obedience to authority - 1960s**
 - Subjects were instructed to inflict pain on others
 - Issues raised: psychological trauma, deception, lack of informed consent



Milestones in Human Subjects Protections

- **1948 - Nuremberg Code**
 - Establishes principle of voluntary, informed consent
 - Research on humans should have a favorable risk/benefit analysis
 - Right to withdraw without penalty
- **1962 - Kefauver-Harris Bill**
 - Ensures greater drug testing safety
 - Along with Nuremberg Code, establishes that research participants be fully informed of potential risks or harm that may result from taking part in a study
- **1964 - World Medical Association, Declaration of Helsinki:**
 - Interests of the subject should always be given higher priority than those of society
 - Every subject in clinical treatment should get the best known treatment
 - Code continues to be revised

Tuskegee Syphilis Study

U.S. government syphilis experiments - 1932-1973

- 600 African-American male subjects
- Unaware of infection, not informed of being involved in research
- Exposed to risky medical procedures for research purposes, but without therapeutic value
- Not given penicillin long after it became standard, effective treatment
- 28 subjects died; hundreds experienced extreme disabilities; wives were infected; 19 documented cases of congenital syphilis



Tuskegee Outcomes

- U.S. Congress commissions a Syphilis Ad Hoc Study panel in 1973 to investigate Tuskegee study
- Immediately stops study and recommends federal regulation of human subjects research
- Compensates subjects for medical expenses to the time of their death, though treatment is palliative; it is too late for effective reversal of disease
- Provides medical treatment for subjects, infected spouses and children
- New legislation governing human subjects research

U.S. Human Subjects Review Law



- 1974 – National Research Act establishes current Institutional Review Board (IRB) process and national commission for protection of human subjects
- 1978 – National Commission (Belmont) Report establishes principles governing human subjects research in U.S.
- 1991 – Common Rule established in the code of the Department of Health and Human Services (Title 45 Code of Federal Regulations [CFR] 46, Subpart A)

Vectors of Harm

Harms can come...

- as a direct result of the procedures in which subjects participate

or

- as a result of the disclosure of private information about participants or other living individuals identified in the research

Possible harms to human subjects of research

- **Physical**
 - E.g., illness or injury as a result of exercise, shock, ingestion, medical procedures
- **Psychological**
 - E.g., embarrassment, shame, shock, trauma, unpleasant self knowledge, fright
- **Social**
 - E.g., stigma, loss of status, damage to relationships
- **Economic**
 - E.g., employment, commerce
- **Legal**
 - Civil or criminal liability

National Commission (Belmont) Report - 1978

Eight-page document, establishes three principles for human subjects protection:

I. Respect for Persons

II. Beneficence

III. Justice

I. Respect for Persons



- **Treat individuals as autonomous agents**
- **Protect persons with diminished autonomy**

Requirements for IRB approval:

Voluntary and informed consent process

Protection of privacy and
confidentiality

II. Beneficence

- **Do no harm**
- **Maximize potential benefits and minimize potential risks**

Requirements for IRB approval:

Risks justified by potential benefits

Study design minimizes risks

Conflicts of interest are managed adequately



III. Justice

- **Distribute risks and potential benefits equally among those who may benefit from research**

Requirements for IRB approval:

Vulnerable subjects not targeted for convenience

People likely to benefit not systematically excluded



U.S. Human Subjects Review Law

- Federally funded research must undergo IRB review and approval
- Establishes protections, including special provisions for pregnant women and individuals with diminished autonomy, e.g., children, fetuses, prisoners
- Research procedures must protect subjects from undue risks, and protect privacy and confidentiality

A project must both be *research* and involve *human subjects* to require IRB review

Research Defined

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(45 CFR §46.102; underlining added)

Human Subject Defined

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

(45 CFR §46.102; underlining added)

Projects that often do not require human subjects review

- Journalism
- Art projects
- Informational interviews
- Oral histories
- Case studies

See www.evergreen.edu/humansubjectsreview/nonhsr.htm.

And when in doubt, ask!

Ethical considerations for any research project

People providing information for research can still be at risk of harm even if they aren't the *subject* of research. For example, individuals could be at risk when asked to provide:

- Critique of authority or other organizations
- Proprietary information
- Information about controversial policies or practices
- Sensitive personal information
- Emotionally difficult information

What is an IRB?

- A board of individuals charged with protecting the rights and welfare of human subjects of research
- IRBs review and approve research plans
- IRB membership is representative of disciplines and backgrounds at the institution

Categories of HSR Applications

- **Exempt** — minimal risk activities defined in law and includes educational evaluations, work with public officials, anonymous surveys, and others (see 45 CFR Part 46.101(b)); **exemptions must be approved by IRB administrator at Evergreen**
- **Expedited** — minimal risks to subjects or minor changes to board reviewed projects
- **Board Reviewed** — any project that presents more than minimal risk to subjects or that works with certain protected populations (e.g., prisoners)

HSR Review Criteria and Issues

- **Complete Application**

- Answers to the six questions
- Informational cover letter (or script, if appropriate)
- Consent agreement form (or script, if appropriate)
- Copies of advertisements, emails, letters, etc., used to recruit participants

Content should be consistent between all documents.

In answer to the six questions:

1. Summarize your project in an abstract
2. Explain the procedures to which humans will be subjected
3. Describe how participants will be recruited
4. Describe the possible risks to subjects, and how you will mitigate those risks
5. Describe the benefits to be gained by the study
6. Describe how the information to be gained by this study will be used and who potentially will see it

1. Abstract

- Summarize your study
 - What do you hope to find out?
 - How will you find it out?

2. Procedures

- Describe exactly what interactions you will have with participants and what procedures they will undergo
- Be detailed: surveys, interviews, photography, recordings, blood draws, physical examinations, etc.
- Include time estimates for interaction, follow-up interactions, research settings, etc.

3. Recruitment

- What type of participants are you looking for (age, race, gender, employment, affiliation, health status, etc.)?
- What methods will you use to recruit participants (On-the-street, email contacts, social media, existing contact lists, etc.)?
- What are your sampling procedures (random, snowball, etc.)
- Does your recruitment require cooperation from another organization? Do you have written approval?

4. Risks

- Describe the risks to participants of your study – and not only physical risks
 - Emotional
 - Social
 - Economic
 - Civil/criminal liability
- “None” is not a good answer
- No more than minimal risk means no risks greater than those encountered in daily life
- Outline plans for mitigating risks through protection of private information, plans to provide personal and emotional safety, follow up referrals, etc.

5. Benefits

- What may be learned that makes the participation of human subjects worthwhile
- Benefits may be individual, institutional or societal
- Provide a good reason for putting your subjects through the procedures you propose -- i.e., How does the benefit outweigh the risk?

6. Use of Information

- Disclose how information will be disseminated, to whom ...
 - In publications
 - On the web
 - With other individuals or organizations
- How will you maintain promised confidentiality or ensure anonymity?

Achieving INFORMED Consent

Your subjects need to know:

- Your purpose and research procedures
- Risks and discomforts for them
- Your plans to eliminate risks and discomfort
- Provisions for confidentiality
- That their participation is truly voluntary, at all points in the research
- Contact information for the researcher and the human subjects review administrator at the college

Informed consent is a process, not an event.

Core Design Considerations

- Have a good research model designed to get reliable outcomes
 - If you don't have a reasonable chance of getting good outcomes, the value of your research may not outweigh even minimal risks
- A study is ethical or not at the outset
 - The findings of a study will not make it ethical; ends do not justify means

HSR Process at Evergreen

- Submit signed hard copy application to Academic Deans Office in Library 2002
- Initial reviews take up to two weeks
- Resubmissions and re-reviews may also take up to two weeks
- Must not start research until approval received

After you are approved...

- Request any modifications to your research plan, including recruitment, protocols, etc., before implementing modifications in your project
- If harm results, stop the research and report to the IRB Administrator. Do not begin again until cleared by the IRB.
- Keep records of consent for at least three years.
- Destroy any information that you promised to destroy.

Curiosity is Not “Need to Know”



Special Considerations

- Agreements from cooperating institutions (schools, employers, tribal governments, etc.)
- Vulnerable populations (children, prisoners, et al.)
- Online surveys and consent
- Anonymity vs. confidentiality
- Identity is more than just a name

Case Study #1

A researcher wishes to understand how exposure to battlefield trauma may impact veterans' abilities to maintain long-term relationships. The researcher plans to approach veterans at a private athletic club that caters to veterans. He will meet with subjects in the club coffee shop to interview them about their experiences while overseas and their personal relationships since returning to the States.

What ethical concerns or questions does this study raise?

Case Study #2

A researcher is trying to determine if there is a link between the amount of exercise people get and the number of days they miss work because of illness. The researcher creates an online survey that collects self-reported personal medical information, demographics (age, race, ethnicity, gender), and information about exercise habits and work attendance. The survey does not collect names or contact information, though the researcher will receive an ISP address for each online survey that is completed.

What ethical concerns or questions does this study raise?

Case Study #3

A researcher is conducting a survey about alcohol and marijuana use among 18-20 year olds. After having the participants sign a research consent form, the researcher is collecting the information using an in-person survey and entering the information in a program on her laptop.

What ethical concerns or questions does this study raise?

Case Study #4

A student wishes to learn about and compare the efficacy of depression treatments that involve use of psychiatric drugs and those that do not. He plans to interview ten mental health practitioners about the advantages and disadvantages of various treatments according to their experience with patients.

What ethical concerns or questions does this study raise?

Online Resources

www.evergreen.edu/policies/policy/useofhumansubjects

(link to Evergreen HSR Policy)

www.evergreen.edu/humansubjectsreview/

(link to Evergreen HSR information and application)

www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

(link to federal regulations)

www.hhs.gov/ohrp/irb/irb_guidebook.htm

(link to HHS IRB Guidebook)

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