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SCHOOL of PUBLIC HEALTH

Ethics in Health Services Research

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Section A

Overview

Belmont Report Principles

- Respect for persons
  - Individuals should be treated as autonomous agents
  - People with diminished autonomy are entitled to protection

Belmont Report Principles

- Beneficence
  - Do no harm
  - Maximize possible benefits and minimize possible harms
- Justice
  - The benefits of the research should accrue to those who bear the burden of participation

Impetus for the Belmont Report

- Medical experiments conducted by Nazi physicians in the 1930s and early 1940s
  - Lack of autonomy
  - Inhumane treatment
  - Research findings intended for others

Nuremberg Code

- Nuremberg Code, 1947
  - Informed consent without coercion
  - Human experiments based on animal research
  - Expected results should justify the research
- Nuremberg Code, 1947
  - Scientists must be qualified
  - Physical/mental suffering avoided
  - No expectation of disability or death from the research

Declaration of Helsinki

- Declaration of Helsinki (drafted 1953, adopted 1964)
  - Ethical principles for “therapeutic” and “non-therapeutic” research

Other Events

- The Milgram Study (published 1963)
  - Deception
- The Tuskegee Study (started 1932, exposed 1972, stopped 1973)
  - Informed consent
  - Physical harm
  - Deception

Events after Tuskegee

- 1974—National Research Act
  - Institutional review boards
  - Informed consent
- 1979—The Belmont Report
- 1981—Code of Federal Regulations
- 1991—Common Rule

Federal Oversight

- Office of Human Research Protections
  - Structure and function of IRBs
- Food and Drug Administration
  - New drugs and devices

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Section B

Human Subjects Protection Program

Objectives of Human Subjects Protections Program

- Risks balanced by benefits
- Minimize risks of harms

Types of Harms

Physical	Drug side effects
	Adverse surgical outcomes
	Injury
Psychological	Emotional distress
	Anxiety
	Relapse
	Precipitation of depression
Legal	Arrest, prosecution
	Civil or criminal liability

Types of Harms

Social	Embarrassment
	Ostracism
	Stigma
	Loss of status
	Retribution
Economic	Loss of job or income
	Loss of insurance/insurability
	Reduced employability
	Financial loss

Harm/Reduction of Risk of Harm

Harm	Reduction of Risk of Harm
Many unpleasant side effects	Frequent monitoring, long-term follow-up
Distress from questions about suicide	Eliminate sensitive questions Warn about sensitive items and ability not to answer Make counselor available
Embarrassment from questions about relations with co-workers	Anonymous participation Confidentiality protections
Prosecution for illegal activities	Confidentiality protections Delete questions Certificate of Confidentiality

Types of Benefits

- Direct benefits—research subject gets something from participation that he/she would not get otherwise
- Examples—access to medical care information from a blood test, chance to talk about an important issue, learn a new skill

Types of Benefits

- Societal benefits
  - Contribution to basic scientific knowledge
  - Development of new product, technique
  - Information for decision-making

Harm/Reduction of Risk of Harm

Harm	Reduction of Risk	Likely Direct Benefit	Likely Society Benefit
Many unpleasant side effects from study drugs	Frequent monitoring Long-term follow-up	Access to a new drug treatment Access to medical care Referrals for other health problems	Low—drug similar to existing drugs and no better side effects Moderate—more effective, fewer side effects High—new drug
Distress from questions about suicide	Eliminate sensitive questions Warn about sensitive items and ability not to answer Make counselor available	Chance to talk about problem Access to counseling	Low—questions don't directly address hypotheses Moderate—will help explain important contributory relationships High—questions directly measure independent or dependent variables and will advance scientific knowledge
Embarrassment from questions about relations with co-workers	Anonymous participation Confidentiality protections	Chance to talk	
Prosecution for illegal activities	Confidentiality protections Delete questions Certificate of Confidentiality	Chance to talk	

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Section C

Informed Consent and Vulnerable Populations

Informed Consent

- Process
  - Recruitment
  - Explanation of research
  - Confirmation of understanding
  - Documentation of agreement

Elements of Informed Consent

- Who is doing the research
- Purpose
- Procedures
- Duration of participation

Elements of Informed Consent

- Risks or discomforts
- Anticipated benefits
- Confidentiality protections
- Assurance of voluntary participation

Privacy and Confidentiality

- Privacy—limited access to an individual and to information about that person
- Confidentiality—how access to and use of private information is structured

Potential Breaches of Confidentiality

- During data collection
  - Knowledge of participation
  - Overhearing interviews
  - Access to names, identifiers
- Data protection during and after analysis
  - Identifying information
  - Paper storage
  - Computer security

Vulnerable Subjects

- Ability to give informed consent
  - Children—assent and parental permission
  - Cognitively impaired—determination of ability to give consent, proxies
  - Comatose or unconscious patients—proxies

Vulnerable Subjects

- Voluntary consent/absence of coercion
  - Prisoners
  - Students
  - Employees
- Heightened risk
  - Pregnant women
  - Sick people

Vulnerable Subjects

- Justice (equitable distribution of risks, benefits)
  - Women
  - Elderly
  - Racial/ethnic minorities
  - Economically disadvantaged
  - Terminally ill people

Institutional Review Board

- At least five members
- At least one non-scientist
- At least one person unaffiliated with organization
- Experts in areas of research conducted by organization

Types of Review

- Exempt—no risk
  - Determination made by IRB chair
- Expedited review—minimal risk
  - Complete review by IRB chair or one designated member
- Full committee review—greater than minimal risk
  - All committee members conduct review

Criteria for Approval

- Risks to subjects are minimized
- Risks are reasonable in relation to any anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought
- Informed consent will be appropriately documented
- Privacy is protected
- When appropriate, safety monitoring is provided
- Appropriate safeguards are in place if vulnerable subjects are involved

Weighing the Science

- A poorly designed study will not answer the research question/hypotheses and is therefore unlikely to have a benefit
- A well-designed but high risk study that addresses a minor issue is likely to have benefits of less weight than the risks

Continuing Review

- At least once a year
- Review for . . .
  - Any adverse events or problems
  - Any changes in the risk/benefit balance
  - Any changes in procedures

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Section D

Health Insurance Portability and Accountability (HIPAA)

HIPAA Privacy Rule

- Health Insurance Portability and Accountability Act of 1996
- Privacy regulations effective April 14, 2003
- New, specific rights to individuals about their health information
- Requires **covered entities** to use and disclose **protected health information** only in permitted ways

Protected Health Information (PHI)

- About an individual's health, treatment, billing/payment for services
- About people who are alive or deceased
- In any form—paper, electronic, recorded, spoken

Examples of PHI

- Patient visit for health problem treatment
  - Name, address, phone number
  - Diagnosis
  - Department and doctor names
  - Test results
  - Billing data
  - Any linking identifiers

Examples of PHI

- Research subject
  - Name, address, etc.
  - Results of tests performed as part of trial
  - Questionnaire responses

Covered Entity

- Providers that transmit PHI electronically
- Health plans
- Clearinghouses that receive PHI
- Examples—Johns Hopkins School of Medicine, Johns Hopkins Hospital, Johns Hopkins Health Plan
- JHSPH is a “hybrid entity”

PHI from a Covered Entity Can Be Used in Research When . . .

- Authorization is obtained from study subject or . . .
- A waiver is obtained from IRB or privacy board

Authorization

- What information will be used/collected
- Who will use/disclose information
- Why information is needed and how used
- Who from outside will see information
- That information may not be protected if shared with others
- When authorization ends
- Ability to cancel permission

Waivers

- Waiver of authorization
  - Minimal risk to privacy
  - Adequate protection of identifiers
  - Plan to destroy identifiers

Waivers

- Waiver of authorization
  - Assurance that . . .
    - Research cannot be conducted without waiver AND
    - Research cannot be conducted without PHI
- Partial waiver of authorization to undertake recruitment