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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
- 1991—Common Rule
Federal Oversight

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

Human Subjects Protection Program
Objectives of Human Subjects Protections Program

- Risks balanced by benefits
- Minimize risks of harms
## Types of Harms

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td>Drug side effects</td>
</tr>
<tr>
<td></td>
<td>Adverse surgical outcomes</td>
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<tr>
<td></td>
<td>Injury</td>
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<td>Psychological</td>
<td>Emotional distress</td>
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<td>Anxiety</td>
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<td>Relapse</td>
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<tr>
<td></td>
<td>Precipitation of depression</td>
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<tr>
<td>Legal</td>
<td>Arrest, prosecution</td>
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<tr>
<td></td>
<td>Civil or criminal liability</td>
</tr>
</tbody>
</table>
## Types of Harms

<table>
<thead>
<tr>
<th>Social</th>
<th>Embarrassment</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Ostracism</td>
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<td>Stigma</td>
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<td>Loss of status</td>
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<td>Retribution</td>
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<td>Economic</td>
<td>Loss of job or income</td>
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<td>Loss of insurance/insurability</td>
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<td></td>
<td>Reduced employability</td>
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<td>Financial loss</td>
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</tbody>
</table>
### Harm/Reduction of Risk of Harm

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

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