Informed Consent with Vulnerable Populations

IRB Forum
September 24, 2019
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Overview

• Define vulnerable subjects and types of vulnerabilities
• Assess and manage informed consent process for vulnerable subjects
Criteria for IRB Approval

“When some or all of the subjects are likely to be vulnerable to coercion or undue influence, ... additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

Department of Health and Human Services, (45 CFR 46.111(b))
Vulnerable to Coercion or Undue Influence

• Persons may be considered vulnerable because the individual may have difficulty providing voluntary informed consent due to limitations in decision-making capacity or situational circumstances.

National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants, 2001
Difference between Coercion and Undue Influence

- **Coercion** occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.

- **Undue influence** occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.

The Belmont Report, 1979
Capacity to Provide Informed Consent

• This is the functional assessment regarding a decision
• May vary
• May be defined by state laws
Who is vulnerable?

Federally regulated groups
• Pregnant Women/Fetus*
• Prisoners
• Children

Other vulnerable groups
• Cognitively impaired
• Acutely ill
• Economically disadvantaged
• Educationally disadvantaged
• Students
• Employees
Federal Regulations

• Subparts B, C, and D of 45 CFR 46 provide additional protections
  • Allowable categories of research for a group of subjects
  • Requirements of each category
### Types of Vulnerabilities

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Cognitive or inability to</td>
<td>• individuals with a diminished capacity to understand or communicate</td>
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<tr>
<td>communicate</td>
<td></td>
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<tr>
<td>Institutionalized</td>
<td>• individuals who are subject to the authority of others</td>
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<tr>
<td>Contrasting</td>
<td>• formal or informal subordination to others</td>
</tr>
<tr>
<td>Medical</td>
<td>• serious medical condition</td>
</tr>
<tr>
<td>Economic and/or Social</td>
<td>• belonging to a marginalized group</td>
</tr>
</tbody>
</table>
What type of vulnerability do parolees, who are detained in a treatment center as a condition of parole, have?

- Cognitive/Inability to Communicate
- Institutionalized
- Economic
- Medical
- Social
- Contrasting
What type of vulnerability do children have?

- Cognitive/Inability to Communicate
- Institutionalized
- Contrasting
- Medical
- Economic
- Social
What type of vulnerability does a person with moderate Alzheimer's have?

- Cognitive/Inability to Communicate
- Institutionalized
- Contrasting
- Medical
- Economic
- Social
What is a possible vulnerability for individuals with terminal cancer?

- Cognitive/Inability to Communicate
- Institutionalized
- Contrasting
- Medical
- Economic
- Social
What type of vulnerability does the homeless population have?

- Cognitive/Inability to Communicate
- Medical
- Institutionalized
- Economic
- Contrasting
- Social
What type of vulnerability does a lab technician have when the investigator is also the supervisor of the lab?

- Cognitive/Inability to Communicate
- Institutionalized
- Contrasting
- Medical
- Economic
- Social
Consent Impairments Temporary or Long Lasting

• Urgent situations
• Under the influence of a substance
• Mental health condition
• Brain injury or neurological condition
• Developmental conditions
Evaluating Subject’s Informed Consent Capacity

- Communication: Expressing choice
- Understanding: Recalling information
- Appreciation: Applying information to a situation
- Reasoning: Weighing risks/benefits of options

Dastidar & Odden, The Hospitalist, 2011
Adapting Assessments to Evaluate Consent Capacity

- Study specific
- Cognitive evaluations
- Frequency and timing of assessments
Methods to Managing Informed Consent

• Anticipate potential changes with a person’s ability to provide informed consent
• Engage the individual, family, or legally authorized representative
• Dedicate a conversation to the consenting process:
  • Highlight procedures, especially those that carry more than minimal risk
  • Discuss limitations and commitments required by the participant
  • Use visual tools where necessary
IRB Application

- Ensure an adequate IRB application is submitted and addresses:
  - Vulnerable groups
  - Consenting process
  - Tools used to aid in consenting process
A local investigator is taking part in a multicenter Phase II study of the efficacy of an investigational combination antipsychotic/mood-stabilizer that may have an improved side-effect profile compared to the separate medications currently available.

The study will enroll patients who are being treated for schizoaffective disorder and are having side effects from their current medications which are unacceptable and interfering with their medication adherence. The subjects must not have a decisional impairment at the time of enrollment, and must undergo a 14-day washout period from all antipsychotics and mood stabilizers prior to starting the study drug.

A potential participant is identified and confirmed to have no current decisional impairment based on an evaluation of current medical state and a review of medical records. The participant is consented for the study, and is asked to return to the clinic on days 7 and 14 during the washout to monitor symptoms related to psychosis and changes in mood. On study day 11, the participant goes to the police station and confesses to having committed a recent crime. The subject becomes aggressive and assaults a police officer. There is a struggle to detain the participant, who is injured during the struggle and requires medical attention.
References


• Link to OHRP regulations for the Protection of Human Subjects: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitr=20180719&n=pt45.1.46&r=PART&ty=HTML

• Link to The Belmont Report - https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf
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Wednesday, September 25, 2019, 9am – 12pm

Tuesday, October 1, 2019, 1pm – 4pm

Wednesday, October 9, 2019, 9am – 12pm

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