The Belmont Report
History, Principles and Application

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Belmont Report - History

- **Ethical Principles and Guidelines** for the Protection of Human Subjects of Research

- **Summarizes the basic ethical principles** identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- **Created in reaction to previous human subject violations** (e.g. Nuremberg Trials on human experimentation; Tuskegee Syphilis Experiment, etc.)

- **Named after the conference room** where the Commission convened at the Smithsonian Institution’s Belmont Conference Center; held in 1976.
## A. Defined boundaries between research and practice

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice</td>
<td>Interventions designed solely to enhance the well-being of an individual</td>
<td>Reasonable expectation of success</td>
</tr>
<tr>
<td>Research</td>
<td>Activity designed to test a hypothesis; contributes to generalized knowledge</td>
<td>Permits a conclusion to be drawn</td>
</tr>
</tbody>
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B. Consists of 3 basic principles:

1. Respect for Persons
2. Beneficence
3. Justice
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1. Respect for Persons

- Treat people as autonomous (having the right to self-govern) agents

- Protect those who have diminished autonomy (vulnerable populations), e.g. children, prisoners, elderly
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2. Beneficence

- Do no harm
- Maximize benefits/minimize risks
- NOT an act of kindness or charity, but a concrete obligation
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3. Justice

• Distribution of both benefit and burden

• 5 Formulations:
  
  1. Everyone gets an equal share
  2. Distribution according to need
  3. According to individual effort
  4. According to societal contribution
  5. According to merit
C. Application

**Respect for persons**

**Informed Consent**
- Obtain and document
- Voluntariness/no coercion
- Protect privacy

**Beneficence**
- Procedures with least risk
- Risks reasonable in relation to benefits
- Maintain confidentiality

**Justice**
- Select participants equitably
- Avoid exploitation of vulnerable populations

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Respect for persons Beneficence  Justice

Informed Consent  Risks/Benefits  Enrollment

IRB  Researcher  Subject

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Serve to preserve the public trust in research

Privilege granted to the researchers by the public and the subjects