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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.



Belmont Report - Principles

A. Defined boundaries between research and practice

Term	Definition	Outcome
Practice	Interventions designed solely to enhance the well-being of an individual	Reasonable expectation of success
Research	Activity designed to test a hypothesis; contributes to generalized knowledge	Permits a conclusion to be drawn



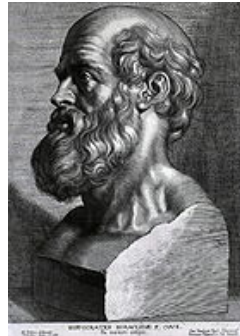
Belmont Report - Principles

B. Consists of 3 basic principles:

1. Respect for Persons



2. Beneficence



3. Justice





Belmont Report - Principles

1. Respect for Persons

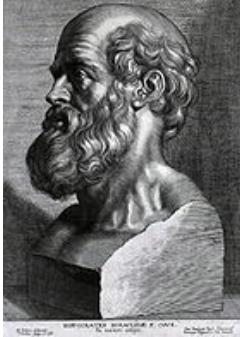


- Treat people as autonomous (having the right to self-govern) agents
- Protect those who have diminished autonomy (vulnerable populations), e.g. children, prisoners, elderly



Belmont Report - Principles

2. Beneficence



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



Belmont Report - Principles

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



Belmont Report - Application

C. Application

Respect for persons



Informed Consent

- Obtain and document
- Voluntariness/ no coercion
- Protect privacy

Beneficence



Risks/Benefits

- Procedures w/least risk
- Risks reasonable in relation to benefits
- Maintain confidentiality

Justice



Enrollment

- Select participants equitably
- Avoid exploitation of vulnerable populations



Belmont Report - Application

Respect for persons



Informed Consent



IRB

Beneficence



Risks/Benefits



Researcher

Justice



Enrollment



Subject



Belmont Report

Serve to preserve the public trust in research

Privilege granted to the researchers by the public and the subjects



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