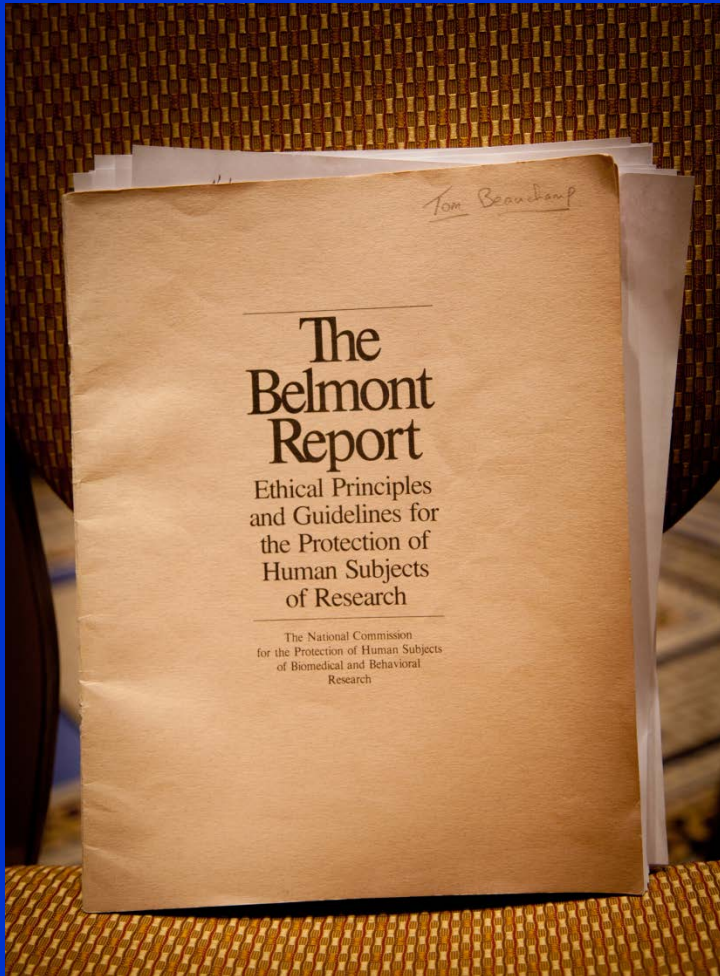


RETI 2014

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BELMONT REPORT



3 Ethical Principles

- **Respect for Persons**
- **Beneficence**
- **Justice**

Respect for Persons

- Treat individuals as autonomous agents
- Do not use people as a means to an end
- Allow people to choose for themselves
- Give extra protection to those with limited autonomy



Beneficence

- Acts of kindness or charity that go beyond duty
- Obligations derived from beneficence

{
Do no harm
Prevent harm
Prevent evil
Promote good



Consider All Risks

- Physical
- Psychological
 - embarrassment
- Social
 - stigmatization
- Economic
 - employment risk
 - insurability
- Legal
 - criminal/civil liability

Justice



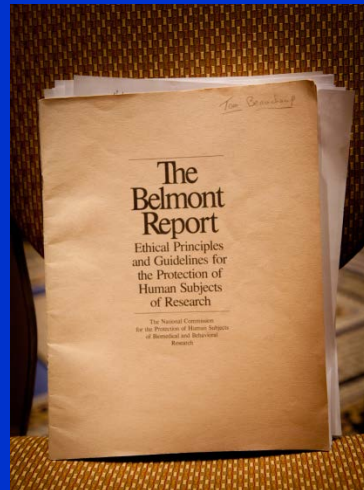
- Treat people fairly
- Fair sharing of burdens and benefits of research
- Not procedural justice, but distributive or social justice



The Ethical Principles

BELMONT

- Respect for Persons
- Beneficence
- Justice



MY GRANDMOTHER

- Show respect
- Do the right thing
- Be fair



Applying Research Ethics



Criteria for IRB approval

45 CFR 46.111

21 CFR 56.111

- Risks are minimized
- Risks are reasonable in relation to benefits
 - To subjects, if any
 - Importance of knowledge
- Selection of subjects is equitable
- Informed consent will be obtained
- Informed consent will be documented
- Safety monitoring, when appropriate
- Protection of privacy, when appropriate
- Additional safeguards for vulnerable populations