

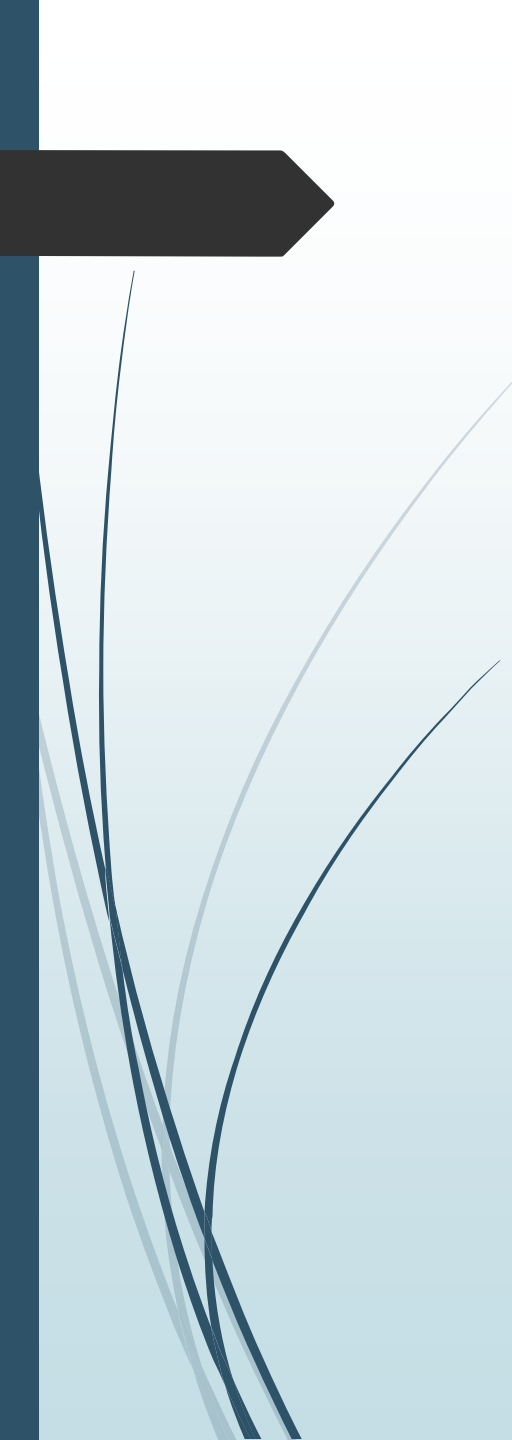


Ethics of Genetic Research

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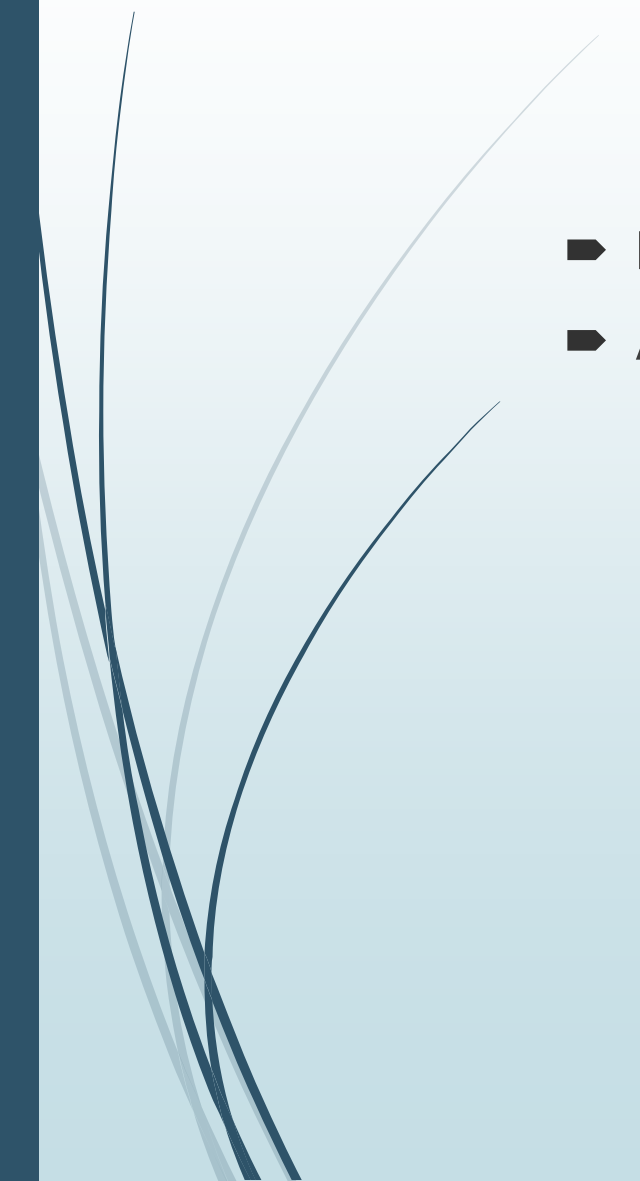
“Ethical Principles and Guidelines for the Protection of Human Subjects in Research,” known commonly as *Belmont Report* (National Commission, 1979)

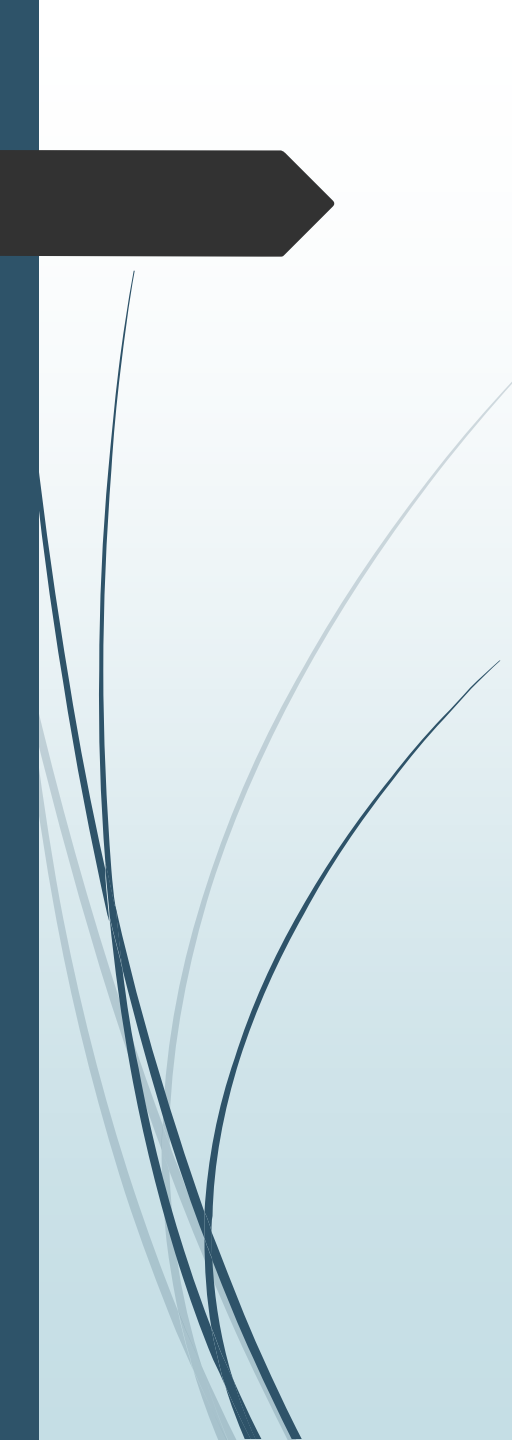
► Three principles:

1. **Respect for persons, or autonomy:** informed consent
2. **Beneficence and non-maleficence:** risk/benefit ration, minimizing harm
3. **Justice:** fair subject selection



Common Rule

- National Research Act (1974)
 - Adopted by 14 additional agencies in 1991
- 



Advanced Notice of Proposed Rulemaking (ANPRM), delayed until July 19, 2018 (comments were due on March 19, 2018)

Revised recommendations for the use of genetic data

1. Informed consent for all biospecimens (blood, tissue, etc) collected for research
2. Informed consent for all biospecimens, even if it will be de-identified
3. No informed consent necessary for biospecimens that are initially collected for purposes other than research, but ultimately used for research, as long as they are de-identified
4. Informed consent for “broad use” of biospecimens for future research is permissible (so that researchers don’t have to go back again and again to get consent for future research purposes)



Genetic Exceptionalism – Four reasons genetic data is different:

1. Subject and data aren't in the same place
2. It is unclear to some that a “person” is involved
3. The significant amount of information contained in genomic data
4. The data isn't merely about the donor – it is about family, racial and ethnic groups, etc.



(1) Four Questions Raised by Research on Genetic Data:

- What is the nature of what is being donated?
 - Do persons have a right to control what is no longer a part of their bodies?
 - Are there issues of re-identification?



(2) Four Questions Raised by Research on Genetic Data:

- Is the notion of “privacy” evolving, such that some of our concerns about confidentiality are obsolete?
 - “The most readily available source of identified genotypes comes from individuals who deposit their results along with their surnames in public genealogy databases” (Clayton, 2014)
 - The social media analogy



(3) Four Questions Raised by Research on Genetic Data:

- How do we weigh off the harms of collecting genetic data with the benefits?
 - The promise of the use of genetic data, big data, and personalized medicine, is weighed against the autonomy rights of individuals
 - “It is possible to overemphasize individual rights at the expense of group advantage” (Rivera, 2014)
 - The justice issue – will fear of harm to groups deter underrepresented individuals from participation in genetic research?



Four Questions Raised by Research on Genetic Data:

- Incidental Findings

- Are they communicated? To whom are they communicated? Some advocate “Intergenerational monitoring” (Cwik, 2017) – but ethical monitoring makes de-identification impossible



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Thank you!