Ethical Principles
Ada Sue Selwitz, M.A.
Executive Integrity/Compliance Advisor,
Office of the Vice President for Research
Co-Director, Regulatory Support
Center for Clinical and Translational Sciences
University of Kentucky

Beneficence

What are the Ethical Principles Upon Which the IRB System of Review is Based?

Ethical Principles

- Respect for Persons
  - Autonomous Individuals/Diminished Autonomy
  - Consent, Privacy, Confidentiality
- Beneficence
  - Minimizing Risks/Maximizing Benefits
  - Risks Reasonable in Relation to Benefits
  - Risks/Benefits to Whom?
- Justice
  - Fair Sharing of Benefits & Burdens of Research
  - Inclusion/Exclusion

Belmont Report, 1979

Applying the Ethical Principles is NOT EASY
## Applying Ethical Principles is Not Easy

- IRB Member Preferences (i.e., Biases)
- Subjective Decision Making
- Conflicts Between or Within the Ethical Principles

### Conflicts

#### “Equal Moral Force”


#### “No Single Overarching Super Principle”


## Ethical Principles

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Belmont Report, 1979
Women of Child Bearing Potential: Phase I Trial – How Ethically Do You Decide if Women Should be Included?

Employee Records or Medical Records

- If Respect for Persons Super Over Arching Principle –
  - Could You Do Research Reviews on Hundreds of Records?
  - How Do We Justify Ethically?
  - How Do We Justify From a Regulatory Perspective?

Fraternity Student No Direct Benefit, No Risk to Student/Only Wants to Include Males

Example: Conflicts within Principle

- Survey Research in Abortion Clinics – Strategies for Obtaining Informed Consent
- IRB: Letting Clinical Staff Obtain Consent Undue Influence
- PI Felt Invasion of Privacy for Researchers to See Who Subjects Were
- How Could Risk of Undue Influence be Minimized?
- Respect for Persons

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