New IRB Member Orientation

Part II:

IRB Ethical Principles

The Belmont Report

- Respect for persons: Informed consent
  - Individual autonomy
  - Protection of individuals with reduced autonomy
- Beneficence: Assessment of risks & benefits
  - Maximize benefits & minimize harms
- Justice: Selection of subjects
  - Equitable distribution of research costs & benefits

Respect for Persons

- People are autonomous
- Those with diminished capacity should be protected

45 CFR 46.116: Informed Consent

"…No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative."

45 CFR 46.116: Informed Consent

"No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

Basic Elements of Informed Consent - 45 CFR 46.116

1. Statement that the study is research
2. Purpose of the research
3. Duration of subject participation
4. Description of procedures that the subject will participate in
5. Identification of those that are experimental,

Basic Elements of Informed Consent *(Continued)*

6. Description of reasonably foreseeable risks or discomforts

7. Description of benefits to the subject or others likely to come from the research

8. Alternative procedures or treatments that could be pursued by subject

9. How confidentiality of records will be maintained

Basic Elements of Informed Consent *(Continued)*

10. For greater than minimal risk studies:

--Is any remuneration available?

--Is any medical treatment available if injured?

--If yes, what and where to go with questions,

Basic Elements of Informed Consent *(Continued)*

12. Participation is voluntary

--Can refuse to participate without prejudice, loss of services or benefits,

--Can withdraw at anytime with the same lack of prejudice, loss of services or benefits

Additional Considerations

- Who administers consent?
- Are they trained?
- What is the back-up?
- Resources when the subjects have questions
- Resources for staff associated with the subject's care when they have to field questions?

Additional Considerations

- On-going &/or periodic communication
- Newsletters, website, letters,
- How are study results shared?

Conclusion

- Why have consent?
- Ethical foundations
- Consent as a valuable research tool

THE BELMONT REPORT: BENEFICENCE

Beneficence in the Research Setting

1. Valid Study Design
2. Favorable Risk: Benefit
3. Competent Investigators

Valid Study Design

- Will study design answer the research question?

- How does the IRB know?

Risk Benefit Ratio

Risk/Benefit Ratio

"Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."

Institutional Review Board Guidebook, 1993

Benefit

"A valued or desired outcome; an advantage."

Institutional Review Board Guidebook, 1993

[Note: compensation is NOT a benefit.]

Departmental Review

- Closest to the science of the research being proposed
- Know their researchers' skills & abilities
- Need to know what is being proposed
- Need to be represented on the IRBs

THE BELMONT REPORT: JUSTICE

Belmont's Justice

1. Blend of Judeo-Christian tradition of protection of widows and orphans

2. Marxist dictum "from each according to ability; to each according to need"

3. Seen in subject selection.

Justice as Seen in Research Studies

- Unbiased Subject Selection
- Fair Recruitment