FLORIDA ATLANTIC UNIVERSITY
DIVISION OF RESEARCH

Risks and Benefits in Research

FAU HRPP

Overview

- IRB Criteria of Approval
- Risk assessment
- What is a benefit?
- Statements in protocol and consent document

IRB Criteria of Approval (45CFR46.111)

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Risk Assessment

*CABLES Model of risk assessment:

Cognitive/psychological

Affective

Biological/physical

Legal

Economic

Social

**Koocher, G. P. (2002). Using the CABLES Model to Assess and Minimize Risk in Research: Control Group Hazards. Ethics & Behavior, 12, 75-86.*

Risk Assessment

Cognitive/ Psychological	Affective	Biological/Physical
• Threats to a participant's academic achievement, intellectual function, or self-esteem. • ***Example***: Requesting the participant to perform a task such as problem solving. • ***Minimization***: Inform participants that the task is for research purposes only and has no bearing on any real life determinations including grades, employment status, or other standings.	• Emotional distress during or after research activities. • ***Example***: Collection of data involving sensitive participants such as domestic abuse, PTSD, or sexual violence. • ***Minimization***: Make available services that may provide counsel to participants; Continually monitor participant during participation for signs or distress and "check in" to remind participant that they may stop at any time	• Physical injury as result of research participation. • ***Example***: Bruising from venipuncture; drug side effects; placebo side effects; Randomized trial when standard of care may be more effective than proposed intervention. • ***Minimization:*** Use standard procedures when possible; Inform participants of all risks and provide likelihood of risks, as necessary.

Risk Assessment

Legal	Economic	Social
• Breach of confidentiality of data may put person at risk for legal consequences. • ***Example***: Participants reveal participation in selling and purchasing of illegal substances such as heroin; Research with undocumented immigrants. • ***Minimization***: Collect only what is needed; Try to keep data as anonymous as possible; Obtain certificate of confidentiality, if not NIH funded.	• Financial burdens or loss of employment affiliated with research participation. • ***Example***: Asking employees to voice concerns about management and identifiers are connected to responses. • ***Minimization***: Collecting as few identifiers necessary for data analysis; Providing compensation for time and travel, as allowable by research sponsor.	• Collection of data that may be considered socially stigmatizing if identification of subject were revealed. • ***Example***: Results of research impact the group (racial, ethnic, sex, culture, etc.); Participant is unintentionally identified as engaging in socially stigmatizing behavior or having a socially stigmatizing attribute/ characteristic. • ***Minimization***: Maintaining confidentiality of data and ensuring only authorized team members have access to identifiers; Publishing results with as little direct identification as possible.

Risk Assessment

- Two main factors to consider: probability and magnitude;
- How probable is it that the risk will be present and what is the magnitude, or how harmful is the risk?;
- Take under advisement the population being studied and research procedures.

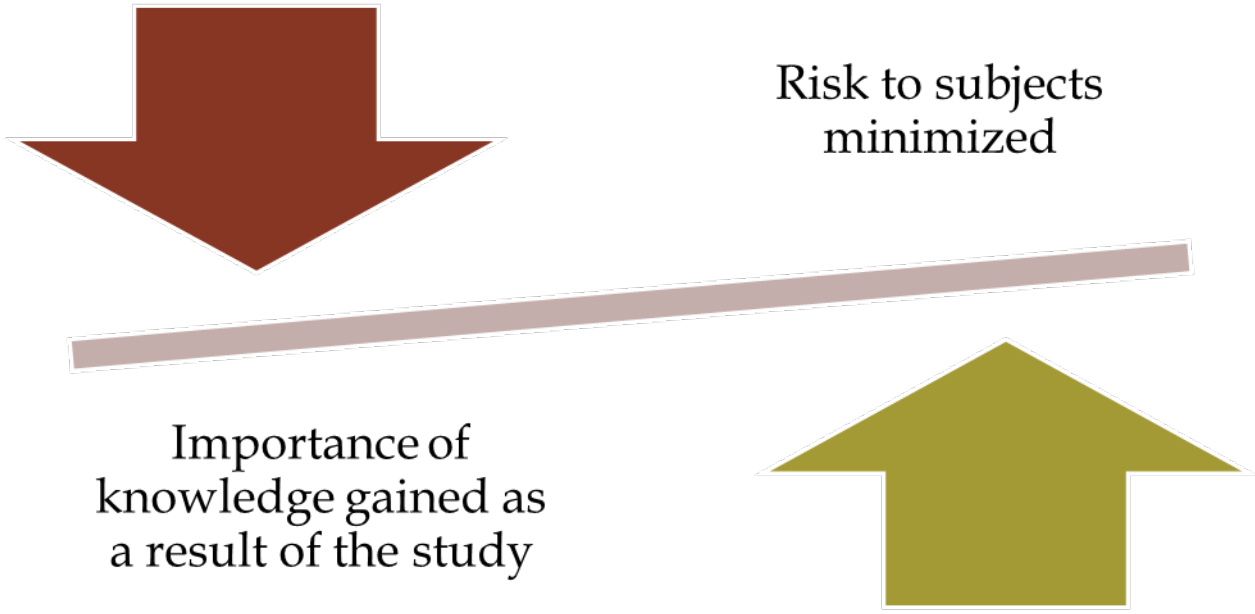
What is a Benefit?

Benefits

- The IRB must ask are the risks to subject reasonable to anticipated benefits;
- Many research projects have no direct benefit to subject but may have greater benefit to scientific knowledge or society/ population;
- Compensation for research participation is not considered a direct benefit.

What about Benefits?

- The IRB must ask are the risks to subject reasonable to anticipated benefits;
- Many research projects have no direct benefit to subject but may have greater benefit to scientific knowledge or society/ population;
- Compensation for research participation is not considered a direct benefit.
- What about a “No Benefit” study?



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Stating Risks and Benefits

Writing the Protocol/ Application and Informed Consent Document(s)

Statements of Risk and Benefits

- Provide a description of the foreseeable risks to the subjects.
- For EACH identified risk, include:
  - Likelihood of the risk,
  - Seriousness to the subject; and
  - What measures will be taken to minimize the risk.
- What is the highest level of risks of harm to the subjects, resulting from this research?;
- If possible, use the following categories to assess the likelihood: "common" "likely" "infrequent" "rare“;
- State any direct risks to the public or community, which could result from this research.

Statements of Risk and Benefits

Do Not Overstate… ✖

"You may benefit from this research by knowing you helped to contribute to science."

"This research is very important and you are part of something vital by agreeing to participate."

"These treatments may be very beneficial to you and lead to cure of X."

Instead Try… ✓

"This drug may not help you. All patients will receive standard therapies with randomization to the additional treatment. The knowledge may inform future treatments and benefit future patients."

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