

IRB Approval Criteria: Evaluating Potential Risks and Benefits

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POLICY:

- I. UIC IRBs identify risk in accordance with the criteria for IRB approval. The UIC IRBs evaluate risks, benefits, and the risk/benefit ratio for all research protocols that are reviewed, as applicable.

PROCEDURE:

- I. Regardless of funding source, the PI must submit the materials, or answer questions in sufficient detail, as required by the appropriate Initial Review Application form, Prompt Reporting Form, Amendment form, Continuing Review form, or Prompt Reporting form so that the IRB may make determinations as to the risks and the risk/benefit ratio of the research.
- II. The IRB identifies and analyzes potential sources of risk and measures to minimize risk, including physical, psychological, social, legal, or economic risks. The IRB will evaluate the PI's submission using the appropriate review guide checklists applicable to the type of research [DHHS, FDA, VA (which includes effects on insurability)] to determine the following:
 - A. Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.
 - B. Risks to participants are minimized, when appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
 - C. Risks to participants are reasonable in relationship to the potential benefits, if any, to participants, and the importance of the knowledge that may be expected to result from the research.
 - D. The IRB should consider risks and benefits that may result directly from the research. In most instances, speculation about the long-term effects of applying any knowledge that might be obtained from the research, such as the long-term effects on public policy, is likely outside the scope of the IRB review as to the risk/benefit analysis for most research topics that meet the requirements of *The Belmont Report*.

III. The IRB also considers a wide range of benefits, including therapeutic, educational, informational, or broad empowerment benefits using the appropriate review guide checklists applicable to the type of research (DHHS, FDA, VA). Benefits may accrue to the participants or their community.

REFERENCES:

[21 CFR 56.111\(a\)\(1\), 21 CFR 56.111\(a\)\(2\)](#)

[38 CFR 16.111\(a\)\(1\), 38 CFR 16.111\(a\)\(2\)](#)

[45 CFR 46.111\(a\)\(1\), 45 CFR 46.111\(a\)\(2\)](#)

[VHA Handbook 1200.05 3, VHA Handbook 1200.05 7, VHA Handbook 1200.05 10](#)