

Children's
Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-10
Effective Date: June 20, 2005

POLICY TITLE:

IRB REVIEW CRITERIA – NEW STUDIES

POLICY:

The IRB shall review all new research projects involving human participants to ensure adherence to the ethical principles of respect for persons, beneficence and justice and compliance with applicable federal regulations, state law, and institutional policies for the protection of research participants.

PROCEDURE:

- 10.1 In consideration of approval of a new research project involving human participants, the IRB shall review application materials to determine if all of the following criteria are met:
- A. Risks to subjects are minimized:
 - 1. by using procedures consistent with sound research design and which do not unnecessarily expose subjects to risk; and
 - 2. when applicable, by use of procedures already being performed on the subjects for diagnostic or treatment purposes [45 CFR 46.111(a)(1) and 21 CFR 56.111(a)(1)];
 - B. Risks to subjects are reasonable in relation to anticipated benefits [45CFR 46.111(a)(2) and 21 CFR 56.111(a)(2)]. To satisfy this requirement, the IRB must:
 - 1. identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive if not

2. participating in the research;
 2. determine that the risks will be minimized to the extent possible;
 3. identify the probable benefits to be derived from the research;
 4. determine that the risks are reasonable in relation to the benefits;
 5. ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.
- C. Selection of research participants is equitable [45 CFR 46.111(a)(3) and 21 CFR 56.111(a)(3)]. When determining whether the burdens of research are being distributed equitably, the IRB shall consider:
1. Whether the burdens of participating in the research fall on those most likely to benefit from the research;
 2. If the solicitation of participants places a disproportionate share of the research burden on any single group;
 3. If the nature of the research justifies or requires using the proposed research participant population;
 4. Would it be possible to conduct the proposed study with other, less vulnerable participants;
 5. Has the selection process excluded potential participants who are likely to benefit; and
 6. If the participants are susceptible to pressures (undue influence or coercion), are there mechanisms in place to reduce the pressures or minimize their impact.
- D. Informed consent will be sought from each prospective participant or legally authorized representative as required (see IRB policy 13)[45 CFR 46.111(a)(4) and 21 CFR 56.111(a)(4)];
- E. Informed consent will be appropriately documented [45 CFR 46.111(a)(5) and 21 CFR 56.111(a)(5)];
- F. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects [45 CFR 46.111(a)(6) and 21 CFR 56.111(a)(6)];
- G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data [45 CFR 46.111(a)(7) and 21 CFR 56.111(a)(7)];
- H. When some or all of the subjects are likely to be vulnerable (e.g., children, pregnant women, prisoners, mentally disabled persons,

economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of these subjects [45 CFR 46.111(b) and 21 CFR 56.111(b)].

- I. When the research subjects include children, determine whether assent will be required, taking into account the ages, maturity, physical and psychological state of the children. When assent is required, determine that adequate provisions are made for soliciting and documenting assent [45 CFR 46.408(a) and (e) and 21 CFR 50.55 (a) (b) and (g)].

Submitting Committee: Institutional Review Board

Approved by: Douglas S. Dreher 6/20/05
Chair Date
Elizabeth Trias 6/20/05
Manager Date