

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

DEPARTMENT: Institutional Review Board
POLICY NUMBER: IRB-003
REPLACES: _____
EFFECTIVE DATE: June 20, 2005
REVISION DATE: December 14, 2011

TITLE: Human Participants of Research

SUMMARY:

Children's IRB shall ensure the protection of human participants as defined in state and federal regulations enrolled in research conducted under its jurisdiction.

POLICY/PROCEDURE:

- 3.1 Children's IRB shall review human subjects research within its jurisdiction to ensure the protection of participants. Human research participants are defined as:
- A. A living individual, about whom an investigator conducting research obtains data through intervention or interaction with the individual, or collects identifiable private information [45 CFR 46.102(f)(1-2)];
 - B. Deceased persons if the research uses their private identifiable health information [Washington state law RCW 70.02.140 and federal policy 45 CFR 164.502(f)];
 - C. A human participant of research may be either healthy or a patient [21 CFR 50.3(g)];
 - D. Interventions in human participants include physical procedures by which data are gathered, and manipulations of the subject or the subject's environment for research purposes [45 CFR 46.102(f)(2)];
 - E. Interactions with human subjects include communications or interpersonal contacts conducted for research purposes [45 CFR 46.102(f)(2)];
 - F. Private information includes information about behavior that occurs in a context in which the subject can reasonably expect that no observation or

recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g., medical records. [45 CFR 46.102(f)(2)].

- 3.2 Certain groups of human research participants who are likely to be vulnerable to coercion or undue influence, include children, prisoners, pregnant women, mentally disabled (cognitively impaired) persons, and economically or educationally disadvantaged persons. Additional safeguards shall be incorporated in studies involving these groups of participants to protect the rights and welfare of these participants and minimize coercion and undue influence [45 CFR 46.111(b)].
- A. Research projects involving children shall be reviewed in accordance with the additional protections for children involved as subjects in research [45 CFR 46 Subpart D] and for children in clinical investigations [21 CFR 50, Subpart D].
 - B. Research projects involving prisoners shall be reviewed in accordance with the additional protections pertaining to biomedical and behavioral research involving prisoners as subjects. [45 CFR 46, Subpart C].
 - C. Research projects involving pregnant women and fetuses shall be reviewed in accordance with the additional protections for pregnant women, human fetuses, and neonates involved in research. [45 CFR 46, Subpart B.]
- 3.3 Whenever employees of Children's are to be used in research the IRB will ensure that adequate safeguards are in place to address any potential for coercion or undue influence on employees. Whenever employees of Children's are to be used as "healthy subject pools" in research, the IRB will scrutinize the recruitment process to ensure that consent is obtained under circumstances that minimize the possibility of coercion or undue influence, and that other methods of recruitment of healthy participants are considered to facilitate participation of equivalent healthy participants not susceptible to coercion.

Submitting Office: Institutional Review Board

Approved by:

\s\ Douglas Diekema, MD, MPH, 12/14/11
Chair, Institutional Review Board

\s\ Laurie Bolton, JD, 12/14/11
Director, Office of Institutional Assurances