

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-2
Effective Date: June 20, 2005

POLICY TITLE:

IRB JURISDICTION

POLICY:

The IRB shall review all new and continuing research projects that meet federal and state definitions of research involving human participants and that fall within Children's jurisdiction.

DEFINITIONS:

The federal definition of research: **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

The federal definition of human subject: **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

