

Children's

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

OPERATING PROCEDURES/POLICIES

Committee:	<u>Institutional Review Board</u>
Policy Number:	<u>IRB-1</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

AUTHORITY OF THE IRB

POLICY:

The IRB shall review all new and continuing research projects that fall within Children's jurisdiction to provide for the protection of the rights and welfare of human participants involved in such research. No research involving human participants may begin until Children's IRB has granted its approval or accepted a waiver of IRB review under a duly executed institutional agreement (IRB Policy 2). Children's IRB is governed by all applicable state and federal regulations, including but not limited to 45 CFR 46, 21 CFR 50 and 21 CFR 56.

PROCEDURE:

- 1.1 Formal application for IRB review must be initiated by the Principal Investigator submitting a complete IRB application and all required materials to the Children's Institutional Review Board. [IRB Policy 11 (Full IRB) and IRB Policy 22 (Expedited Review) or IRB Policy 27 (Exempt Review Status)]
- 1.2 The IRB has the authority to approve, require changes to, or disapprove all research activities that fall within its jurisdiction (IRB Policy 2). The IRB will notify the principal investigator of the research study in writing of its decision to approve, require changes to or disapprove the proposed research activity.
- 1.3 The Vice President of Research shall have the authority to administratively disapprove of any project before or following IRB approval. If a project is administratively disapproved, the Vice President of Research shall address a

letter to the investigator outlining the reasons for disapproval. However, the Vice President of Research may not approve research if it has been disapproved by the IRB.

- 1.4 In consideration of approval of a new research project involving human subjects, the IRB will review the application as detailed in IRB Policy 11 (Full IRB) and IRB Policy 22 (Expedited Review) or IRB Policy 27 (Exempt Review Status). In consideration of approval of a continuing research project involving human subjects, the IRB will review the application as detailed in IRB Policy 14.

Submitting Committee: Institutional Review Board

Approved by: *Douglas S. Duheine* *6/20/05*
Chair Date

Elizabeth Tries *6/20/05*
Manager Date