

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-9</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

IRB RECORDS AND CONFIDENTIALITY

POLICY:

The IRB shall prepare and maintain adequate documentation of its activities and shall retain documents no less than for a period of three (3) years following the conclusion of the study. IRB records are confidential and shall be maintained as records and proceedings of a hospital committee established pursuant to Federal regulation. The IRB shall permit an authorized representative of the Office of Human Research Protection (OHRP) or the U.S. Food and Drug Administration (FDA), at a reasonable time and with sufficient notice, to inspect and copy those records required to be maintained under Federal regulations.

PROCEDURE:

- 9.1 Children's IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
 - A. A copy of all IRB applications submitted and reviewed along with consent and assent forms, research protocols, scientific evaluations, if any, amendments, progress reports, reports of injuries to subjects and any other information submitted by Investigators and Sponsors [45 CFR 46.115(a)(1) and 21 CFR 56.115(a)(1)];
 - B. Minutes of IRB meetings which set forth attendance, actions taken, vote including number of votes for, against, abstaining, or absent and any discussion of, and resolution of controverted issues, IRB required findings and determinations, and the basis for requiring changes in or disapproving research. [45 CFR 46.115 (a)(2) and 21 CFR 56.115 (a)(2)];
 - C. Status (renewal) reports and final reports, notification of changes and other records of continuing review activities [45 CFR 46.115(a)(3) and 21 CFR 56.115(a)(3)];

