

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

DEPARTMENT: Institutional Review Board
POLICY NUMBER: IRB-009
REPLACES:
EFFECTIVE DATE: June 20, 2005
REVISION DATE: December 14, 2011

TITLE: IRB Records and Confidentiality

SUMMARY:

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.

POLICY/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)];
- D. Copies of all correspondence between IRB and investigators [45 CFR 46.115(a)(4) and 21 CFR 56(a)(4)];
- E. A list of current IRB members including name, earned degrees, representative capacity, indications of experience such as board certifications, licenses and relationship to Children's [45 CFR 46.103(b)(3), and 45 CFR 46.115(a)(5) and 21 CFR 56.115(a)(5)];
- F. Written policies and procedures for IRB in the same detail as described in 45 CFR 46.103(b)(4), 45 CFR 46.103(b)(5) and 21 CFR 56.108 (a) and (b) [45 CFR 46.115(a)(6) and 21 CFR 56.115(a)(6)];
- G. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5) and 21 CFR 50.25 [45 CFR 46.115(a)(7) and 21 CFR 56.115(a)(7)].

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