

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

DEPARTMENT: Institutional Review Board
POLICY NUMBER: IRB-8
REPLACES: IRB-8
EFFECTIVE DATE: June 20, 2005
REVISION DATE: July 29, 2008
POSTED FROM:

TITLE: Meetings, Minutes and Quorum

SUMMARY:
See Policy/Procedure

POLICY/PROCEDURE:

The IRB shall meet every two weeks and on an emergency basis as necessary to conduct initial and ongoing review of research protocols. Minutes of all meetings shall be recorded and maintained [45 CFR 46.115 and 21 CFR 56.115]. IRB approval shall be granted only by majority vote at a convened meeting during which a quorum is present [45 CFR 46.108(b) and 21 CFR 56.108(c)].

08-1 Meetings

08-1.1 Meetings will be held every other Thursday throughout the year, unless directed otherwise by the IRB Chair or Manager.

08-1.2 Emergency meetings may be called by the Chair or IRB Manager with at least forty-eight hours notice to members.

08-1.3 The IRB will have an agenda for each of its meetings. The agenda will identify each IRB application, i.e., name of Principal Investigator, title of the research study, and IRB application number for all research project applications awaiting action by the IRB. The agenda will identify the IRB members assigned as primary reviewers for each application awaiting action. The agenda will identify the status of the application, e.g., new study, renewal (continuing review study), full board modification, deferral, or reconsideration. See sample agenda Appendix 17.F.

08-2 Minutes

08-2.1 Minutes of all IRB meetings shall be recorded and include [45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2)]:

08-2.1.1 Attendance at the meeting;

08-2.1.2 Business items of IRB that are discussed at the meeting. These may include approval of minutes from prior meetings; reports submitted for IRB review, e.g., Modification Report, Expedited Review Report, Adverse Events Report; reports of single patient emergency uses; reports of non-compliance. Educational or training items provided to the IRB and announcements of

educational or training opportunities, e.g., conferences, workshops. Reminder by IRB Chair of Children's conflict of interest policy and need for members to leave meeting during deliberations and vote on studies in which they have a potential conflict.

08-2.1.3 Actions taken by the IRB on each application undergoing initial or continuing review;

08-2.1.4 The vote on each of these actions including the number of members voting for, against, abstaining. Members who are absent for the vote, due to conflict of interest or other reason, will be noted by name as absent for the vote;

08-2.1.5 The basis for requiring changes in, disapproving, suspending or terminating research;

08-2.1.6 If vulnerable groups are included in the research (e.g., children and minors, prisoners, pregnant women, human fetuses or neonates) documentation of all required findings for research with these vulnerable groups [45 CFR 46 Subparts B, C, and 45 CFR 46 and 21 CFR 50 Subpart D). The documentation of IRB findings shall be specific to the research protocol;

08-2.1.7 If the IRB approves a waiver of consent or waiver for obtaining signed consent, the required findings for such waivers shall be documented [45 CFR 46.116 (d) and 117(c)]. The documentation of IRB findings shall be specific to the research protocol;

08-2.1.8 A written summary of the discussion of controverted issues and their resolution;

08-2.1.9 Period of approval to be no greater than a year from the date of the convened meeting. When assigning period of approval the IRB shall consider factors including the perceived level of risk, whether there is an independent data and safety monitoring board, the degree of vulnerability of research participants, the category of research with children; the experience of the researchers, and if there is any past history of non-compliance on part of researchers. The minutes shall reflect the IRB's deliberations in determining what approval period to assign the research.

08-2.2 The minutes shall be sent for review and approval via email to the IRB members attending the meeting. Members will be instructed to send any comments, proposed changes or additions to the minutes to the IRB staff within one week of their receipt of the same. Absence of a response from an IRB member will be considered an approval. After one week, final changes will be made to the minutes. The final version of the minutes will be distributed to the IRB members. Copies of the minutes shall also be sent to the President of the Research Institute (the institutional official) and to the Medical Director (the institutional official responsible for appointing IRB members and patient safety).

08-2.3 Minutes shall be retained for at least three years after completion of the research [45 CFR 46.115(b) and 21 CFR 56.115(b)].

08-3 Quorum

08-3.1 The IRB review and approval process shall be conducted during meetings at which a quorum of members is present. For purposes of a meeting, a quorum shall be a majority of the voting members. For purposes of a vote, a quorum shall be a majority of the voting members present who have no conflicting interest [45 CFR 46.108(b) and 21 CFR 56.108(c)].

08-3.2 In no event shall a quorum be constituted without the presence of one member whose primary concerns is in a nonscientific area [45 CFR 46.108(b) and 21 CFR 56.108(c)].

08-3.3 Studies involving prisoners must be reviewed by a quorum in which a majority of the IRB members have no association with the prisons involved and in which at least one member is present who serves as a prisoner representative with appropriate background and experience to serve in that capacity. [45 CFR 46.304(a) (b)].

Submitting Office: Institutional Review Board
Office of Institutional Assurances

Approved by:

\s\ Douglas S. Diekema, M.D., M.P.H., Chair, July 29, 2008

\s\ Laurie J. Bolton, J.D., Director, July 29, 2008