

Children's

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-6
Effective Date: June 20, 2005

POLICY TITLE:

IRB MEMBER TRAINING

POLICY:

Members of Children's Institutional Review Board shall receive training in human subjects protections to ensure that members are familiar with the basic ethical principles, the federal regulations, state law and institutional policies for the protection of human subjects enrolled in research.

PROCEDURE:

New Members' Training

- 6.1 The Manager of the IRB shall provide an in-person orientation to new members appointed to the IRB. Each new member of the IRB shall receive an Institutional Review Board Member Manual. The materials included in the manual which are covered in the in-person orientation include:
- A. The ethical principles governing research with human subjects as outlined in the Belmont Report. Members also receive copies of the Nuremberg Code, the Declaration of Helsinki, and the article "What Makes Clinical Research Ethical?", Emanuel, E.J., et al, Journal of American Medical Association, May 24/31, 2000, Vol. 283, No. 20, pages 2701-2711. (Appendix 11)
 - B. The federal regulations, 45 CFR 46, 21 CFR 50, 21 CFR 56. During the orientation, particular emphasis is placed on the federal regulations governing the protection of children enrolled in research (45 CFR 46 and 21 CFR 50, Subpart D).
 - C. Children's Federal Wide Assurance and the interinstitutional agreements of Children's with: i) University of Washington; ii) Fred Hutchinson Cancer Research Center; and iii) Pediatric Central IRB (Ped CIRB) of the National Cancer Institute. (Appendix 10)
 - D. IRB policies.
 - E. Overview of Children's IRB, including the IRB review process for new and continuing studies requiring full IRB review, the IRB reviewer

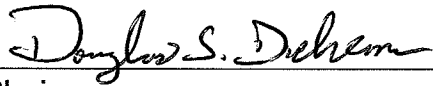

worksheet, the IRB application forms, the IRB meeting schedule and IRB membership roster. New IRB members receive information about the contents and distribution of the IRB agenda prior to the IRB meetings, how IRB deliberations are documented, and who to contact in the IRB office.

- 6.2 New members of the IRB who have not taken previous human subjects protections training, will also be required to take the basic training in human subjects protections offered on a quarterly basis by the IRB Chair.
- 6.3 New members of the IRB shall receive additional resources and training as needed. Community and non-scientist members are offered resources, e.g., medical dictionary, the Merck Manual of Diagnosis and Therapy, to assist them in the review of the IRB applications.

Ongoing education of IRB Members

- 6.4 Children’s IRB shall provide ongoing education for IRB members. Types of ongoing education provided to IRB members include distribution and discussion of articles relevant to research ethics, particularly research in children, copies of the bimonthly journal IRB: Ethics & Human Research, attendance at local and regional workshops, conferences, and training sessions.
- 6.5 Children’s IRB will provide training and ongoing education to IRB members and IRB staff, including the IRB Chair, Manager, and Coordinators to include attendance at national conferences relevant to the protection of human research participants.
- 6.6 Children’s maintains a small IRB library and has books, publications, and tapes (CDs) available on human subjects protections and research ethics.

Submitting Committee: _____ Institutional Review Board

Approved by:	 _____ Chair	6/20/05 _____ Date
	 _____ Manager	6/20/05 _____ Date