

Children's

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-4
Effective Date: June 20, 2005

POLICY TITLE:

MEMBERSHIP AND TERM

POLICY:

Children's Hospital and Regional Medical Center (Children's) IRB will conduct its business with the participation of the following persons: regular voting members, alternate voting members, non-voting members and *ad hoc* reviewers. The IRB shall at all times be sufficiently qualified through the professional competence, expertise and diversity of its membership to ensure that a thorough and competent review is undertaken that assures respect for its advice. No member of the IRB shall be involved, except in a consultative capacity, in any review activity in which he or she has a conflicting interest.

PROCEDURE:

4.1 Regular Voting Members

- A. The IRB shall have at least eight regular voting members, including the chairperson.
- B. At least one IRB member will be a scientist and one member a non-scientist [45 CFR 46.107(c) and 21 CFR 56.107(c)].
- C. At least one IRB member will be unaffiliated with Children's nor a part of the immediate family of a person affiliated with Children's [45 CFR 46.107(d) and 21 CFR 56.107 (d)].
- D. Scientist members of the IRB will have experience in biomedical research involving children, and shall include no less than one board certified pediatrician.
- E. Non-scientist members will have experience in issues considered to be relevant to human subjects research in children. These may include experience in ethical, legal, human rights, child health and welfare, or child behavioral or development issues.

- F. Non-affiliated members may be a scientist or non-scientist recruited from the greater Seattle area.
- G. Children's shall ensure that the IRB membership possesses the expertise necessary to ascertain the acceptability of the research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice [45CFR 46. 107 (a) and 21CFR 56.107 (a)].
- H. Children's shall ensure that the IRB membership possesses the professional competence and diversity necessary to review research involving human participants, with special emphasis on children and minors [45 CFR 46.107(a) and 21 CFR 56.107(a)].
- I. When Children's IRB reviews research involving the use of minors who are prisoners or in the juvenile justice detention system, an *ad hoc* voting member shall attend the meeting and serve as a prisoner advocate in accordance with the federal regulations, 45 CFR 46.304. The ad-hoc voting member who serves as a prisoner advocate shall have the background and experience necessary to serve as a representative for prisoners.
- J. Regular voting members will be appointed for three (3) year terms. IRB membership may be renewed at the request of the IRB Chair with the approval of the Medical Executive Committee and the Board of Trustees as long as the member continues to possess the required qualifications. If a regular member is chosen as the IRB Chair, the duration of his/her membership will be extended automatically to allow completion of the terms of appointment as Chair.
- K. Reappointment of regular voting members shall be requested by the IRB Chair to the Medical Director based on the member's qualifications and continued interest.
- L. The Medical Director shall solicit nominations of new IRB members based on the qualifications of the candidate and the areas of expertise most useful to the IRB.
- M. The Medical Director shall appoint all regular voting members with approval by the Medical Executive Committee and the Board of Trustees.

4.2 Alternate Voting Members

- A. The IRB, at its discretion, may recruit alternate voting members for any of its regular voting members. Alternates will be selected in a manner that maintains the Board's necessary expertise and diversity.
- B. Alternate members regularly attend IRB meetings and arrange with their paired regular voting members who shall attend the scheduled IRB meetings.
- C. Alternate voting members shall have voting rights and have all the privileges of the regular voting members. Alternate voting members will be included in determining or establishing quorum.

- D. If an alternate voting member is in attendance at the same IRB meeting as their respective (paired) regular voting member, the alternate voting member will not vote and will not be included in determining or establishing quorum.
- E. The procedure for appointment and reappointment of an alternate voting member shall be the same as that of a regular voting member; the duration of their membership shall be the same as that of a regular voting member.

4.3 Non-Voting Members

- A. The IRB may recruit non-voting members whose presence at the meeting would be consultative and educational and aid the IRB in conducting its duties.
- B. Non-voting members may take part in all IRB meetings, participate in discussions, and make recommendations to influence decisions, but may not vote on the decisions.
- C. Non-voting members will not be included in determining or establishing a quorum. The procedure for appointment of non-voting members shall be the same as that of a regular voting member; the duration of their membership will not be limited.

4.4 Ad hoc Reviewers

- A. The IRB Chair may invite any individual who is not a member of the IRB and has special expertise to function as *ad hoc* reviewer of a project application to assist the IRB in its review process.
- B. *Ad hoc* reviewers will have access to all documents submitted to the IRB relevant to the specific project under review. The ad hoc reviewers will sign a Children's Confidentiality Agreement (Appendix 16.C) prior to receiving documents from the IRB.
- C. *Ad hoc* reviewers may participate in deliberations and make recommendations on the project, but may not vote.
- D. The identity of *ad hoc* reviewers shall be kept confidential.

4.5 IRB Chair

- A. The IRB Chair shall be a respected, active member of Children's medical staff, with qualifications as a physician-scientist, with demonstrated training and expertise in the areas of human rights and ethical issues, and well informed in regulations relevant to the use of human participants in research.
- B. The Chair will be appointed to a five (5) year term, renewable for additional five-year terms as long as the member continues to possess

- the required qualifications and at the bequest of the Medical Director, Medical Executive Committee and the Board of Trustees.
- C. If the current Chair does not wish to extend his/her appointment, or is not approved by the Medical Director for reappointment, the procedures for the selection of a new Chair become activated.
 - D. If a new IRB Chair is to be appointed, the Medical Director shall nominate a qualified candidate with previous IRB experience for approval by the Medical Executive Committee and the Board of Trustees.
 - E. During planned absences, the IRB Chair shall designate an experienced voting member of the IRB to assume the responsibilities of the Chair *pro tempore* during the period of his/her absence. Any member of the IRB serving as Chair *pro tempore* shall have at least one year of IRB experience and preferably more. The IRB Chair shall provide written notification to the authorized institutional official for the IRB and the Medical Director when a Chair *pro tempore* has been designated.

To be effective and efficient in its operations, and to be responsive to the research community it serves, the IRB may increase, above federally mandated minimums, the number of its members in any category.

4.6 IRB Membership Roster

- A. The IRB Office shall maintain a roster of IRB members. The membership roster will include names of IRB members, their earned degrees, whether the IRB member is affiliated or non-affiliated with Children's, whether the member is a scientist or non-scientist member of the IRB, their primary scientific or non-scientific specialty, gender, and other relevant information about the members' experience or relationship with the organization that would describe that members' anticipated contributions to IRB deliberations. [45 CFR 46.103(b)(3) and 21 CFR 56.115(a)(5)]
- B. Changes to IRB membership shall be reported to OHRP on a quarterly basis.
- C. The IRB Office shall maintain curriculum vitae or resumes of current IRB members. On occasion, IRB members may be retired or not employed, and may not have a current curriculum vitae or resume for the IRB Office file.

4.7 IRB Members and Conflicts of Interest

- A. No member of the IRB may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. [45 CFR 46.107(e) and 21 CFR 56.107(e)].
- B. All IRB members shall complete a Survey on Outside Interests on an annual basis and abstain from voting on any research project in which the member

- has a conflicting interest. Appendix 16.D.
- C. The IRB Chair shall remind members at the beginning of each IRB meeting that any member with a conflicting interest in a research project being reviewed at the meeting, shall be required to leave the room while the IRB deliberates and votes on said research project.

Submitting Committee: Institutional Review Board

Approved by:

<u>Douglas S. Dehene</u>	<u>6/20/05</u>
Chair	Date
<u>Elizabeth N. Trias</u>	<u>6/20/05</u>
Manager	Date