

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

**DEPARTMENT:** Institutional Review Board  
**POLICY NUMBER:** IRB-004  
**REPLACES:**  
**EFFECTIVE DATE:** December 11, 2008  
**REVISION DATE:** July 13, 2011

**TITLE:** Membership and Term

**SUMMARY:**

Seattle Children's IRB will conduct its business with the participation of the following persons: regular voting members, alternate voting members, and consultants. The IRB shall at all times be sufficiently qualified through the professional competence, expertise and diversity of its membership and through use of consultants when necessary to ensure that a thorough and competent review is undertaken. 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.

**POLICY/PROCEDURE:****004-1 Regular Voting Members**

- 004-1.1 The IRB shall have at least five regular voting members, including the chairperson.
- 004-1.2 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)].
- 004-1.3 At least one IRB member will neither be affiliated 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)].
- 004-1.4 Non-affiliated members may be a scientist or non-scientist.
- 004-1.5 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)].
- 004-1.6 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)].

- 004-1.7 When Children's IRB reviews research involving the use of minors who are prisoners or in the juvenile justice detention system, a voting member shall attend the meeting and serve as a prisoner advocate in accordance with the federal regulations, 45 CFR 46.304. The voting member who serves as a prisoner advocate shall have the background and experience necessary to serve as a representative for prisoners.
- 004-1.8 Regular voting members will be appointed for two (2) year terms, which can be renewed. IRB membership may be renewed by the IRB Chair. 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.
- 004-1.9 The Institutional Official shall solicit nominations of new IRB members based on the qualifications of the candidate and the areas of expertise most useful to the IRB.
- 004-1.10 The Medical Director shall appoint all voting members.

### **004-2 Alternate Voting Members**

- 004-2.1 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.
- 004-2.2 Alternate voting members shall have voting rights and have all the privileges of the regular voting members.
- 004-2.3 If an alternate voting member is in attendance at the same IRB meeting as their respective regular voting member, the alternate voting member will not vote and will not be included in determining or establishing quorum.
- 004-2.4 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.

### **004-3 Consultants**

- 004-3.1 The IRB may recruit consultants whose presence at the meeting would be consultative and educational and aid the IRB in conducting its duties.
- 004-3.2 Consultants may take part in IRB meetings, participate in discussions, and make recommendations to inform decisions, but may not vote on the decisions.
- 004-3.3 Consultants will not be included in determining or establishing a quorum.

### **004-4 IRB Chair**

- 004-4.1 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.
- 004-4.2 During absences, the IRB Chair/Institutional Official 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.

#### **004-5 IRB Membership Roster**

- 004-5.1 The HSPP 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)]
- 004-5.2 Changes to IRB membership shall be reported to OHRP.
- 004-5.3 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 HSPP Office file.

#### **004-6 IRB Members and Conflicts of Interest**

- 004-6.1 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)].
- 004-6.2 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.
- 004-6.3 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 Office: Institutional Review Board

Approved by:

\\s\ Douglas Diekema, MD, MPH July 13, 2011  
Chair, Institutional Review Board

\s\ Laurie Bolton, JD, July 13, 2011  
Director, Office of Institutional Assurances