

**Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute**

SUBJECT: Institutional Review Board (IRB) Membership

POLICY

I. Purpose:

- A. To establish an IRB with oversight responsibility for the protection of human subjects participating in research studies conducted at Children's Hospital of Wisconsin (CHW) and/or institutions that have a Federal Wide Assurance (FWA) in effect designating the CHW IRB as the IRB for review of studies conducted at that institution (hereinafter, "FWA-Affiliated Institution"). This policy describes the requirements for membership and composition of the CHW IRB. This policy is compliance with Title 45 of the Code of Federal Regulations, part 46.107.

II. Policy:

- A. Composition:
1. The CHW IRB shall be composed of no less than five (5) voting members sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for their advice and counsel in safeguarding the rights and welfare of human subjects.
 2. Of the permanent members selected for IRB membership:
 - a. At least four must be from the CHW Medical Staff, including a member of the Pharmacy and Therapeutics Committee.
 - b. at least one must be from a scientific area of interest,
 - c. at least one must be from an area of interest that is primarily non-scientific (lawyer, clergy, ethicist), and
 - d. at least one must be independent of CHW and/or FWA-Affiliated Institutions (community member).
 - e. NOTE: One member may fulfill the requirements of both b. and c.
 3. At least one (1) and a maximum of three (3) alternate members will also be formally appointed and listed in the membership roster. The roster will identify the primary member(s) for whom each alternate may substitute.
 - a. Alternate members must meet the same criteria as voting members with respect to qualifications to serve.

- b. Alternate members shall have received and reviewed the same materials that the substituted member received or would have received prior to the meeting.
- c. Alternate members are subject to all CRI policies governing voting members (e.g., educational requirements, term etc.)

B. Qualifications of IRB Members and Institutional Support:

1. Selection Criteria: Each member will be evaluated/re-evaluated for the following criteria:
 - a. For scientific members, documented professional experience;
 - b. Competence to review complex research proposals and make appropriate human subject protection decisions with integrity, reasonableness, and consistency;
 - c. Knowledgeable about the research community in which they will be asked to serve;
 - d. Current knowledge of relevant ethical principles, Federal regulations, state and local laws, and Children's Research Institute (CRI) policies for the protection of human subjects or commitment to receive relevant educational training before reviewing research involving human subjects;
 - e. Lack of conflict of interest or perceived conflict of interest whereby the interest would prohibit participation in reviewing a significant number of research proposals;
 - f. Willingness and availability to serve the full term of appointment;
 - g. Willingness to comply and be held accountable for adherence to CRI policies; and,
 - h. Commitment to review IRB items in a confidential manner.
2. Institutional support:
 - a. CHW, through CRI, will provide the IRB with resources and professional and support staff sufficient to carry out their responsibilities under CHW's FWA effectively.
 - b. Educational training and oversight mechanisms will be established to ensure IRB members and staff maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal regulations, OHRP and FDA guidance, other applicable guidance, state and local laws, and CRI policies for the protection of human subjects.
 - c. IRB members will not receive compensation for their participation. IRB members may be reimbursed for out-of-pocket costs, such as travel and supplies, in accordance with CHHS policy.

C. Selection, Term, and Removal

1. The IRB Chair shall be a member of the CHW Medical/Dental Staff with experience in human subject research studies who is

designated by the CHW President or his/her designee. (S)he shall possess the same qualifications as other IRB members.

- a. Once appointed, the IRB Chair's term shall be for 3-years and may be renewed indefinitely.
 - b. The IRB Chair may be removed by the CHW President, the President's designee, or the CHW Board of Directors with cause.
2. Voting Medical Staff members, both primary and alternate, shall be appointed by the President of the Medical-Dental Staff, with the approval of the CHW President or the President's designee.
 3. Voting community members, both primary and alternate, shall be appointed by the IRB Chair.
 4. Once a member has been selected and agrees to the appointment, they shall serve for three-year terms. Terms may be renewed indefinitely.
 5. Two (2) consecutive absences or more than six (6) absences in a one-year period could result in the removal of a member from service on the IRB. In addition, a member may be removed for any one of the following:
 - a. lack of participation in IRB meetings, including frequent abstention from voting activities;
 - b. ineffectiveness (as determined by the IRB Chair) due to a consistent lack of preparation or follow-up as necessary to ensure the objectives of the IRB are being met;
 - c. failure to attend training sessions as offered by CRI;
 - d. except under emergency circumstances, failure to notify the IRB Coordinator or Chair in advance of an absence thus preventing the use of a designated alternate; and,
 - e. frequent early departures from the meeting resulting in loss of quorum.

D. Membership Roster

1. A list of the current members, both primary and alternate will be maintained. The list will identify members by name, earned degrees, representative capacity, indications of experience (e.g., board certifications and licenses) sufficient to describe each member's primary anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution.
2. Any changes in IRB membership or other authorized institutional officials listed on CHW's most recent Assurance on file with DHHS must be timely reported to the Office of Human Research Protections (OHRP).

E. Non-Voting Participants

1. The IRB Chair may, in his or her discretion, invite individuals with competence in special areas to assist in the review of a proposed research protocol that requires expertise beyond or in addition to that available to the IRB. These individuals must be independent of the Investigator and/or Sponsor of the proposed research, are not eligible to vote and cannot be counted towards quorum.

PROCEDURE

A. Membership approval process

1. IRB_Membership Applications shall be completed to request to serve on the IRB panel. The application must include the following :
 - a. Current CV or resume that is signed and dated;
 - b. Contact information;
 - c. Description of research experience and/or IRB experience;
 - d. Documentation of willingness to comply with CRI's policies and applicable federal and state regulations;
 - e. Signed confidentiality statement; and
 - f. Commitment to receive continuing education on the responsible conduct of research and protection of human subjects, including the IRB process, changing regulations, and informed consent requirements.
2. Decisions will be communicated to the applicant in writing within ten (10) business days of receipt of the application.

B. The IRB coordinator(s) will be responsible for maintaining:

1. Member files including current CVs or resumes, training certificates and other relevant documentation
2. Membership rosters in accordance with policy provision D.1., above.

C. The IRB Coordinator will be responsible for reporting any changes in IRB membership or other authorized institutional officials listed on CHW's most recent Assurance on file with DHHS to the Human Protections Administrator (HPA) for forwarding to OHRP and otherwise assist the HPA in ensuring the filing is kept current and up-to-date.

References:

- A. 21 CFR 50
- B. 21 CFR 56
- C. 45 CFR 46

Documentation (Documents & Forms):

- A. HRRB Membership Application
- B. HRRB Membership Roster
- C. OHRP Federal Wide Assurance

(signed copy on file)

Peggy Troy, President of CHHS