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**Boston
Children's
Hospital**

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Owner Susan Kornetsky:
Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

IRB Member: Selection, Responsibilities, and Evaluation Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy is to outline the process for appointing Institutional Review Board (IRB) members. It also provides procedures to assure appropriate representation on the IRB and prevent competing business interests from influencing the IRB review process.

Policy Statements

Boston Children's Hospital maintains an Institutional Review Board (IRB) that includes members with the appropriate expertise to review the wide variety of research protocols commonly conducted by the hospital, as well as members who fairly represent the interests of the community.

1. The IRB members will be knowledgeable about regulatory requirements and will review individual research protocols objectively and impartially.
2. Individuals who serve research business and research development roles for the hospital are neither permitted to serve as IRB members nor IRB administrators.

Administrative Management

1. The roster of IRB membership and the curriculum vitae are maintained in the IRB Office.
2. Membership updates are sent to Office of Human Research Protections (OHRP) as changes in

membership occur. The Director of Clinical Research Compliance is responsible for reporting the changes to OHRP.

3. Non-affiliated members are offered an honorarium of \$100 and a parking voucher for each meeting they attend. All other members do not receive any monetary compensation.
4. The Chair and Vice Chair have a portion of their salary covered for their service to the IRB.
5. On an annual basis, statistics regarding the activities of the IRB are compiled and reviewed with the Chair, the Senior Director of Clinical Research Compliance, and the Institutional Official.

Procedures

Appointment

The Medical Staff Executive Committee (MSEC) appoints IRB members. The MSEC will consider the recommendations of the Vice President of Research Administration, the IRB Chair, and the Senior Director of Clinical Research Compliance.

The MSEC will receive the curriculum vitae (CV) and/or resume of any individual who is recommended. Copies of the CV and/or resume will be submitted to the Office of the Senior Director of Clinical Research Compliance.

Committee Composition

Members are selected to assure continual diversity and experience on the IRB, and are to include both persons of various backgrounds and professions.

Boston Children's Hospital has many different disciplines. IRB members are selected from departments that have the most active clinical research programs. However, the IRB also keeps in mind the need for expertise in all areas and ensures appropriate representation.

Consideration will be given to the local patient and community populations to achieve membership that is representative of the Boston Children's Hospital community.

In addition to the regulatory requirements, the following characteristics will be taken into consideration:

1. The need to have representatives from the major disciplines that conduct clinical research at Boston Children's Hospital.
2. At least one member and their immediate family members must be unaffiliated with the hospital and one member must belong to a nonscientific profession. It is desirable to have at least two to three IRB members with these qualifications.
3. Individuals who understand the psychological, emotional, and behavioral needs of children.
4. Individuals who are capable of determining whether a specific location is safe to perform research on children.
5. Individuals of multiple ethnic and cultural backgrounds.
6. An IRB member who can serve as prisoner representative when needed.

Responsibilities

1. Term Length

- a. Members are appointed for a three-year term with renewable terms for an undefined period. As terms end and vacancies are established, the goal of consistency of members and the need for new ideas are taken into consideration.
- b. Membership is established in compliance with the existing regulations of the Department of Health and Human Services (45 CFR 46), the Food and Drug Administration, and the State.

2. Voting

- a. The IRB Chair serves as a voting member but is to abstain from voting except in the event of a tie.
- b. Regulatory expertise on the IRB as it pertains to human research protections is provided by the Senior Director of Clinical Research Compliance. This individual is considered a voting member and is the alternate member for the Chair.
- c. The Director and IRB Analysts are alternate voting members of the IRB.
- d. No IRB member, IRB staff, ex-officio member, or guest present at the meeting will be permitted to contribute to the meeting proceedings in any manner which may influence IRB member decision making because of business associated goals of the hospital.
- e. The Vice President for Research Administration, the General Counsel, and the Investigational Drug Pharmacist are non-voting members. Additional non-voting members may be appointed from time-to-time.
- f. The IRB operates on a primary and alternate member system.
 - i. Each primary IRB member is allowed to request that an alternate member be present in the event they need to be absent.
 - ii. Alternates are allowed to attend and contribute to all meetings; however, they may not vote if the primary member is also present.

Review Process Assignments

1. IRB members are assigned to serve as either primary or secondary reviewers for new protocols, continuing reviews, amendments/revisions, unanticipated problems, and other administrative and ethical issues pertinent to human subject protections.
2. All members are expected to read all protocols and submissions before a meeting and to participate in meeting discussions.
3. The IRB administrative staff assign reviewers based on the member's knowledge and expertise. The IRB administrative staff are responsible for ensuring that at least one member attending the meeting has the necessary knowledge and expertise to review the protocol.
4. When the agenda includes protocols that involve vulnerable populations, the IRB administrative staff is responsible for ensuring that at least one member attending the meeting has

knowledge and experience in working with the study population.

- a. Example: For research sponsored by the Department of Education and/or funded by the National Institute on Disability and Rehabilitation Research that purposefully require inclusion of children with disabilities and/or individuals with mental disabilities as research subjects, the IRB will include at least one person who is knowledgeable about and experienced in working with these categories of participants.
5. Boston Children's Hospital reserves the right to reschedule protocols for review based on the experience and expertise of the members attending the IRB meeting and to seek expert consultation if deemed necessary.
 6. If an IRB member is unable to attend a meeting, they are to contact the IRB office as soon as possible, to ensure that an alternate member be assigned. If it is determined that a member cannot attend after the protocols are distributed, there are two possible options:
 - a. The member who cannot attend may review the protocol and submit written comments. However, this will not be included in a quorum.
 - b. The IRB member may contact the IRB office and another IRB member will be assigned the review.

Evaluation

On an annual basis the IRB Chair and the Senior Director of Clinical Research Compliance meet to discuss the membership of the IRB. At this time, they determine if the membership includes individuals with varying backgrounds, with the experience and expertise needed to review the scope of biomedical and behavioral research conducted at Boston Children's Hospital.

Written Evaluation

In addition, the Chair and Senior Director of Clinical Research Compliance will provide a written evaluation to all members which will include:

1. The number of meetings they have attended during the year
2. Whether their reviewer worksheets are completed and turned in
3. Timeliness to review responses to conditional approvals, **and**
4. Whether they contribute to the regulatory and ethical discussion of protocols at the meeting.

3-year Term Review

1. In addition, if there are specific concerns about any member, the IRB Chair will confidentially speak with the individual member.
2. At the end of an IRB member's three-year term, the IRB Chair and the Senior Director of Clinical Research Compliance will meet with the member to discuss either their rotation off the IRB or their willingness to serve another term.
3. This is also an opportunity for the IRB Chair to provide feedback to IRB members and vice

versa.

Self-Assessment Survey

In addition to individual member reviews, IRB members are asked to complete an anonymous self-assessment survey, regarding how the Chair functions, the administrative support members receive from the IRB office, how the IRB functions, and their perceived needs for additional training.

1. Survey results will be aggregated and shared with the full committee so that any necessary discussions and improvements can be made.
2. This information will also be shared with the Institutional Official and with the President as part of the IRB Chairs annual review.

Approval Signatures

Step Description

Approver

Date

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