

Status **Active** PolicyStat ID **13320946**



**Boston
Children's
Hospital**

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Effective 9/1/2020
Next Review 8/29/2025

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

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

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy establishes the method by which the position of Boston Children's Hospital Institutional Review Board (IRB) Chair and Vice Chairs are filled and their major responsibilities.

Policy Statements

The Chief Operating Officer of Boston Children's Hospital appoints the Chair and Vice Chairs of the Institutional Review Board. The Chief Operating Officer may appoint an acting or interim Chair/Vice Chairs during any period of vacancy.

Procedures

Selection and Appointment

For the Chair, other than to make a temporary or interim appointment, the Chief Operating Officer shall convene an advisory committee to solicit and review nominations from qualified clinical researchers.

1. The advisory committee shall include at least one member of the Institutional Review Board and at least one member of the Medical Staff Executive Committee.
 - a. The advisory committee shall consult with the Institutional Official, the Director of

Clinical Research Compliance, and the Office of General Counsel.

- b. The advisory committee may make its own nominations.
2. Nominees shall be or be eligible to be, full or Associate Professors at Harvard Medical School and be members in good standing of the medical staff of Boston Children's Hospital; be proficient in clinical research and without conflicts of interest that would curtail their ability to serve objectively and according to the mission of the IRB as defined in applicable laws, regulations, and policies.
3. The advisory committee shall recommend to the Chief Operating Officer at least three candidates in order of desirability. The Chief Operating Officer shall then select from among the candidates recommended or request additional candidates.
4. Once the Chair is selected, the Chief Operating Officer will consult with the newly appointed Chair to determine appropriate candidates for Vice Chairs. The Chief Operating Officer will appoint the Vice Chairs based on the recommendations offered.

Responsibilities

In addition to IRB membership, the responsibilities of the Chair include the following:

1. Primary responsibility of conducting IRB meetings
2. Ensure the operation of the IRB within all applicable regulatory requirements
3. Conduct expedited reviews
4. Advise and consult with investigators regarding human subject protection issues and IRB requirements
5. Provide an activity and issues report to Medical Staff Executive Committee on an annual basis
6. Participate in noncompliance investigations
7. Contribute to the development of policies and procedures
8. Serve as a liaison between the IRB, the investigators, the Institutional Official, and the Chief Operating Officer.
9. Work with the Director of Clinical Research Compliance to resolve administrative issues of concern

The Vice Chairs are responsible for assuming all the responsibilities in the Chair's absence and are involved in all activities listed above on an ongoing basis.

Evaluation

1. Self-Assessment Survey: On an annual basis, IRB members will be asked to complete an anonymous self-assessment survey that includes questions regarding evaluation of the IRB Chair and Vice Chairs.
 - a. Members are questioned about leadership, time management at meetings, allowing members to express concerns, and the representation of the IRB's interests and concerns to investigators and the institution.

- b. In addition, the survey contains questions regarding how the IRB functions, perceived areas for improvement, and needs for additional training. This survey also provides feedback to the Chair and Vice Chairs regarding IRB operations and changes they may want to implement.
 - c. Results from this survey are provided to the Institutional Official and the Chief Operating Officer.
- 2. In addition, on an annual basis the Chief Operating Officer evaluates the performance of the IRB Chair and Vice Chairs, by consulting with the Institutional Official, the Senior Director of Clinical Research Compliance, the Office of General Counsel, and the Chair of the Clinical and Translational Research Executive Committee as deemed necessary.
- 3. Annual Meeting with the Chief Operating Officer: The Chief Operating Officer meets with the IRB Chair on an annual basis to discuss the evaluation and any issues raised by the IRB Chair.
 - a. The Chief Operating Officer may invite other individuals such as the Institutional Official, General Counsel, and other leadership to the meeting as deemed appropriate.
 - b. The meeting is also used as an annual opportunity to discuss and update the Chief Operating Officer on the human research protection program as well as outreach activities for participants, prospective participants, and their communities.

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Approval Signatures

Step Description

Approver

Date