



Committee on Clinical Investigation Chair: Selection, Responsibilities, and Evaluation

Policy

- The Chief Executive Officer (CEO) of Children's Hospital appoints the Chair and Vice Chair of the Committee on Clinical Investigation. The CEO may appoint an acting or interim Chair/Vice Chair during any period of vacancy.

Purpose

This policy establishes the method by which the position of Chair and Vice Chair of the Committee on Clinical Investigation is filled at Children's Hospital. The major responsibilities of the Chair and Vice Chair are also described.

Procedure

Selection and Appointment

During any period of temporary vacancy, the CEO may appoint an interim or acting Chair or Vice Chair.

Other than to make a temporary or interim appointment, the CEO shall convene an advisory committee to solicit and review nominations from qualified clinical researchers. The advisory committee shall include at least one member of the Committee on Clinical Investigation, and at least one member of the Medical Staff Executive Committee. The advisory committee shall consult with the Institutional Official, the Director of Clinical Research Compliance, and the Office of General Counsel. The advisory committee may make its own nominations.

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 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 Committee on Clinical Investigation as defined in applicable laws, regulations, and policies.

The advisory committee shall recommend to the CEO at least three candidates in order of desirability. The CEO shall select from among the candidates recommended, or request additional candidates.

Responsibilities

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

- Primary responsibility for conducting CCI meetings

- Ensure operation of CCI within all applicable regulatory requirements
- Conduct expedited reviews
- Advise and consult with investigators regarding human subject protection issues and CCI requirements
- Provide an activity and issues report to Medical Staff Executive Committee on an annual basis
- Participate in noncompliance investigations
- Contribute to the development of policies and procedures
- Serve as a liaison between the CCI, the investigators, the Institutional Official, and the CEO
- Work with the Director of Clinical Research Compliance to resolve administrative issues of concern

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

Evaluation:

On an annual basis, IRB members will be asked to complete an anonymous survey/self assessment that includes questions regarding evaluation of the IRB Chair(s). Members will be questioned about leadership, time management at meetings, allowing members to express concerns, and representing the IRB's interest and concerns to investigators and the institution. In addition, the survey will contain questions regarding how the Committee functions, perceived areas for improvement and needs for additional training. This will also provide feedback to the Chair(s) regarding committee operations and changes they may want to implement as they lead the committee. Results from this survey will be provided to the Institutional official and CEO .

In addition on an annual basis the CEO will evaluate the performance of the Chair and Vice Chair of the Committee on Clinical Investigation, by consulting with the Research Strategy Committee, the Institutional Official, the Director of Clinical Research Compliance, and the Office of General Counsel as deemed necessary. The CEO will meet with the IRB chair on an annual basis to discuss the evaluation and any issues raised by the IRB chair.

Related Content

None Identified

Document Attributes

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