



Consultants, Observers, and Guests

Policy

Boston Children's Hospital is committed to establishing an Institutional Review Board (IRB) that has the appropriate expertise to review clinical research protocols and to take into consideration the medical, emotional, social, and psychological needs of the parents, children, and adolescents that participate in research. As necessary, the Institutional Review Board (IRB) may seek the services of consultants in order to provide appropriate review. These individuals may be either internal or external to the Hospital. A consultant may be selected to assist in the review of an individual protocol or may be asked to attend a meeting and provide education on an issue or topic of general interest to the committee. Consultants do not count as part of a quorum or vote. A consultant may not have any conflict as defined for IRB members and will be asked if they have any conflict prior to serving that role.

From time to time the IRB will invite guests to observe its deliberations.

Consultants, observers and guests will also be asked to sign a confidentiality agreement before attendance at any meeting or being provided with any IRB protocol.

Purpose

To outline circumstances under which consultants may be used, and the associated procedures. The role of observers and guests is also included.

Procedures

Consultants

The determination that a consultant is required may be made under certain circumstances during the review process. Such circumstances are as follows:

- The Director of Clinical Research Compliance, in consultation with the IRB Chair, determines upon pre-review that a consultant is required, **or**
- Members of the Institutional Review Board may request at any time during the review process to add a consultant to the review process.

This determination will be based on the topic of the protocol and the expertise of the voting members.

- The consultant will be selected by the Chair. The Chair may consult with the principal investigator, Department Chair, Division Chief, or any other individual deemed appropriate to determine a suitable consultant.
- A consultant may
 - Be an individual who is either internal or external to Boston Children's Hospital.
 - Be asked to review a protocol or provide education on a topic of specific concern to the IRB.

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- Be asked to provide information to the Institutional Review Board by written report, attending a meeting(s), or both.
 - May participate in all discussions; however, he or she is not authorized to vote on the study.
- Use of consultants will be documented in the protocol file and minutes.
 - All individuals who are asked to serve as consultants will be:
 - Provided with the conflict of interest guidelines to determine whether any conflict of interest exists prior to their work with the Institutional Review Board. If there is any conflict of interest they will not be allowed to consult, and another consultant will be selected;
 - Sign a confidentiality agreement and Advised that all discussions at the meeting are considered confidential.
 - Asked for a written report, as appropriate, which will be filed in the protocol.

Observers and Guests

Observers and guests may attend the IRB meetings at the discretion of the Chair. Guests and observers are individuals with a particular interest in the IRB and do not attend regularly. Neither guests nor observers count as part of the quorum. All observers and guests are advised that the deliberations of the Institutional Review Board are confidential and will be asked to sign confidentiality agreements. They are also not permitted to observe the final discussion and vote for any protocol in which they may have a potential or actual interest.

Related Content

None Identified

Document Attributes

Title	Consultants, Observers, and Guests		
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