

Status **Active** PolicyStat ID **13320957**



**Boston  
Children's  
Hospital**

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Effective 9/1/2020  
Next Review 1/1/2026

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Manager  
Department Research  
Applicability Boston Children's  
Hospital- Policies  
& Procedures

## Consultants, Observers, and Guests Policy/Procedure

### Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

### Scope

This policy outlines circumstances under which consultants may be used and the associated procedures. It also outlines the procedures for observers and guests.

### Policy Statements

#### Consultants

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.

1. As necessary, the IRB may seek the services of consultants in order to provide appropriate review.
  - a. These individuals may be either internal or external to BCH.
  - b. 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 IRB.
  - c. Consultants do not count as part of a quorum or vote.
  - d. A consultant may not have any conflict as defined by IRB members and will be asked

if they have any conflict prior to serving this role.

2. All individuals who are asked to serve as consultants will be:
  - a. Provided with the Conflict of Interest guidelines to determine whether any conflict exists prior to working with the IRB.
    - i. If there is any conflict of interest, they will not be allowed to consult, and another consultant will be selected.
  - b. Asked to sign a confidentiality agreement and be advised that all discussions at the meeting are considered confidential.
  - c. Asked for a written report, as appropriate, which will be filed in the protocol.
3. Use of consultants will be documented in the protocol file and meeting minutes.

## Observers and Guests

From time-to-time the IRB will invite or receive requests from guests to observe its deliberations.

Observers and guests are:

1. Not part of the quorum count.
2. Not permitted to observe the final discussion and vote for any protocol in which they may have a potential or actual interest.

## Confidentiality Agreement

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

## Procedures

### Consultants

Based on the protocol topic and the expertise of the voting members, a determination that a consultant is required may be made under certain circumstances during the review process. Such circumstances are as follows and can be requested at any time:

1. The Senior Director of Clinical Research Compliance in concordance with the IRB Chair determines upon pre-review that a consultant is required or
2. IRB Members find that a consultant would be advantageous for a review.

The consultant will be selected by the IRB Chair.

1. The Chair may consult with the Principal Investigator, Department Chair, Division Chief, or any other individual deemed appropriate to determine a suitable consultant.
2. A consultant may:
  - a. Be an individual who is either internal or external to Boston Children's Hospital.

- b. Be asked to review a protocol.
- c. Be asked to provide education on a topic of specific concern to the IRB.
- d. Be asked to provide information to the IRB by written report, attending a meeting(s), or both.
- e. Participate in all discussions; however, they are not authorized to vote on the protocol.

## Observers and Guests

Observers and guests may attend the IRB meetings at the discretion of the Chair. Guests and observers are:

1. Individuals with a particular interest in the IRB and do not attend regularly.
2. Advised that the deliberations of the IRB are confidential and will be asked to sign confidentiality agreements.

### Approval Signatures

Step Description

Approver

Date