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**Boston  
Children's  
Hospital**

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Applicability Boston Children's  
Hospital- Policies  
& Procedures

## Department/Division Scientific Review of Human Research Policy/Procedure

### Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

### Scope

This policy outlines the procedures that all departments and divisions are required to observe in performing scientific review. It also defines the criteria to be considered during the review process.

### Policy Statements

All research involving intervention or interaction with human subjects that is submitted to the Institutional Review Board (IRB) must undergo scientific review at the department or division level prior to IRB review.

Some departments may opt to require scientific review for non-interventional studies as well.

Responsibility for scientific review rests with each department or division. Departments and divisions are responsible for developing their own mechanism for assuring appropriate scientific review and establishing an explicit and formal process of scientific review that assesses and evaluates the scientific merit, complexity, and potential risks of each research protocol, before that protocol is submitted to the IRB for review.

In order to assure that scientific review occurs prior to IRB submission review, the IRB protocol application cannot be submitted to the IRB until scientific review and approval are documented as complete. This process is automated by the CHERP (Children's Hospital Electronic Research Portal)

protocol submission system.

The IRB requires that any scientific review correspondence (e.g. questions and responses, letters of final approval) be submitted as part of the protocol application. This information often facilitates IRB deliberations and may expedite the review process.

The IRB reserves the right to review and comment on the scientific review process as it relates to human subjects protection. If the IRB identifies areas of significant scientific concern, these issues are referred to the Chair or Division Chief for reconsideration at the scientific review level.

## Procedures

### Documentation of Scientific Review Process

Each Department Chair/Division Chief designates scientific review coordinator(s) and provides this information in writing to the IRB.

1. Names of Department scientific review coordinators are then made available to investigators through the electronic IRB submission system.
2. Department Chairs and Division Chiefs are required to update their scientific review coordinator(s) as necessary.

### Criteria for Scientific Review

The following provides basic criteria to guide those assigned responsibility for scientific review:

1. Are the specific aims and corresponding hypotheses clearly stated?
2. Is the primary outcome (and secondary outcomes, as appropriate) stated and defined?
3. Has an appropriate literature search been performed, such that the rationale for the study is adequately presented? Item to note: When risks to the subject are high, an extensive search is required.
4. Does the question or hypothesis being tested provide important knowledge to the field?
5. Are there adequate preliminary data in the literature (or from the investigator) to justify the research?
6. Is it feasible or reasonable to achieve the results in the proposed time frame, including the time required to recruit, retain, or follow subjects?
7. Are the proposed tests or measurements appropriate and are they necessary to answer the scientific question?
8. Are the individuals conducting the trial properly qualified and trained to perform the protocol procedures?
9. Does the research present risk to the subjects? And, if so, is it acceptable?
10. Are the research procedures consistent with sound research design and do not unnecessarily expose subjects to risk?
11. How do the risks of the new treatment/therapy compare to standard treatment/therapies?

12. Is any standard of care denied as part of this study?
13. If the protocol includes a placebo that might present a risk (even if not great), is the placebo essential for the conduct of the trial? If so, have/should other study designs been/be considered?
14. Does the research include an appropriate representation of gender, minorities, and children?

## Elimination of Multiple Scientific Reviews

Scientific review is only required of one department or division. Certain locations within the Hospital require scientific review in addition to departmental review. In order to avoid multiple scientific review processes, Department Chairs/Division Chiefs may defer the scientific review to another division. If this occurs, it is to be indicated in the appropriate section of the protocol application.

1. A separate gene and cellular therapy scientific review committee has been established to review these complex protocols prior to submission to the IRB. This replaces the departmental scientific review.
2. Protocols that utilize the resources of the Institutional Centers for Clinical and Translational Research (ICCTR) undergo scientific review at the ICCTR and this replaces departmental scientific review.

Approval Signatures

Step Description      Approver      Date

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