

Status **Active** PolicyStat ID **17410527**



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Effective 3/1/2025
Next Review 2/29/2028

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

Department/Division Review of Human Research

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Policy Statements

This policy outlines the procedures for Department/Division review of human research. It also defines the criteria to be considered during the review process.

All research protocols submitted to the Institutional Review Board (IRB) must undergo Department/Division review prior to IRB review.

Department/Division review is a separate process from Scientific Review, and typically occurs following Scientific Review (see: [Scientific Review Policy](#)).

Department Review is conducted by the Department Chair/Division Chief (or designee) in the home Department/Division of the Principal Investigator (PI) to attest that a protocol is approved for submission to the IRB, the PI meets the institutional requirements for serving as a PI, and the PI/ research staff have appropriate resources and qualifications to perform the proposed research.

Procedures

Documentation of Department/Division Review Process

Each Department Chair/Division Chief (or designee) provide documentation of Department/Division review via the electronic IRB submission system.

Criteria for Department/Division Review

In the submission of Department/Division review, the Department Chair/Division Chief (or designee) attests to the following:

1. The protocol has been approved for submission to the IRB.
2. The PI meets the institutional requirements for serving as a PI.
3. The PI and staff have:
 - a. The appropriate resources (funding, equipment, space, support services) to perform the research.
 - b. The time necessary to oversee the conduct of the research.
 - c. The appropriate qualifications, training, credentials/licensure to perform the associated research procedures.
4. The PI's plans for covering the expenses associated with providing medical care in the event of a research related adverse incident have been reviewed and approved.

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
Contributor(s)	Susan Kornetsky: Manager	1/17/2025
Document Owner	Susan Kornetsky: Manager	1/17/2025

Applicability

Boston Children's Hospital- Policies & Procedures

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