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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

Research Study Activation/Release, Approval, and Expiration Date Policy/Procedure

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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.

Definitions

Activation/Release Date: Boston Children's Hospital's (BCH) institutional date granting a research study may begin enrollment and conduct of research activity.

Approval Date: The date that the IRB certifies the research study meets all regulatory requirements for IRB approval per 45 CFR 46.111 and that ethical considerations have been sufficiently addressed.

Expiration Date: The last day on which research activities may occur, unless a new approval is given. Not all research will have an expiration date.

Policy Statements

This policy defines Institutional Review Board (IRB) research dates: activation/release, approval, and expiration and provides examples of the approval notices.

In accordance with 45 CFR 56.109 (f), Boston Children's Hospital has adopted procedures to assure that

"an Institutional Review Board (IRB) shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research."

Procedures

Approval Date

The IRB calculates the date of initial IRB approval in the following manner:

1. IRB Full Board (Convened) Pathway Approval Dates:
    a. When the convened IRB determines a protocol is outright Approved, then the date of the convened IRB meeting is the approval date.
    b. When the convened IRB meeting determines a protocol is Conditionally Approved, the IRB approval date remains the date the study was conditionally approved at a convened IRB meeting. The date the designated IRB reviewer determines that the research protocol has satisfied all of the IRB conditions as a requirement of approval is reflected in the CHeRP action "Research Team Response Adequate".
2. IRB Expedited Pathway Approval Dates: When a research study is reviewed and approved through an expedited review process, the date the expedited reviewer enters Approval action in CHeRP serves as the research approval date.

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Activation/Release Date

This date could be:

1. Same date as the approval date
2. Date of the CHeRP action "Research Team Response Adequate" when the designated IRB Reviewer determines that the research protocol has satisfactorily addressed all conditional requirements from the convened IRB meeting
3. The date when all required ancillary reviews (i.e. the Clinical Trial Agreement) is finalized
4. Date when the investigator completes human subjects training.

Expiration Date: One year from the approval date (minus one day), unless otherwise determined by the IRB upon review and approval.

1. Example: A protocol that is approved on April 10, 2024 expires at midnight on April 9, 2025 and all research activity must stop until the IRB approves continuing renewal.

Final Approval Notice: This will include the following:

1. Approval Date
2. Activation/Release Date
3. Expiration Date
4. Notice of Approval (date approval letter is written)

Examples

1. Research protocol reviewed at a Convened IRB Meeting: A research protocol reviewed by the convened IRB receives conditional approval on 09/02/24. On 11/01/24 the PI submits the requested changes and the designated reviewers determines via CHeRP "Research Team Response Adequate". The Clinical Trial Agreement is later finalized on 12/01/24. The following dates are utilized:

   NOTICE OF FINAL APPROVAL

   IRB Approval Date: 9/2/2024

   IRB Activation/Release Date: 12/1/2024

   IRB Expiration Date: 9/1/2025
2. Consent Form: The consent form includes:
   a. Protocol ID
   b. Activation/Release Date
   c. Expiration Date: Do Not Use After

   Image 1
3. Administrative Update: A research protocol that is not Food & Drug Administration (FDA) regulated is reviewed through expedited review and receives approval by the IRB member on 11/22/22. However, the Clinical Trials Business Office (CTBO) ancillary review is completed on 11/30/2022. The following dates are utilized:

   NOTICE OF EXPEDITED APPROVAL

   IRB Approval Date: 11/22/2022

   IRB Activation/Release Date: 11/30/2022

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Related Content

- Department of Health and Human Services Regulations: § 56.109 IRB review of research
- IRB Policy: Continuing Review and Administrative Update (For more information on IRB submission expectations of continuing research)

Attachments

Image 1

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	2/2/2025
Committee Chair(s)	Susan Kornetsky: Manager	2/1/2025
Contributor(s)	Susan Kornetsky: Manager	2/1/2025
Document Owner	Susan Kornetsky: Manager	2/1/2025

Applicability

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