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**Boston
Children's
Hospital**

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Effective 9/1/2022
Next Review 8/29/2025

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Applicability Boston Children's
Hospital- Policies
& Procedures

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

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

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

Definitions

Activation/Release Date: Boston Children's Hospital's date that a research study can be active to enrollment.

Approval Date: The date that the research study meets all of the IRB and regulatory requirements

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

Policy Statements

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. Convened IRB Reviewed Study
 - a. When a research study is approved at a convened IRB meeting, the date of the convened IRB meeting is the approval date.
 - b. When the research study is conditionally approved at a convened IRB meeting, the date of the IRB approval 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 conditions required, reflected in the CHERP action "Research Team Response Adequate".
2. Expedited Study: When a research study is reviewed and approved through an expedited review process, the date the expedited reviewer approves the research is approval date.

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 the conditional requests 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, 2022 will expire and can no longer be used after midnight on April 9, 2023.

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)
5. Wording for protocols reviewed at a convened meeting:
The IRB approval date of reflects the date that the Institutional Review Board reviewed this protocol at a convened meeting. *[Since all research personnel have now completed the CITI web-based tutorial...]* *[Since the Clinical Trial Agreement has now been finalized]* ...*[Since you have addressed the Committee's concerns...]* ... we are now releasing the final approval notice.

Examples

1. Research protocol reviewed at a Convened IRB Meeting: A research protocol reviewed by the convened IRB receives conditional approval on 09/02/19. On 11/01/19 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 12/01/19. The following dates are utilized:

NOTICE OF FINAL APPROVAL

IRB Approval Date: 9/2/2022

IRB Activation/Release Date: 12/1/2022

IRB Expiration Date: 9/1/2023

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

Protocol ID: IRB-P#####	Activation Date: 12/1/2022	Do Not Use After: 9/1/2023
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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

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)

Approval Signatures

Step Description	Approver	Date
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