Activation/Release, Approval, and Expiration Dates

Purpose

This policy defines research dates: approval, activation/release, and expiration and provides examples of the approval notices.

Policy

In accordance with 45 CFR 46.190e, Boston Children's Hospital has adopted procedures to assure that "An 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."

For more information concerning Continuing Review and institutional Administrative updates, see IRB policy: ***Continuing Review and Administrative Update***.

This defines the dates utilized for tracking research: approval, activation/release, and expiration and notices.

Procedure

Definition of Dates

Approval Date:

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

- When a research study is approved at a convened meeting, the date of the convened meeting is the date of IRB approval.
- When the research study is approved with conditions at a convened meeting, the date of IRB approval remains the date the study was conditionally approved at a convened meeting. The date the designated reviewer determines that the research has satisfied all conditions required is reflected in the CHERP action Research Team Response Adequate.
- When a research study is reviewed and approved through an expedited review process, the date the expedited reviewer approves the research is the date of IRB approval.

Activation/Release Date: For logistical and administrative purposes BCH utilizes an activation/release date to determine the day the research can be activated to enrollment. The activation/release date is the date the research has satisfied all IRB and institutional requirements . This date could be:

- The same as the approval date
- The date of the Research Team Response Adequate when the designated IRB reviewer determines the PI has satisfactorily addressed the conditional approval request for research approved with conditions at a convened meeting.
- The date when required all ancillary reviews (for example the Clinical Trial Agreement) is finalized
- The date when the investigator completes human subjects training.

Expiration Date: One year from the approval date unless otherwise determined by the IRB upon review and approval.

- Example: A protocol that is approved on April 10, 2018 will expire and can no longer be used after midnight on April 9, 2019.

Final Approval Notice

Final Approval Notice will include the following:

- Approval Date
- Activation/Release Date
- Expiration Date
- Notice of Approval (date approval letter is written)
- 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.

Example

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 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: 9/2/2019

IRB Activation/Release Date: 12/1/2019

IRB Expiration Date: 9/1/2020

Consent Form:

The consent form includes:

- Protocol ID
- Activation/Release Date
- Expiration Date: Do Not Use After

Protocol ID: IRB-P########	Activation Date: 12/1/2020	Do Not Use After: 9/1/2020

Administrative Update

A research protocol that is not FDA regulated is reviewed through expedited review and receives approval by the IRB member on 11/22/19 and the CTO ancillary is completed on 11/30/2020. The following dates are utilized:

NOTICE OF EXPEDITED APPROVAL

IRB Approval Date: 11/22/2019

IRB Activation/Release Date: 11/30/2019

Related Content

IRB Policy

Continuing Review and Administrative Update

Document Attributes

Title	**Protocol Activation: Release Date and Approval Date**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	4/1/2005 5/4/2007 6/20/2005 3/10/2010 5/1/2015 12/6/2019 1/31/2020
Reviewed/ Revised by	Susan Kornetsky		
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