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 day the IRB determined the protocol could be approved or conditionally approved at a convened meeting or at the time of approval by the expedited review member.

Activation/Release Date: The day the approval letter and finalized consent document is released. This day could be:

- The same day as the approval day
- The day when the PI has satisfactorily addressed the conditional approval request
- When a Clinical Trial Agreement is finalized
- 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
  - 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.

The two concerns raised by the IRB are that the PI must complete the CITI web-based training and the Clinical Trial Agreement must be finalized. On 11/01/19

the PI notifies the IRB Administrator that they have completed the training on 11/01/19 and on 12/01/19 the Clinical Trial Agreement is finalized. The IRB Administrator releases approval on 12/01/01.

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: Month DD, YYYY	Do Not Use After: Month DD, YYYY

Administrative Update

A research protocol is reviewed through expedited review and receives approval by the IRB member on 11/22/19 and the IRB Administrator releases the approval letter on 11/30/19. 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
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children's Hospital, 2020	**Last Modified**	1/31/2020
Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		