Activation / Release / Approval and Expiration Dates

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."

Purpose

The Purpose of this policy is to provide guidance as to what approval/release/activation and expiration dates should be included on reports of action from the IRB.

Procedure

At the time of initial or continuing review the Committee will determine the period of time until continuing review is required. This determination may be based on the level of risk associated with a protocol and whether the committee would like to be updated more frequently about the progress of the research. Criteria that may be used to determine whether review should occur more frequently include:

1. The magnitude of adverse events may be irreversible, life threatening, disabling or,
2. The type and risk of adverse events is completely unknown or,
3. Based on prior knowledge or experience the frequency of adverse events is of potential concern or,
4. There have been noncompliance concerns that warrant more frequent monitoring.

Approval Date: The day the Institutional Review Board actually 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 could be the same day as the approval day or may be the day when the PI has satisfactorily addressed the conditional approval request, when a Clinical Trial Agreement is finalized or the investigator completes human subjects training.

Expiration Date: One year from the approval date unless otherwise determined by the Committee upon review and approval. A protocol that is approved on April 10, 2007 will expire and can no longer be used after midnight on April 9, 2008.

On the Final Approval Notice the following will be noted:

- Approval Date and Activation/Release Date
- Include the following information in the Approval Notice:
    - Notice of IRB Approval

- IRB Approval Date:
- IRB Activation/Release Date:

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.

Consent Form:

- Include Activation Date and Expiration Date

Activation Date: *date approval released* **Expiration Date:** *1 year from convened meeting date, expedited approval date, or time period specified by the IRB*

New Protocol Example

A Research Protocol receives conditional approval on 09/01/01. The two concerns raised by the Committee are that the PI must complete the CITI web-based training and the Clinical Trial Agreement must be finalized. On 11/01/01 the PI notifies the office that she has completed the training on 11/01/01 and on 12/01/01 the Clinical Trial Agreement is finalized and the IRB Administrator releases approval on 12/01/01.

Approval Notice:

Notice of IRB Approval

IRB Approval Date: September 1, 2001

IRB Activation/Release Date: December 1, 2001

Consent Form:

Activation Date: December 1, 2001 **Expiration Date: August 31, 2002**

In addition Deferral/Conditional Approval letters should include the following statement:

Please send your response and revised consent form to this office within 90 days of the Date of Review listed above or this protocol will be withdrawn from the review process and administratively terminated.

Related Content

Document Attributes

Title	**Protocol Activation: Release Date and Approval Date**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	04/01/05 05/04/07 06/20/05 03/10/2010
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children's Hospital, 2015	**Last Modified**	5/1/15
Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		