Continuing Review and Administrative Update

Purpose

This policy provides guidance on the Continuing Review and Administrative Update processes. Th applicability and procedures of the regulatory requirements of Continuing Review and the institutional Administrative Update are described.

Policy

The Institutional Review Board is responsible for reviewing all approved research on a continuing basis.

The Revised Common Rule went into effect on January 21, 2019. This policy differentiates between research approved prior to this date and thereafter. It also addresses the institutional administrative update process for those protocols that are transitioned to no longer require Continuing Review or do not require Continuing Review.

The different requirements for FDA and non-FDA regulated research are included.

Procedure

Continuing Review Applicability

Research approved prior to January 21, 2019 and all FDA regulated research approved before or after 1/21/2019

1. Research approved at a convened IRB meeting or through expedited review prior to January 21, 2019 and all FDA regulated research will undergo continuing review. Review will be conducted at intervals appropriate to the degree of risk but not less than once per year.

2. Protocols originally approved at a convened IRB meeting may undergo expedited continuing review:

   a. When:

      - The research is permanently closed to the enrollment of new subjects and
      - All the subjects have completed all research-related interventions; and
      - The research remains active only for long term follow-up of subjects; or

   b. Where no subjects have been enrolled and no additional risks have been identified; or

   c. Where remaining research activities are limited to data analysis

3. Continuing review may be conducted through expedited procedures, if:
   a. It is non-FDA regulated research, (not conducted under investigational new drug application or investigational device exemption), and
   b. Where the permitted expedited categories do not apply, but the IRB has determined and documented at a convened meeting that the research
      i. Involves no greater than minimal risk and
      ii. No additional risks have been identified.

Time Interval

Upon initial review of a protocol, the IRB determines the time interval for the next continuing review. Review must occur within 1-year of the last approval date for a protocol to remain active; however, the IRB may decide more frequent review is necessary.

- Convened IRB: For a protocol reviewed by the convened IRB, Continuing Review must occur within 1 year of the protocol being approved at a convened meeting.
- Expedited Review: For a protocol approved under expedited review that still requires Continuing Review, the review must occur within 1 year of the date the IRB Chair or designated IRB member(s) provide initial approval.

More Frequent Review

More frequent review may be based on a specific time interval or on a requirement to report back after a specified number of patients have been studied. In making the determination that more frequent review is required, the IRB takes into consideration:

- The risk of the protocol and
- The type of information the IRB would like to receive in order to assure appropriate oversight on an ongoing basis.

Criteria used to consider whether more frequent review is required includes the following**:**

- High-risk protocols where there is concern about significant adverse events that may be permanent, irreversible, or disabling, or that may significantly compromise the research subject.
- Protocols where the potential risks are completely unknown, unless the minutes document that approval is granted for 1 year.
- Protocols that involve newborns that include conditions for which it is not possible to perform studies in older children.
- Protocols submitted with data from preliminary studies that raise concern regarding the possibility of serious adverse events.

If more frequent review is required, the investigator will be informed in the approval notification and the CHeRP electronic system will be set to notify the investigator at the required time.

At the time of Continuing Review, the convened IRB or expedited reviewer will assure that all criteria for approval of research continue to be met.

Review Tracking

The IRB administrative office is responsible for tracking Continuing Reviews and for notifying investigators when review is required. The Continuing Review form must be submitted and approved prior to the protocol's expiration date, and ample time must be allowed for the IRB to address any needed questions to the Principal Investigator (PI).

1. Three months before the protocol's expiration, the CHeRP electronic system will send an automated notice to the PI and research team.
2. If the Continuing Review is not received, then
    a. A second notice will be sent at 2 months before the expiration date.
    b. A third notice will be sent 1 month before the expiration date.

For more information and examples of dates, see IRB policy: ***Activation/Release, Approval, And Expiration Dates***

Continuing Review: Expedited and Convened IRB Review Process

Expedited Review

Continuing Reviews which qualify for expedited review may be reviewed through the procedures described in the IRB policy, ***Expedited Review***.

Convened IRB

All Continuing Reviews which do not qualify for expedited review are placed on the agenda for the convened IRB meeting. One IRB reviewer is assigned to each Continuing Review. No member with a conflict of interest may serve as a reviewer. All members receive a copy of the Continuing Review form. The Form includes:

1. The number of subjects accrued:
    a. Enrolled (signed consent form)
    b. Withdrawn due to subject request
    c. Withdrawn due to toxicity/adverse events
    d. Lost to follow-up
    e. Completed study (without events leading to early termination)
    f. Currently active on study
    g. Other category
    h. Removed for ineligibility
2. A summary of adverse events and any unanticipated problems that involve risks to subjects or others, and any withdrawal of subjects from the research or complaints about the research since the last IRB review.
3. If applicable, a summary of any relevant recent literature and interim findings.
4. If applicable, data and safety monitoring reports may be submitted.
5. Any relevant multi-center trial reports.
6. If applicable, monitoring reports from sponsors.

7. Any other relevant information, particularly information about risks associated with the research.
8. Links to the currently approved protocol, recruitment documents, and informed consent documents.
9. Information regarding reliance arrangements

Through CHeRP, IRB members have electronic access to the complete IRB protocol file and relevant IRB minutes, including amendments/revisions, unanticipated problems, and previous Continuing Review approvals.

IRB members are provided with a Continuing Review worksheet to complete.

When reviewing the current informed consent document, the IRB ensures that**:**

- The currently approved or proposed consent document is still accurate and complete; and
- Any significant new findings that may relate to the subject's willingness to continue to participate are provided to the subject.

The IRB may request and rely on a current statement from the DSMB or the sponsor that indicates that it has reviewed study-wide adverse events, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the Committee.

In general, when taking an action of conditional approval at the time of Continuing Review, any noted conditions need to be satisfied before an investigator may continue research activities related to the conditions specified. However, during the Continuing Review, the IRB may make determinations that currently enrolled subjects may continue, but no new subjects may be enrolled until a designated IRB member reviews a revised protocol and verifies that conditions are met.

After the convened IRB meeting, the investigator is sent notification of the action taken. When approved, the informed consent dates are modified to reflect the new period of approval and expiration.

The IRB will use the same criteria and take the same actions described in the IRB policy, ***Convened IRB: Operational Review Procedures***

Administrative Update Applicability

Research approved after January 21, 2019 and Non-FDA regulated research

Research approved through expedited review after January 21, 2019 that has:

1. Not been determined by the IRB to require continuing review and
2. Is not FDA regulated will undergo an institutional administrative update at annual intervals.

Investigators will be required to complete an **administrative update** in order to assure continued and ongoing oversight pertaining to other elements of the human research protection program at Boston Children's Hospital.

Research approved prior to January 21, 2019 and is not FDA regulated may transition to an administrative update process if at the time of continuing review, the research has progressed to the point that it only involves one or both of the following, which are included as part of the IRB-approved study:

1. Data analysis, including analysis of identifiable private information or identifiable biospecimens or
2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

   In these cases, all informed consents will have been deactivated and there would be no additional requirements to transition the protocol to the Revised Common Rule.

Studies subject to administrative updates are approved for a period of no longer than 1 year and may not continue after expiration without undergoing subsequent administrative update review.

Administrative Update Process

The IRB administrative office is responsible for tracking Administrative Updates and for notifying investigators when review is required.

The Administrative Update Review form must be submitted and approved on an annual basis with expiration dates established on the same basis as Continuing Reviews. The CHeRP electronic system will send notice to the PI and the research team:

1. Three months before the protocol's expiration, the CHeRP electronic system will send an automated notice to the PI and research team.
2. If the Administrative Update is not received, then,
   a. A second notice will be sent at 2 months before the expiration date.
   b. A third notice will be sent 1 month before the expiration date.

If the Administrative Update form is not approved before the expiration date, the protocol will expire.

Expiration/Lapse of IRB Approvals for Continuing Review or Administrative Updates

If an investigator fails to provide Continuing Review or Administrative Update and the IRB has not reviewed and approved a research study by the specified expiration date, human subject research activity must stop.

- Exception: If there are individual patients on a protocol that may be placed at harm if the research does not continue, the investigator must obtain permission from the IRB Chairperson for individual subjects to continue.

Related Content

IRB Policies

Activation/Release, Approval, and Expiration Dates

Convened IRB: Operational Review Procedures

Expedited Review

Document Attributes

Title	**Continuing Review and Administrative Update**		
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