



Continuing Review

Policy

The Committee on Clinical Investigation (CCI) is responsible for reviewing all approved research on a continuing basis.

Review must occur, within one year of the last approval date, however, the CCI may determine that review should occur at more frequent intervals. For a protocol reviewed by the full committee continuing review must occur within 1 year of the protocol being approved at a convened meeting. For a study approved under expedited review, continuing review must occur within 1 year of the date the IRB Chair or IRB member(s) designated by the Chair gives final approval.

Protocols originally approved by full committee review may undergo expedited review

- Where:
 - the research is permanently closed to the enrollment of new subjects;
 - 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.

Continuing review of research, not conducted under investigational new drug application or investigational device exemption where the other permitted expedited categories do not apply but the IRB as determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Purpose

The Purpose of this policy is to provide guidance on the continuing review

Procedures

Upon initial review of a protocol, the CCI determines the time interval for the next continuing review notice. Review must occur within one year of the last approval

date in order for a protocol to remain active; however, the Committee may decide more frequent review is necessary. For a protocol reviewed by the full committee continuing review must occur within 1 year of the protocol being approved at a convened meeting. For a study approved under expedited review, continuing review must occur within 1 year of the date the IRB Chair or designated IRB member(s) provide initial approval. More frequent review may be based on a specific time interval, or based 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 CCI takes into consideration the risk of the protocol, and the type of information the Committee would like to receive in order to assure appropriate oversight on an ongoing basis. Criteria used to consider whether more frequent review is required include 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 one 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 database will be set to notify the investigator at the required time.

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

Approximately two months before the date of the CCI meeting at which continuing review is scheduled to occur, the CCI staff prepares a reminder notice and sends it to the PI. A second and third notice may also be sent if the Continuing Review form is not received. With the initial notification, the investigator receives a list of the amendments that have occurred to date that have been reviewed and approved by the CCI.

If there is no response to the third notice, the protocol will be administratively closed and an administrative closure notice will be sent to the PI.

Continuing Review – Expedited Review:

All continuing reviews which qualify for expedited review as described by the Secretary of DHHS in the Federal Register, 45 CFR46.110(a), and by the FDA in the Federal Register, 21 CFR 56.110(a) are reviewed through the procedures described in the Expedited Review policy.

Continuing Review of protocols that meeting one of the following categories may be reviewed and approved by an IRB analyst in their capacity as an IRB member.

- 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
- where no subjects have been enrolled and no additional risks have been identified ;or
- Where remaining research activities are limited to data analysis

Continuing Review – Full Board:

All continuing reviews which do not qualify for expedited review are placed on the agenda for full CCI review at a convened meeting. One Committee 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:

- An Executive Summary of the protocol which includes the purpose, eligibility criteria, procedures, risks and benefits, or Part B of the protocol application
- The number of subjects accrued;
 - enrolled (signed consent form)
 - withdrawn due to subject request
 - withdrawn due to toxicity/adverse events
 - lost to follow-up
 - completed study (without events leading to early termination)
 - currently active on study
 - other category
 - removed for ineligibility
- 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 CCI review;
- A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review.
- If applicable, data and safety monitoring reports may be submitted;
- Any relevant multi-center trial reports;
- If applicable, monitoring reports from sponsors.
- Any other relevant information, particularly information about risks associated with the research;
- Information regarding requests for changes;
- Changes in sponsorship;
- Changes in research personnel; and
- A copy of the current informed consent document and any newly proposed consent documents.

Primary reviewers are provided with copies of federal grant information, abstracts and publications, and other supporting materials as applicable. A copy of the complete protocol is provided to the primary reviewer. Upon request, any CCI member may have access to the complete CCI protocol file and relevant CCI minutes

prior to or during the convened CCI meeting. In addition all members have access to the CCI database to review the amendment/revisions submitted as well as additional details for adverse/unexpected reports. CCI members are provided with a continuing review worksheet to complete.

When reviewing the current informed consent document, the CCI 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 CCI 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. The CCI must still receive and review reports of local, on-site adverse events and unanticipated problems that involve risks to subjects or others, and any other information needed to ensure that its continuing review is substantive and meaningful. At its discretion, the CCI may require additional information for continuing review.

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

Expiration/Lapse of IRB Approval:

If an investigator fails to provide continuing review information to the CCI, or the Committee has not reviewed and approved a research study by the specified continuing review date, the research must stop, unless the Committee finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.

Related Content

Document Attributes

Title	Continuing Review		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05, 03/23/07 07/17/07 07/23/07 05/14/09
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Children's Hospital Boston, 2012	Last Modified	06/02/2011

Approved	<hr/> <p>Susan Kornetsky Director of Clinical Research Compliance</p> <p>Carleen Brunelli, MBA, PhD Vice President for Research Administration</p>
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