Amendments and Revisions

Purpose

This policy outlines the procedures for review and the acknowledgement of amendments and revisions to approved research.

Policy

Boston Children's Hospital's Institutional Review Board must review and approve any requested amendments/modifications to human subject protocols before implementation.

The only exception to this requirement is a protocol deviation or change that may be necessary to eliminate an apparent immediate hazard to a given research subject.

If an investigator needs to modify a protocol to remove an immediate safety hazard or risk to the subject, this must be reported to the IRB within 48 hours. These changes will be reviewed by the IRB as events that may represent unanticipated problems involving risks to participants or others, and to determine whether the change was consistent with ensuring the participants' continued welfare.

The IRB will determine whether subjects who have previously enrolled in the research should be provided with information about the amendment/modification and whether they are required to re-consent.

The approval of a modification does not alter the original approval date or expiration date assigned to the research protocol/informed consent.

Procedure

IRB approval of modifications to research protocols and informed consent documents may be requested at any time.

Prior to use or distribution, the IRB must review and approve any materials given to subjects throughout their participation in the study (e.g. reminders, letters, etc.) or following their participation (e.g. study results, thank-you letters).

Submitting the Amendment/Modification

Investigators may submit any amendment/modification by completing an **Amendment Form** in the CHeRP electronic system. The form must be completed in full and the investigator may attach additional information as pertinent.

Investigators are advised to submit:

1. Documents with tracked changes (to show the revisions)
2. Documents with consistent revisions

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3. A listing of the changes
4. The rationale for the changes

The investigator should specifically indicate whether the changes result in any substantive changes in the study design which could require re-review by the Scientific Review Committee.

If the amendment requires modification of the informed consent document, the investigator should also provide specific justification for whether re-consent of subjects who have already been enrolled will be required.

Pre-Review Process

Upon receipt of the amendment request, the IRB administrator will initiate the pre-review and if necessary, ask the investigator for clarifications.

The administrator will make an initial determination as to whether the amendment warrants review by the convened IRB or if it can be reviewed through the expedited review process.

If the IRB administrator is unsure as to whether the amendment request warrants review by the convened IRB or expedited review, they will assess the submission with the Director of Clinical Research Compliance or the IRB Chair/Vice Chairs.

Convened IRB Review

If it is determined that the amendment needs to be reviewed by the convened IRB, the IRB administrator will post the amendment on the agenda for the next scheduled IRB meeting.

1. Amendments will be assigned a primary and a secondary reviewer.
2. All members will have electronic access to the full protocol and any revised documents (e.g. consent, recruitment materials, assessments, questionnaires etc.).
3. The entire protocol history and all previous reviews may also be viewed as necessary in CHeRP.
4. The amendment is then reviewed at the convened IRB meeting.
5. As part of the review, the convened IRB will:
    a. Determine whether subjects who have previously enrolled in the research should be provided with information about the amendment. This will occur when such information may impact a subject's willingness to participate in the research and whether re-consent is required.
    b. Consider whether re-review by the Scientific Review Committee is required, depending on whether the requested changes have a significant impact on the study design.
6. A report of the IRB's actions will be sent to the investigator.

Expedited Review

A proposed change in research related activities that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study may be approved through expedited review procedures. This includes minor changes to previously approved research.

For these changes, expedited review will be performed by the IRB Chair, Vice Chair, or designated experienced IRB member.

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The expedited reviewer who is performing the expedited review has electronic access to the amendment request which specifies: the requested changes and any revised documents.

The expedited reviewer may ask for further justification from the Principal Investigator (PI) for the requested amendment. If there are questions or concerns that the PI needs to address, the IRB administrator will communicate these concerns to the PI. If there are no issues for the PI to address, the amendment can be approved.

As part of the review, the reviewer will determine whether the amendment qualifies as:

1. A minor revision or
2. An amendment that qualifies for expedited review and that subjects who have previously enrolled in the research should be provided with information about the amendment. This occurs when such information may impact a subject's willingness to participate in the research.

The expedited reviewer will also determine whether they wish to see the investigator's revisions or if the IRB administrators may verify that the changes have been made.

Amendments/ modifications that are approved through expedited review are summarized and provided to the convened IRB on a monthly basis.

Minor Modifications: Definition and Examples

Minor modification: A change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or the design of the study.

Examples of minor modifications may include:

- Changes in the research staff/personnel for a protocol
- Non-substantive revisions in the informed consent document
- Revisions or modifications in the informed consent to provide better clarification
- Changes to improve the clarity of statements or to correct typographical errors, provided that such changes do not alter the content or intent of a statement
- The substitution of assessments with alternate assessments that present minimal risk
- An increase or decrease in proposed human research subject enrollment supported by a statistical justification
- Narrowing the range of inclusion criteria
- Broadening the range of exclusion criteria only if the risk/benefit assessment remains unchanged
- Decreasing the number or volume of biological sample collections, provided that such a change does not affect the collection of information related to safety evaluations
- An increase in the length of confinement or number of study visits for the purpose of increased safety monitoring, provided the risk/benefit ratio does not change.
- A decrease in the length of confinement or number of study visits, provided that such a decrease does not affect the collection of data related to safety evaluations
- Alterations in human research subject payment that do not add any element of undue influence

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- Addition of recruitment notices, recruitment sites, or a population, provided there is no change in the risk/benefit determination

Administrative Revisions Approved by IRB Analysts

It has been determined that the following administrative revisions may be reviewed and approved by the IRB Analysts and do not require completion of an amendment worksheet as they do not constitute changes in the research protocol

- Change in study title
- Change in recruitment information only to reflect staff/contact information
- Administrative notices from other study locations (i.e. A study is closed at a site because enrollment is complete.)
- Amendments to documents (i.e. protocol, consent, recruitment) that are strictly administrative (i.e. wording changes to improve clarity)
- Correcting typographical or cut/paste errors
- New documents by sponsors that are purely administrative

Related Content

IRB Form

Amendment

Document Attributes

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Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		

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