Amendments/Revisions

Policy

- The Children's Hospital Committee on Clinical Investigation must review and approve any requested changes/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 CCI 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 Committee will determine whether subjects who have previously enrolled in the research should be provided with information about the amendment or revision and whether they require re-consent.

Procedure

IRB approval of modifications to research protocols and informed consent documents may be requested at any time. **The approval of a modification request by the IRB does not alter the original approval date or expiration date assigned to the research protocol/informed consent.**

Prior to use or distribution, CCI must also review and approve any additional recruitment materials or other materials given to subjects during their participation in the study (i.e. reminders, letters, etc.) or following their participation (study results, thank-you letters).

Process to Submit

Investigators may submit any amendment/revision by completing an Amendment Form. The form must be complete, and the investigator may attach additional information as pertinent.

Investigators are advised to submit not only a listing of the changes, but to provide a rationale for the changes. This applies to both the protocol and the informed consent documents. The investigator should specifically discuss 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. The protocol application, protocol, consent, recruitment notices etc should be revised to incorporate all changes, however it is also important for the PI to save all approved older versions as well. Documents should be submitted with the changes highlighted.

Amendments and Revisions Review Process

Upon receipt of the Amendment Form, the IRB administrator makes an initial determination as to whether the requested amendment warrants review by the full IRB Committee, or whether the amendment can be reviewed through the IRB's expedited review procedures. If the IRB administrator is unsure as to whether the amendment request warrants review by the full Committee or expedited review, he or she will check with the Director of Clinical Research Compliance or the IRB Chairperson/Vice Chairperson

Amendments/Revisions through Full Committee Review

If it is determined that the amendment needs to be reviewed by the full Committee, the IRB administrator perform an administrative pre review and after that is completed will post the amendment on the agenda for the next scheduled IRB meeting. Amendments will be assigned a primary and a secondary reviewer. All members will receive a copy of the amendment form which specifies the requested changes, a copy of the full protocol, a revised consent document, recruitment materials, a revised protocol if changes have been incorporated and any other revised documentation (recruitment notice, assessments, questionnaires etc. The complete protocol file is made available to any IRB member that requests it. The expedited reviewer is also provided with a worksheet to complete to make sure the regulatory criteria continue to be met. The amendment is then reviewed at the convened IRB meeting. As part of the review, the Committee will determine whether subjects who have previously enrolled in the research should be provided with information about the amendment when such information may impact a subject's willingness to participate in the research and whether re-consent is required. The Committee will also 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. A report of the Committee's actions will be sent to the investigator. The expedited reviewers will also determine whether they wish to review the changes or whether the IRB administrators may verify the changes have been made

Amendments/Revisions through 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..

The individual who is performing the expedited review is provided with the amendment form which specifies the requested changes, a copy of the full protocol, a revised consent document, recruitment materials, a revised protocol if changes have been incorporated and any other revised documentation (recruitment notice, assessments, questionnaires etc. The expedited reviewer is also provided with a worksheet to complete to make sure the regulatory criteria continue to be met. The expedited reviewer member 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 a minor revision or amendment that qualifies for expedited review and whether subjects who have previously enrolled in the research should be provided with information about the amendment 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 changes back or whether the IRB administrators may verify the changes have been made

Amendments/revisions and modifications that are approved through expedited review are summarized and provided to the full committee on a monthly basis.

Definition of Minor Revisions and Amendments

A minor modification is defined as a change that would not materially affect an assignment 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, minor revisions in the informed consent document, and/or a change in the number of subjects to be enrolled
- 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 inducement
- changes to improve the clarity of statements or to correct typographical errors, provided that such changes do not alter the content or intent of the statement
- the addition or deletion of qualified investigators
- the addition or deletion of study sites
- revisions or modifications in the informed consent to provide better clarification, revised lay language, or inclusion of missing elements
- 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 performed by the IRB analysts and do not require completion of a amendment worksheet as they do not constitute changes in the research protocol

- Corrections made during the Legacy conversion process to the electronic the CHeRP system correction
- Change in study title
- Change in recruitment information only to reflect staff/contact information changes and administrative changes, i.e. wording changes to improve clarity
- Administrative notices from other study locations (i.e. study closed at other site because enrollment is complete)
- Amendments to the protocol that are strictly administrative, i.e. wording changes to improve clarity
- Correcting typographical errors, or cut-paste errors.
- Changed names or contact information in consent or recruitment documents.
- New documents by sponsors that are purely administrative

Related Content

None identified.

Document Attributes

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