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Subject: Post-IRB Approval Reviews
Division: IRB
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IRB Policy 111.1: AMENDMENTS OR ADDENDA

Policy

Investigators have a continuing responsibility to inform the IRB of all modifications or addenda to the protocol or consent form,

It is the responsibility of the investigator to submit all amendments and addenda to approved protocols for review and approval by the IRB before implementation. Changes may not be initiated without prior IRB review (full or expedited review as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

Expedited Review

Amendments, which represent minimal risk changes to a project may receive expedited review by the IRB Chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. If the Chairperson or reviewer determines that the change represents a minimal risk revision, approval may be granted. If, however, the Chairperson or reviewer determines that the amendment/addendum does not qualify for an expedited review, the amendment request will be presented to the full Board for review and comments.

Full IRB Review

Amendments and/or addenda that do not qualify for expedited review will be decided at a convened meeting of the full IRB. Such changes include, but are not limited to the following:

1. Proposals to add an investigational new drug or device to an already approved study,
2. Changes that are perceived to significantly affect the risk/benefit ratio for subjects,
3. Changes made as a result of significant or unexpected toxicity in subjects,
4. Principal investigator changes
5. Significant revision of eligibility criteria, to include or exclude study participants,
6. Introduction of a new procedure or instrument,
7. Revision of the consent process,
8. Addition of a new subject population,
9. Changes in the duration of subject participation period, and
10. Addition of procedures to audiotape and/or videotape subjects.

During a review of amendments/addenda, the IRB will address the following:

1. Is this a minor amendment/addendum to the protocol or informed consent document?

2. Does the investigator's rationale for the amendment/addendum make sense?
3. Is this proposal the result of an adverse event?
4. Does this amendment/addendum alter, in any way, the assessment of potential risks as described in the originally approved protocol? If "yes," is this additional risk justified?
5. Are there potential benefits of this proposal? If "yes," do these potential benefits outweigh the potential risks?
6. Does the amendment/addendum require the investigator to submit a revised protocol?
7. Does the amendment/addendum require the investigator to submit a revised consent form?
8. Does the amendment/addendum change the overall risk level for this study?
9. How often should this study be reviewed by the IRB?

If the IRB approves the amendment/addendum, it will not change the approval/renewal date of a project. If the amendment/addendum changes the risk/benefit ratio, the IRB may require the study to be reviewed more frequently.

If the IRB does not approve the amendment/addenda, it will either recommend changes for the investigator to consider, or recommend that the investigator utilize the previously approved protocol, as is; either way, this will not change the approval/renewal date of the project. Detailed information regarding the review and further requirements will be provided to the investigator in a formal letter, within ten days of the meeting date of the review.

Re-Consent

Re-consent is required for amendments to consent forms which provide pertinent new information for all subjects and may affect/relate to the subjects' willingness to continue in the study. The IRB may require that current subjects (or only the ones who may be affected by the new information) be re-consented with the revised consent form.

If the IRB determines that the new information is important for all subjects, but it would not affect the subjects' willingness to continue study participation, the IRB may require that all subjects be provided with an information sheet, which provides them with the new information. An example of when an information sheet may be used is to provide subjects with new contact information for the Investigator or IRB Chairperson.

Emergency Protocol Changes

Rarely, an investigator may have to make an immediate change in the protocol to protect the safety of research participants. In these instances, the investigator should take *immediate action* to safeguard the health of the participants. If it is not possible for the investigator to notify the IRB prior to an emergency action, the investigator must notify the IRB in writing within 24 hours of the change in protocol, the circumstances that required its immediate implementation, and a revised consent form, if necessary.

Methods to Ensure Investigators Do Not Implement Protocol Changes Without Prior IRB Approval

In order to ensure that investigators do not implement protocol changes without prior IRB approval, the IRB office will conduct random audits of research records, and training programs for investigators. In addition, specific directives will be included in approval letters to investigators.

Applicable Regulations and Guidelines

21 CFR 56.108(a)(3)
45 CFR 46.110