

## Chapter 13

# CHANGING A PROTOCOL AND/OR THE CONSENT FORM

If changes to a protocol become necessary, investigators must obtain Board approval *prior* to instituting such changes. See the section below entitled “Emergency Changes” for procedures involving emergency changes without prior Board approval.

When changes to a protocol are submitted for approval, the entire amended protocol and consent form are subject to review for compliance with current IRB standards.

### A. Types of Review

1. In general, if a study is initially approved under expedited review, then all revisions for the study, whether \*major or \*minor, may undergo expedited review unless the proposed revision changes the risk/benefit ratio for the subjects in the study. In that instance, a revision will require full board review and may necessitate that a study be changed from the expedited “\*minimal risk” category to “more than minimal risk.” If the study status is changed to “more than minimal risk,” then submissions for the remainder of the study must be made according to full board procedures. This same rule applies to research originally reviewed under an exemption that has a change in the risk/benefit ratio.
2. For studies initially approved under Full Board Review, minor revisions will receive expedited review and major revisions will receive full board review.

#### Definitions:

**\*Major** changes are those which directly affect the level of risk to the subjects. Examples include the addition of new, vulnerable populations as subjects or changes in strategies or interventions, drug dosage, product safety, notice of new side effects, period of administration of drugs, or age of subjects. Major changes must undergo full-board review. The CAMC/WVU IRB considers the change in a principal investigator for a study initially reviewed as full board to be a “major” change necessitating full board review.

**\*Minor** changes are those which do not affect the level of risk to subjects. Examples include changing the project duration, increasing or decreasing the sample size, relocating the site of the study, changing sub-investigators, or substituting comparable questionnaires or test instruments. Minor changes **may** be eligible for expedited review.

**\* Minimal Risk means** that the probability and/or magnitude of physical or psychological harm does not exceed that encountered in ordinary daily life or during routine physical or psychological examinations or tests.

If the investigator has any doubt as to whether proposed changes qualify as major or minor, he/she should contact the Research Review Coordinator in the Office of Research and Grants Administration.

## **B. Submissions Required**

1. To request a revision, Principal Investigators must complete the "Modification/ Amendment Form." On the form describe in detail the nature of the requested changes, the reasons for making each change, and any possible effect the changes may have on subjects. Attach supporting information to explain the reasons for the change, etc.
2. For changes involving a different principal investigator or sub-investigator, follow the instructions on the form. The new investigator's signature is required as well as all accompanying materials requested on the form. *Please do not* submit the entire vitae. Note: a change in Principal Investigator for a study initially reviewed as full board is considered a Major change and requires full board review.
3. For changes to a consent form as a result of a revision, submit a copy of the consent form highlighting the proposed changes. Please make certain that the highlighted changes are clear. Also submit one clean copy of the consent form without highlighting the proposed changes. The clean copy will be returned with a stamp of approval. The new consent should have an updated version date. A copy of the most recently stamped approved consent form is also required for comparison purposes.
4. For changes to all other documents (e.g. protocols, advertisements, etc.), submit the highlighted changes indicating differences from the document originally approved. Please make certain that the highlighted changes are clear. The new document should have an updated version date.
5. The number of copies to be submitted will depend on whether the revisions require expedited or full board review. The "Modification/Amendment Form" provides instructions on the number of copies to submit.

## **C. Revision Log**

**The purpose of the log is to provide the IRB and the investigator with an ongoing description of revision activities to the study.**

**All study revisions, amendments and/or modifications must be kept in chronological order on a Revision Log for the study. The log must be submitted with each new Modification/Amendment Form for the study. A sample of the log is available. All elements listed on the sample log must be included. Other elements may be added at the discretion of the principal investigator/study coordinator.**

## **D. Emergency Changes**

**If changes to a protocol become necessary to avoid an immediate hazard to subjects, those changes may be made without prior Board approval, but an attempt must be made to obtain authorization from the IRB chair. Whether or not such authorization is received, the PI must notify the IRB office within five (5) working days of making an emergency change and must submit a written request to amend the protocol within ten (10) working days. The Board will review the request to amend the protocol and also determine whether a change made without prior approval was justified.**

## **E. IRB Procedures for Review of Revisions**

Once a “Modification/Amendment Form” is received in the Office of Research and Grants Administration, the staff will review the form to determine if the revision is to be reviewed under expedited or full board procedures. Note that any submissions for full board review must be received no later than the first working day of the month.

Revisions receiving expedited review will initially be processed by the staff to ensure that all materials have been received from the Principal Investigator in order that the IRB chair (and/or his or her designee) can fully review the revision request. The chair (and/or his or her designee) will formally review the documents submitted and sign off if full approval is given. Once an expedited revision is approved it will be placed on the expedited list for review at the next convened IRB meeting. The Principal Investigator will receive a letter indicating the approval decision. Expedited review may take up to 2 weeks.

Revisions requiring full board review shall be submitted to the IRB office for inclusion in the packets that are sent to IRB members prior to the Board meeting. Such revisions will then receive full-board review at the convened meeting and will be voted on through individual member ballots at the meeting. Following the meeting, the staff will prepare a letter to the Principal Investigator indicating the approval decision. The approval decision about the revision will be recorded in the minutes for the IRB meeting. Full board review generally takes up to one month after submission.

Revisions to a study will be accepted also at the time of renewal as a part of the Continuing Review Progress Report. See the policy and forms on Continuing Review for this process.

For both expedited and full board revisions, the Chair/Board has the authority to approve the revision pending requested changes to the revision, to request more information regarding the revision, to approve the revision, to require more information on the revision in writing, or to request a meeting with the PI concerning the revision, and/or to disapprove the revision.

For both expedited and full board revisions that include a consent form change, the PI will receive a newly stamped approved consent form with the chair’s signature and the new approval date with the approval letter. A copy of this new consent is to be used for all future enrolled subjects on the study.

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