



<b>Policy Name: Full Board Amendment Policy and Procedures</b>			
Approved			Date: 11/01/08
Effective Date: 02/20/09	Page 1 of 4	Section: HRPP 3.6	Policy Number: N/A
Replaces Policy: N/A			Dated: N/A

**I. POLICY**

Changes made to the informed consent, protocol, or HIPAA authorization must be submitted for prospective IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects. The IRB must be notified immediately of any changes made to protect subjects' immediate safety.

Any changes that are not minor in nature must be reviewed and approved at a convened meeting of the IRB.

**II. PROCEDURES**

**A. Principal Investigator Notification to IRB**

The Principal Investigator electronically submits requests for modifications on the Request for Amendment form. Changes in any document must be clearly marked in this submission.

**B. IRB Administration Review and Distribution**

1. The IRB Administrator reviews the amendment for completeness and assigns the completed amendment to the Primary Reviewer (Chair, the Vice Chair, or Chair's designee).
2. The amendment application is given to all IRB members by the IRB Administrator. The amendment application consists of the following items:
  - a) the amendment application;
  - b) a red-line version of the informed consent indicating changes
  - c) information which would relate to participant's willingness to continue participation; and
  - d) other supporting documents (summary request from sponsors, new surveys and questionnaires etc.).

**C. IRB Responsibilities**

1. All IRB members are expected to review all modified documents in sufficient depth to discuss the information at the convened meeting.

2. Using the designated review procedure, the primary reviewer (the Chair, Vice-Chair or the Chair's Designee) will have rights to enter his/her reviewer comments and recommendation of approval, required changes, or disapproval to the on-line application. In addition to the above material, the designated reviewers also receive a red-line version of the protocol indicating changes.
3. Reviewing members can send any questions/concerns to the Administrator or chair prior to the convened meeting. If the recommendation is for additional changes or disapproval, the IRB will send the reviewer's comments to the Principal Investigator for response prior to the Board meeting.

**D. IRB Convened Meeting**

1. The Primary Reviewer's recommendations are included in the agenda distribution.
2. During the meeting, each full Board amendment is presented by the Chair and/or Primary Reviewer(s), discussed and voted on individually. The Principal Investigator will be present if requested by any Board member or if the Chair/Administrator thinks the Investigator needs to be present to clarify issues/concerns.
3. In evaluating the proposed amendment, IRB members and staff consider OHRP, FDA and, as relevant, VA regulatory criteria.
4. In addition to the PI application material, the IRB will review and consider addition information coming from DSMB, sponsors, journal articles etc, which may be relevant to the participant's willingness to continue participation. If the IRB determines that such information would affect participant's willingness to continue participation, the IRB will forward to the Principal Investigator the recommendation to contact and reobtain consent from the participants.
5. When the amendment is the result of an immediate change initiated without IRB approval in order to eliminate apparent immediate hazards to participants, the IRB will review the facts surrounding the hazard in order to determine that the benefits of such change outweighed the risks inherent in instituting such change without IRB approval and that the change was consistent with ensuring the participants' continued welfare. An example would be the Principal Investigator reading a scholarly scientific article reporting the deleterious effects of a drug dose, which, had not been previously reported.
6. The Board may approve, require further modifications to secure approval, table, or disapprove an amendment to a study. If the

Board requests minor changes which do not substantially impact the risk/benefit analysis, the Board may approve the amendment contingent on final review and approval by the Chair or the Chair's Designee.

7. No required changes to the informed consent document will be deferred to the Chair's or Chair's Designee approval unless the Board has stipulated the wording of these changes.

#### **E. IRB Administration Responsibilities Post-Meeting**

1. If the amendment is approved at the meeting, the IRB Coordinator releases the approval to the Principal Investigator.
2. If applicable, the new version of the informed consent/HIPAA authorization is date stamped with the amendment approval date. The original informed consent/HIPAA authorization document is retained for IRB records and marked obsolete. A new version of the amended informed consent/HIPAA authorization document, with an original IRB approval stamp, is sent to the Principal Investigator with instructions to mark the existing informed consent/HIPAA authorization as "obsolete".
3. For amendments in which the Board has approved contingent upon completion of requested minor changes which do not substantially impact the risk/benefit analysis, the IRB Coordinator will notify the Principal Investigator and Study Coordinator in writing of any required changes. When revisions are received in the IRB office, they will be reviewed and if acceptable, the approval will be released.
4. If modifications are substantive in nature or if the Board tables or disapproves the amendment, the Chair will notify the Principal Investigator in writing outlining the Board's requirements.

#### **F. Substantive Modifications Required by the IRB**

1. Principal Investigator's responses to substantive modifications or rewrites due to disapproval are presented to the Full Board for review, discussion and vote at a convened meeting. If approved, the Administrator will release the approval to the Principal Investigator.

#### **G. Responsibilities and Assurances**

1. It is the responsibility of the Investigator as attested in the Principal Investigator assurance, that no modification will be made to the

approved research without IRB approval except in circumstances necessary to eliminate apparent immediate hazards to participants.

2. In addition, the university compliance office performs for cause and routine random audits of research records. One focus in these audits is the determination that modifications either occurred subsequent to IRB approval or were initiated in order to eliminate apparent immediate hazards to participants with subsequent review and approval by the IRB.
3. Furthermore, the training completed by research staff emphasizes the need for IRB approval of all research activities.

### **III. REFERENCES**

- A. [ERMA On-Line Amendment Submission System](#)