



<b>Policy Name: Full Board Amendment Policy and Procedures</b>		
Approved		
Effective Date: <b>05/30/2014</b>	Page 1 of 4	Section: HRPP 3.6
Replaces Policy: 01/27/2012		

## **I. POLICY**

All changes that are greater than minimal risk must be reviewed and approved at a convened meeting of the IRB.

Changes made to the informed consent or protocol 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.

## **II. MEMORANDUM OF UNDERSTANDING**

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

## **III. PROCEDURES**

### **A. Principal Investigator Notification to IRB**

1. The Principal Investigator electronically submits requests for modifications. Changes in any document must be clearly marked in this submission and the appropriate associated paperwork uploaded with the submitted amendment.

### **B. IRB Administration Review and Distribution**

1. The IRB Staff reviews the amendment for completeness and forward the amendment to the Primary Reviewer (Chair, the Vice Chair, or Chair's designee). S/he reviews medication for compliance with the criteria for approval of research.
2. The amendment application is distributed to all IRB members by the IRB Staff prior to the convened meeting. 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 IRB Staff will provide comments regarding the administrative review of the application. The Primary Reviewer (the Chair, Vice-Chair or the Chair's Designee) will enter his/her review comments and recommendation of approval, required changes, or disapproval to the on-line application. If the recommendation is for additional changes or disapproval, IRB Staff will send the reviewer's comments to the study communication leads for response prior to the Board meeting. In addition to the above material, the designated reviewers also receive a red-line version of the protocol indicating changes.
3. In addition to the above material listed in II.B.2 above, Board members will receive a red-lined version of the documents being revised by the amendment. Reviewing members can send any questions/concerns to the Administrator or Chair prior to the convened 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 application material submitted by the Principal Investigator, the IRB may request additional information, e.g. DSMB reports, sponsors reports, journal articles etc., which may be relevant to the participant's willingness to continue participation.

5. If the IRB determines that the information presented in the amendment application and associated documents would affect a participant's willingness to continue participation, the IRB will request the Principal Investigator contact and reobtain the participants.
6. 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.
7. 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.
8. Final review and approval of Board-requested changes to study documents may be deferred to the Chair's or Chair's Designee.

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

1. If the amendment is approved at the meeting, the IRB Staff 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 released to the study contact. The previously approved version becomes "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 Staff will notify the study contact electronically 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 IRB Staff/Chair will notify the study contact 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 the earliest possible convened meeting. If approved, the IRB Staff will release the approval using the above outlined process.

**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 of these audits is the determination that study 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.