

MODIFICATION REVIEW PROCESS

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to the mission of fostering a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the TVAMC.

It is the policy of the TVAMC HRPP to ensure that the applicable Federal, state, and local regulations are carried out in protecting the rights and welfare of subjects who voluntarily participate in investigational studies within this Medical Center, including when previously approved research is modified. This Standard Operating Procedures (SOP) is a written documentation of the plan for conducting reviews of modifications to previously approved research. This policy establishes procedures for the review process that is conducted in accordance with the requirements of the TVAMC HRPP and Federal regulations.

2. RESPONSIBILITIES

TVAMC Medical Center Director: The Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the TVAMC.

Coordinator for Research and Development (C/R&D) and R&D Administrative Officer (R&D AO): The C/R&D & R&D AO maintains responsibility for procedures, policies, and execution of the research program (including expedited review process) conducted at the TVAMC.

Principal Investigators (PI): The PI must abide by this HRPP SOP when applying for modification review of research that meets the appropriate definitions described in this SOP.

3. DEFINITIONS

- a. **Modification to Previously Approved Research for Convened IRB Review:** When a proposed change in a research study is not minor (e.g. procedures involving increased risk or discomfort are to be added), the IRB must review the change at a convened meeting.
- b. **Modifications to Previously Approved Research Eligible for Expedited Review Process:** Modifications or amendments to previously approved research are eligible for the expedited review process if the modification or amendment presents no more

than minimal risk to human subjects. Criteria for determining that changes in previously approved research during the period for which the approval is authorized are minor, include but are not limited to, addition or deletion of investigators, consultants, or other members of the research team, minor grammar and format changes, deletion of procedures that decrease the risks or burden to subjects, protocol clarifications that do not result in change to the actual procedures or risk to subject, changes that do not exceed or increase the risks of the study identified at the initial or continuing review, study closure, and completion of a study.

4. PROCEDURES

- a. **Expedited Review of Modifications or Amendments to Previously Approved Research:** The investigator submits the modification or amendment in the form of a copy of the revised protocol, abstract, or consent form (if applicable) with tracked changes and a clean copy of the revised protocol, abstract, or consent form (if applicable) and the form entitled “Request for Amendment Approval.” The expedited reviewer receives and reviews the materials and all modified documents in-depth (same materials that the convened IRB would have received). To document the review, the expedited reviewer will fill out the designated box indicating review and action on the form and complete the IRB Reviewer Amendment Checklist. If the modification or amendment to previously approved research does not meet criteria or eligibility for expedited review, the modification or amendment is referred for review and action by the convened IRB. All of the IRB members (including alternate members) would then review all modified documents.
- b. **Convened IRB Review of Modifications or Amendments to Previously Approved Research:** The investigator submits the modification or amendment in the form of a copy of the revised protocol, abstract, or consent form (if applicable) with tracked changes and a clean copy of the revised protocol, abstract, or consent form (if applicable) and the form entitled “Request for Amendment Approval.” The primary reviewer, as well as all other IRB members, receives and reviews the materials and all modified documents in-depth. To document the review, the primary reviewer will fill out the designated box indicating review and action on the form and complete the IRB Reviewer Amendment Checklist.
- c. The proposed changes in approved research may not be initiated without approval by the expedited review process or convened IRB, except when necessary to eliminate immediate hazards to the participant. Such changes to eliminate apparent immediate hazards to the participant must be promptly reported by the investigator to the IRB and the IRB (either expedited review or convened IRB) must determine that the change is consistent with ensuring the participants’ continued welfare and provide approval of the change or require stipulations for approval. See the HRPP SOP #7, regarding requirements for participants to sign approved revised informed consents. If modifications or amendments to previously approved research are approved

through the expedited review procedures, the continuing review date does not change, but remains the same as determined at the most recent continuing review.

5. REFERENCES

- VHA Handbook 1200.5 Appendix B
- 26CFR 56.110(a)(b)
- 38 CFR 16.110
- 45 CFR 46.110
- 21 CFR 56.110

6. ATTACHMENTS

- Request for Amendment Approval Form
- Template for memo to IRB

7. REVIEW DATE

January 1, 2012

Signature on File in R&D Office

Lori L. Davis, MD

Coordinator of Research and Development