MODIFICATION REVIEW PROCESS

1. POLICY

The Birmingham VA Medical Center (BVAMC) 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 BVAMC.

It is the policy of the BVAMC 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 BVAMC HRPP and Federal regulations.

2. RESPONSIBILITIES

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

Associate Chief of Staff for Research and Development (ACOS/R&D) and Administrative Officer R&D (AO, R&D): The ACOS/R&D & AO, R&D maintains responsibility for procedures, policies, and execution of the research program conducted at the BVAMC.

The BVAMC R&D Committee makes recommendations to the Director for approval or disapproval of the IRB minutes documenting actions of the IRB. The R&D Committee does not approve or disapprove modifications to research studies (unless they are the approving committee such as EXEMPT studies) however; the R&D Committee does discuss and approve any PI changes.

The BVAMC IRB is responsible for the review and approval of modifications to the investigational studies involving human participants.

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

See HRPP SOP #24 – **HRPP Definitions**

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 “Protocol Amendment” or “Miscellaneous Form”. The IRB Chair 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 Chair will fill out the revised checklist that lists all applicable criteria for an expedited review. This checklist/form (once completed) is then scanned and emailed back to the Investigator, copied for the file, and made available at the next meeting for review by the full convened IRB. 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 to the convened IRB. All of the IRB members present would then review all modified documents. All Expedited reviews are sent to the full board for review and documented in the IRB minutes.

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 either the form entitled “Protocol Amendment”, or “Miscellaneous Form.” The IRB receives and reviews the materials and all modified documents in-depth. To document the review, the IRB Chair will fill out the revised modification checklist that lists the applicable criteria for previously approved research to approve the modification. The IRB notifies the investigator in writing if approved or if further information/stipulations are needed. Information that is requested by the IRB must be submitted in writing by the investigator to the IRB and reviewed at the next convened IRB meeting. This is then documented in the IRB minutes (with the checklist) and copies are placed in the study file and sent to Pharmacy or other services if applicable. Note: if the modifications are to a Department of Defense (DOD) study the modification must be reviewed by the DOD for scientific merit prior to the IRB review. This will be noted in the IRB minutes and on the checklist utilized by the IRB.

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 1200.05 Requirements for the Protection of Human Subjects in Research Appendix B
- Title 26 CFR 56.110 (a)(b)
- Title 38 CFR 16.110
- Title 45 CFR 46.110
- Title 21 CFR 56.110

6. ATTACHMENTS

- Protocol Amendment Form
- Miscellaneous Form

7. RESCISSIONS

IRB Standard Operating Procedure #20, dated August, 2011, June 26, 2013, reviewed August 1, 2018

8. REVIEW DATE

August 1, 2021

Louis Dell'Italia, MD
ACOS, Research and Development