



Stratton VA Medical Center IRB Standard Operating Procedure Amendments to Previously Approved Research

POLICY

It is Stratton VA Medical Center's policy to comply with all applicable federal, state, and local regulations, and ICH guidelines in the conduct of human subject research studies. Written procedures are required to document review of changes to IRB approved research and to report the IRB's actions to the Principal Investigator(s) and the institution.

REFERENCE DOCUMENTS

45 CFR

21 CFR 50, 56

38 CFR 16

VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research

PROCEDURES

Changes in approved research must be reported promptly to the IRB and cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject. When the investigator initiates changes to increase, reduce or eliminate apparent hazards, these are to be promptly reported to the IRB. The IRB will review the change to determine whether it is consistent with ensuring the subjects' continued welfare.

For review of modifications to previously approved research by a convened IRB, all IRB members receive and review sufficient information about proposed modifications to previously approved research to determine whether the modified research continues to fulfill the criteria for approval, including a complete description of the proposed modification. The documents reviewed should include the complete documents received from the clinical investigator. Whenever possible the IRB requires each revision to a research protocol to be incorporated into the written protocol.

Changes in research personnel on a protocol require an amendment, to be reviewed by the IRB, only when:

- The personnel change in the protocol involves an individual named in the original protocol – e.g. John/Mary Smith was named in the originally approved protocol, rather than a title or functional role (e.g. research coordinator, technician), and is no longer involved and a

newly named individual will be involved in the protocol – or the individual simply added.

- The title or role of a functional member (not an individual person) in the protocol has been changed – e.g. instead of using a nurse, a physician is now required.

A PI may choose to identify an individual as a member of a protocol, or a title or function description of a protocol staff person.

Investigator Procedures

All changes, including proposed changes to a research activity or premature completion of a study, are to be submitted to the IRB utilizing the Stratton VA Amendment Form. This form allows the IRB to assess changes in the scope of the research project and evaluate any increases in risks to subjects. The form must contain the five digit MIRB number or the four digit PROMISE number, title of the project, printed name and signature of the Principal Investigator.

If there are any changes to the consent form document (VA Form 10-1086), these should be highlighted in yellow or placed in bold print, with the revised consent from document attached to the Amendment Form.

Check the R&D Office website to determine # of copies to be submitted.

Administrative Procedures

R&D Office staff:

- 1) Checks to ensure the packet is complete.
- 2) Stamps the original packet with current date and “Original”.
- 3) Places the request information on the next IRB agenda
- 4) The HRPP Coordinator or the IRB Chair or Vice Chair assigns one primary reviewer to the protocol from the current list of voting IRB members based on expertise and experience in relation to the research. The Roster of IRB members includes each member’s specialty and is available as a reference. As necessary, the HRPP Coordinator reviews the IRB member CVs. When questions regarding necessary expertise arise, HRPP Coordinator will contact the IRB Chairperson who will determine if the review can be completed by current membership or if an ad hoc member is necessary. If an ad hoc member is necessary, the IRB Chair or Vice Chair will make the appropriate contact, determine who will be contacted to serve as the ad hoc member, or allow the convened IRB to determine who will be contacted to serve as an ad hoc IRB member.
- 5) Provides the primary reviewer with a primary reviewer sheet and a copy of the amendment request with the accompanying documents.

- 6) Provides non-primary reviewers with the amendment request. If the amendment involves a request for changes to the protocol, only the primary reviewer and the IRB Chair will receive the protocol.

IRB Procedures

- Each protocol will be assigned 1 primary reviewer. The reviewer assignment is documented and becomes a part of the agenda. The name of the reviewer will not be shared with Investigators in order to protect members from undue influence.
- Approximately one week prior to the meeting, members will receive the items to be discussed at the next meeting. Prior to the meeting, all IRB members have the responsibility to review the materials received including the consent form document and to ensure that all pertinent components of informed consent are contained and appropriate.
- The IRB reviews proposed changes to research protocols according to the principles outlined in federal regulations 38CFR16, 21CFR50&56, & 45CFR46. The primary reviewer is to conduct an in-depth review of the provided materials. All other IRB members are expected to review materials in enough depth to be familiar with and prepared to discuss the materials at the convened meeting. The primary reviewer is responsible for submitting written reports of their in depth review to the R&D Office and verbal reports to the entire IRB. The report will include documentation of whether the proposed changes increase risks to subjects and whether the changes necessitate subjects be informed. After review and discussion, the IRB has the following options:
 - **APPROVE:** Outright approval of the amendment or change.
 - **REQUIRE MODIFICATIONS:** Modifications are required to secure IRB approval. If modifications are requested, a recommendation will be made for follow-up based on the risks associated with the study and the significance and magnitude of the changes requested. Subsequent review of modifications can be by:
 - a. *Full IRB Review.* Major revisions are required. If there are substantive modifications or clarifications, IRB approval cannot occur until the materials submitted from the PI are reviewed by the convened IRB. If the request is tabled, the IRB may require a completely new request for changes. The IRB can also suspend enrollment.
 - b. *Administrative Review.* If the IRB approves research contingent on specific minor conditions, the IRB Chair, or another IRB member designated by the Chair, may approve the revised

research protocol via the expedited review process. Refer to the SOP on Expedited Review for what can be reviewed through this process.

- **DISAPPROVE:** Disapproval may require the submission of an entirely new amendment request.
- **Whether the IRB chooses to approve, require modifications or disapprove, such decision will be communicated to the principle investigator by the HRPP Coordinator by letter or email.**
- Changes in approved research cannot be implemented until approved by the IRB. If the amendment addresses an issue related to biosafety or radiation safety, the appropriate committee or subcommittee must first approve the amendment. [VHA Handbook 1200.5 7.h] Amendments addressing an issue related to biosafety or radiation safety require that a revised Research Protocol Safety Survey (Biosafety Form - VA Form 10-0398) be submitted. Evidence of approval by the SRS&B (Biosafety & Radiation) will be communicated in the form of an email from the SRS&B Coordinator to the ACOS/R, including a copy (cc) of the email to the SRS&B Chairperson and IRB Chairperson, stating the date of the meeting at which the protocol was reviewed and the date of approval.
- If a PI cannot continue to be responsible for the research (e.g. leave VA, etc), either the PI or the PI's supervisor must immediately submit an amended protocol to replace the PI or to terminate the protocol. The new PI must be appropriately credentialed and privileged and must complete an Investigator Data Form (page18) if they are a new investigator.