

Version Number: 2	Research & Development Policy 151-20	Supersedes Document Dated: 10/18/2010
Effective Date: 3/10/2014	IRB Amendments	Expiration Date: 3/10/2018

I. POLICY

It is Syracuse 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.

II. DEFINITIONS – Refer to SOP 151-01 Appendix B

III. FORMS

- A. Amendment Form
- B. Primary Reviewer Form – Amendments
- C. Regulatory Criteria for Approval Guide for IRB Review

IV. REFERENCE DOCUMENTS

- A. 45 CFR 46
- B. 21 CFR 50, 56
- C. 38 CFR 16
- D. VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research

V. 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 eliminate apparent hazards, these are to be reported to the IRB as soon as possible.

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. Whenever possible the IRB requires each revision to be incorporated into the written protocol.

VI. Investigator Procedures

All changes are to be submitted to the IRB utilizing the Syracuse 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, title of the project, and the printed name, contact number and signature of the Principal Investigator.

Any changes to the consent form (VA Form 10-1086) should be highlighted in yellow or placed in bold print, with the revised consent form attached to the Amendment Form. The investigator should also report the current number of subjects enrolled.

VII. Administrative Procedures

IRB Office staff:

- 1) Checks to ensure the packet is complete.
- 2) Stamps the original packet with the date received.
- 3) Places the amendment request on the next IRB agenda.
- 4) Modifications are reviewed by the HRPP Administrator to determine potential eligibility for expedited review. Those that appear eligible for expedited review are sent to a primary reviewer with the expedited review checklists and any other applicable checklists for review to occur. Amendments determined to be substantive modifications, by either the HRPP Administrator or the primary review, will be reviewed by the Primary Reviewer System, presented to and voted on at the full IRB at the convened meeting. (Substantive, in this case, means a change great enough to no longer meet the criteria for expedited review, as outlined in R&D SOP 151-02.)
- 5) Primary Reviewer System: The HRPP Coordinator or the IRB Chair or Co-Chair assigns one primary reviewer to the protocol from the current list of voting IRB members based on his/her expertise and experience in the research (the IRB roster includes each member's specialty as a reference). As necessary, the HRPP Coordinator may review the IRB member's CV to ensure that he/she is an appropriate reviewer. When questions regarding necessary expertise arise, the HRPP Coordinator will contact the IRB Chair, who will determine if the review can be completed by an IRB member or if an ad hoc member is necessary. If an ad hoc member is necessary, the convened IRB, Chair, or Co-Chair may determine who will serve in this capacity.
- 6) Confirms that the primary reviewer (whether a member of the IRB or a non-voting consultant) does not have a conflict of interest with the protocol under consideration.
- 7) Provides the primary reviewer with a primary reviewer sheet, Regulatory Criteria for Approval Guide for IRB Review and a copy of the amendment request with the accompanying documents.

- 8) Provides non-primary reviewers with the amendment request and the Regulatory Criteria for Approval Guide for IRB Review.

VIII. IRB Procedures

1) Each protocol amendment will be assigned one 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.

2) Approximately 10 days 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, and to ensure that all pertinent components of informed consent are included and appropriate.

3) 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.

4) The primary reviewer is responsible for submitting written reports of his/her in-depth review to the IRB 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 that subjects be informed. After review and discussion, the IRB has the following options:

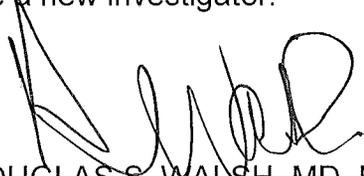
- **APPROVE:** Approval of the amendment as submitted.
- **REQUIRE MODIFICATIONS:** Modifications are required to secure IRB approval. If modifications are requested, a recommendation will be made for follow-up based on the risks associated with the study and the significance of the changes requested. 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. If the amendment poses additional risk to subjects, the IRB may request that the investigator voluntarily suspend enrollment until approval has been granted.
 - b. *Administrative Review.* If the IRB approves research contingent on specific minor conditions, the IRB Chair or an IRB member

designated by the Chair, may grant expedited approval once the conditions have been met. Refer to the IRB SOP 151-02 on Expedited Review for what can be reviewed through this process.

- **TABLED:** Tabled pending receipt of additional substantive information. The IRB determines that it lacks sufficient information about the amendment to proceed with its review. The amended research may not proceed until the convened IRB has approved a revised application incorporating all necessary information.
- **DEFERRED:** The IRB has postponed action until a later time.
- **DISAPPROVE:** Disapproval may require the submission of an entirely new amendment request. The investigator will be given the opportunity to respond to the IRB's disapproval in person or in writing.

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]

If a PI cannot continue to be responsible for the research (e.g., he/she leaves the VA), either the PI or the PI's supervisor must immediately submit an amendment 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 if they are a new investigator.



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