TITLE: Suspensions and Terminations

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the policies and procedures of the VA Central IRB for suspending or terminating the approval of VA Central IRB-approved projects.

2.0 REVISION HISTORY

Date of Initial Approval	July 3, 2008
Revision Dates	March 25, 2010 September 17, 2010 August 10, 2011

3.0 SCOPE

This SOP applies to all individuals or committees involved with research projects under the oversight of the VA Central IRB.

4.0 POLICY

4.1 It is the policy of the VA Central IRB to have and follow approved written procedures for the suspension or termination of the approval of VA Central IRB-approved projects when the need for such action has been determined.

4.2 The VA, the Department of Health and Human Services (DHHS), and the Food and Drug Administration (FDA) require that institutions have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (a) any unanticipated problems involving risk to human research participants or others, (b) any serious or continuing noncompliance with regulatory policy or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval. The VA Central IRB follows these policies and ensures all required notifications are made.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 The VHA Central Office Institutional Official (IO) and the IOs at all the local participating facilities are responsible for the overall assurance of protections for human participants taking part in VA Central IRB-approved projects.

6.2 The VA Central IRB Co-Chair may suspend IRB approval on an urgent basis based on concerns for participant safety; however, any such action must be reviewed by the convened VA Central IRB at the next scheduled meeting or at a special convened meeting. If another designated IRB member determines that a study requires suspension, (See SOP 114, Reportable Adverse Events and Unanticipated Problems In Research) concurrence and action by a VA Central IRB Co-Chair is required.

6.3 The convened VA Central IRB has the authority to suspend or terminate a previously approved VA Central IRB research project based upon interim reports (e.g. serious adverse event reports, reports of unanticipated problems involving risk to participants or others, protocol deviation or violation reports, audit reports, continuing review reports), or whenever deemed necessary for the health and welfare of participants, study team members, or others.

6.3. The VA Central IRB is responsible for initiating the reporting process per VA Central IRB SOP 125, Reportable Action Reporting, if VA Central IRB approval is suspended or terminated.

6.4 Suspensions and terminations by someone other than the convened VA Central IRB must be reported and reviewed by the convened VA Central IRB. If a PI/SC, LSI, or sponsor suspends a protocol or puts it on administrative hold, the VA Central IRB must receive notification of such action and consider its impact on human participant protections.

6.5 The VA Central IRB treats a partial suspension (e.g., suspension of participants entering into the project only) the same as a suspension in terms of administrative and reporting requirements.

7.0 PROCEDURES

7.1 VA Central IRB Co-Chair or Convened VA Central IRB Procedures

7.1.1 The VA Central IRB Co-Chair can suspend on an urgent basis a previously approved VA Central IRB research project due to concerns for patient safety. The VA Central IRB can suspend or terminate a previously approved VA Central IRB research project. Reasons for suspending or terminating the VA Central IRB approval include, but are not limited to, the following:

- The research project no longer meets the criteria for VA Central IRB approval.
- There is confirmed serious or continuing noncompliance with VA Central IRB requirements and/or following the investigational plan.
- There is serious or continuing noncompliance with federal human research protection requirements.

- There has been unexpected harm to the rights or welfare of human participants or there is an unanticipated problem that could affect the rights or welfare of participants or others.

7.1.2 Before suspending or terminating the research approval of a project or the involvement in an approved project by a participating site, the VA Central IRB Co-Chair and/or the convened VA Central IRB as applicable must consider whether the action may adversely affect the rights and welfare of current participants. If this is the case, the VA Central IRB must consider all options and alternatives to protect human research participants. Such options and alternatives include but are not limited to the following:

- Continue treatment by the same or a different investigator
- Transition participants to clinical care outside the research
- Continue follow-up of participants for safety reasons
- Continued reporting of adverse events and unanticipated problems
- Continuation of some research activities under an independent monitor

7.1.3 When study approval is suspended by a VA Central IRB Co-Chair or suspended or terminated by the convened VA Central IRB, the VA Central IRB Co-Chair or convened VA Central IRB as applicable must:

- Ensure protections of the rights and welfare of currently enrolled participants.
- Ensure procedures for withdrawal of enrolled participants take in to account their rights and welfare (e.g., orderly withdrawal of research treatments/procedures according to an approved regimen, making arrangements for medical care outside of a research study, transfer to another researcher, or continuation in the research under independent monitoring).
- Consider whether current participants must be informed of the suspension or termination and if so, ensure appropriate procedures are in place for informing current participants of the termination or suspension, as well as determining whether past participants must also be notified.
- Ensure reporting of adverse events or outcomes, which occur after the suspension, to the VA Central IRB and, for those projects that were terminated, specify a time period after the termination for adverse events to continue to be reported to the VA Central IRB.

7.1.4 If one of the VA Central IRB Co-Chairs suspends a previously approved research project, the action is placed on the agenda of the next meeting of the

VA Central IRB for discussion or the Co-Chair can call for a special convened IRB meeting to review the issue

7.2. VA Central IRB Notification to Institutional Officials and PI or LSI.

7.2.1 The institutional officials described in the MOU and the PI/SC and LSIs are notified in writing if the VA Central IRB Co-Chair or the convened VA Central IRB suspends or terminates the approval of a research project. A copy of the suspension or termination letter is forwarded to the Coordinating Center when applicable. The Office of Research and Development (ORD) funding service is also notified.

7.2.2 If the suspension or termination pertains only to a particular site or LSI's participation in the project, the LSI for that site is notified in writing and a copy of the letter is forwarded to the IO of the applicable VA facility, the PI/SC, and the Coordinating Center if applicable. The ORD funding service is also notified.

7.2.3 The suspension or termination letter includes the following as applicable:

- The reasons for the action taken
- An explanation of the extent of the suspension or termination in terms of participant enrollment, recruitment, interventions, interactions, and data analysis
- Whether follow-up of participants for safety reasons is permitted or required
- Whether past and/or current participants need to be notified of the suspension or termination in writing and whether the VA Central IRB needs to review the notice to participants prior to it being sent
- If a suspension, the corrective actions necessary for the VA Central IRB to consider withdrawal of the suspension
- For terminations, whether adverse events or unanticipated problems still need to be reported
- Notice that the suspension or termination action will be reported by the VA Central IRB VA Central IRB Co-Chair to local Facility Medical Center Directors as applicable and that the action will also be further reported to the VA Office of Research Compliance, OHRP, and the FDA if applicable.

7.3. VA Central IRB Reporting and Record Keeping

7.3.1 The VA Central IRB Co-Chair initiates further reported as required per VA Central IRB SOP 125, Reportable Action Reporting if applicable.

7.3.2 All documentation pertaining to any suspension or termination action is filed in the appropriate VA Central IRB research project file by VA Central IRB administrative staff, as well as the VA Central IRB Noncompliance Log Folder. The VA Central IRB administrative staff also updates the Master VA Central IRB Project Log concerning the status of the project.

7.3.3 The VA Central IRB administrative staff ensures that all follow-up actions as required by the VA Central IRB are tracked and followed-up as required with the affected investigators. For study suspensions, follow-up is conducted on a weekly basis to ensure progress is being made in taking the required corrective actions for re-instatement.

7.3.4 If continuing review is due during a period of suspension, the investigator will be instructed to submit all required documentation for review by the VA Central IRB as interim reports. Upon submission of final corrective action and the decision of the VA Central IRB to re-instate the study, the VA Central IRB can request a further update if needed and then perform a continuing review of the study. Upon approval of the continuing review, a new approval period will be established by the VA Central IRB.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research

8.3 VHA Handbook 1058.01, Research Compliance Reporting Requirements

8.4 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

I have reviewed and approved the contents of this SOP.

Date: 8/10/11

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