



Serious and Continuing Non-compliance

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1 SCOPE AND APPLICABILITY

- 1.1 This Standard Operating Procedure (SOP) applies to all individuals, committees, or other institutional entities involved with human subject research projects under the oversight of the VA Central IRB.
- 1.2 This SOP describes the policies and procedures of the VA Central IRB for addressing allegations and findings of non-compliance with VHA Central Office Human Research Protection Program (HRPP) requirements. It is the policy of the VA Central IRB to ensure prompt reporting to the VA Central IRB, appropriate local facility institutional officials, and appropriate federal agencies of any serious or continuing noncompliance with federal regulations and requirements or the determinations of the VA Central IRB.

2 DEFINITIONS

- 2.1 **Continuing Noncompliance.** Persistent failure to adhere to the laws, regulations, or policies governing human research (VHA Handbook 1058.01).
- 2.2 **Institutional Official (IO).** The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO serves as the official representative of the institution to external agencies and oversight bodies and provides all written communication with external departments, agencies, and oversight bodies. The Principal Deputy Under Secretary for Health is the IO for VHA Central Office and VA Facility Directors are the IOs for local VA facilities. (VHA Handbook 1200.05)
- 2.3 **Serious Noncompliance.** Failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as: (1) involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human subjects, research staff, or others; or (2) substantively compromising the effectiveness of a facility's research protection or human research oversight programs (VHA Handbook 1058.01).
- 2.4 **Suspension of IRB Approval.** A determination by an IRB Chair, a qualified IRB voting member designated by the IRB Co-Chair, or the convened IRB to temporarily interrupt some or all previously approved research activities. The suspended activities may include, but not be limited to, recruiting of new subjects for the research. Suspended studies remain open and require continuing review (VHA Handbook 1200.05).
- 2.5 **Termination of IRB Approval.** A termination of IRB approval is a determination by the convened IRB to permanently halt some or all previously approved research activities including, but not limited to, enrollment of new subjects in research (VHA Handbook 1200.05).

3 RESPONSIBILITY

- 3.1 The Institutional Official (IO) of each local facility is responsible for the overall assurance of protections for human participants within the HRPP of their facility. The IO of the VHA HRPP is responsible for the overall assurance of protections of human participants in VA Central IRB-approved projects.
- 3.2 The VA Central IRB is responsible for reviewing reports of allegations, observations, or evidence of noncompliance, and making a determination of serious and/or continuing noncompliance. The VA Central IRB is also responsible for initiating the reporting process as per VA Central IRB SOP 125, Reportable Action Reporting, if a determination of serious or continuing noncompliance is made.



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3.3 The individuals making the determination must not have any conflicts of interests and must not have any direct involvement in the activity that she or he is examining. If the individual has a conflict of interest or is directly involved in the activity, he or she will immediately return the request to the VA Central IRB Administrator for reassessment.

4 PROCEDURES

4.1 Receipt of Allegations, Observations, or Evidence of Noncompliance

- 4.1.1 Any VA employee or member of a research team (including Without Compensation Employees) who becomes aware of noncompliance, or believes there may be noncompliance with VA Central IRB or VHA HRPP requirements, is required to report this noncompliance to the VA Central IRB within 5 business days of becoming aware of the event. When an RCO from a VA local site discovers possible serious or continuing noncompliance pertaining to a research project approved or overseen by the VA Central IRB, including apparent serious or continuing noncompliance identified during an auditing activity, it must be reported to the VA Central IRB within 5 business days of the identification of the apparent serious or continuing noncompliance.
- 4.1.2 In addition, participants in human research projects, their designated representatives, or members of their local community should be encouraged to report any activities or behaviors that they believe may be noncompliance or inappropriate.
- 4.1.3 Reports from members of the VA research community must be made in writing to the VA Central IRB. Written communications may be directed to the va.central.irm@va.gov or to any member of the VA Central IRB administrative staff or the VA Central IRB members. If telephone communication is made, the reporting individual will be encouraged to submit it in writing using an anonymous (e.g., Gmail, Yahoo) e-mail address, if possible, so that follow-up communications can be made during an investigation, if needed.
- 4.1.4 An oral or e-mail acknowledgement (as applicable) is conveyed or sent to the reporting individual (if not anonymous) by the VA Central IRB Administrator acknowledging receipt of the allegation, observation, or evidence of noncompliance.
- 4.1.5 While noncompliance can be reported to the VA Central IRB by any of the above methods, study team members or others can also report noncompliance to the VA Central IRB by completing and submitting VA Central IRB Form 129, Report of Protocol Deviations, Violations, and/or Noncompliance. The report will be acknowledged and processed in accordance with VA Central IRB SOP 126 except that the Reviewer, while able to review the issue and ask the study team additional questions, cannot make a final determination and must refer the issue for review to the convened IRB. If patient safety is involved the Reviewer must also immediately refer the issue for review to a VA Central IRB Co-Chair for additional review.
- 4.1.6 Upon receipt of a report of apparent serious or continuing noncompliance that is not submitted on the VA Central IRB Form 129, the VA Central IRB Administrator or the VA Central IRB Manager as applicable, adds the issue to the agenda for the next available meeting of the VA Central IRB and sends the report to the applicable Primary Reviewer for the study along with a VA Central IRB Form 152, Documentation of Review by a VA Central IRB Reviewer. If the

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noncompliance involves an obvious safety issue, one of the VA Central IRB Co-Chairs will be immediately informed and a copy of the report sent to him/her via encrypted e-mail or through the SharePoint task management function.

4.2. VA Central IRB Co-Chair Review of Allegations of Noncompliance and Apparent Serious or Continuing Noncompliance

4.2.1 All reports of apparent serious or continuous noncompliance that may involve patient safety are reviewed immediately by one of the VA Central IRB Co-Chairs. If one of the Co-Chairs has a conflict of interest, the other Co-Chair will perform the evaluation.

4.2.2 The VA Central IRB Co-Chair can take one or more of the following actions:

- Determine that no immediate action is required prior to review of the report by the convened VA Central IRB.
- Determine that no immediate action is required but request that additional information be submitted prior to the review by the convened IRB to assist the Board in making a determination.
- Immediately suspend the research activity or a portion of the research activity for patient safety reasons (see VA Central IRB SOP 119, Suspensions and Terminations if this action is taken).
- Take other actions as deemed appropriate to protect the health, safety, or welfare of research participants.

4.3 VA Central IRB Review of Allegations of Noncompliance and Apparent Serious or Continuing Noncompliance

4.3.1 All reports of apparent serious or continuing noncompliance will be reviewed at the next available meeting of the VA Central IRB. For other reports, such as protocol deviations or violations, reports of unanticipated problems involving risks to subjects or others, and any other type of report regarding protocol compliance, even though apparent serious or continuing compliance was not identified by the individual submitting the report, the report can be referred to the convened VA Central IRB for review by the Primary Reviewer for the study if the Reviewer indicates the report may constitute apparent serious or continuing noncompliance. A special VA Central IRB meeting may also be convened to review the alleged noncompliance or report of apparent serious or continuing noncompliance.

4.3.2 The VA Central IRB Primary Reviewer who initially reviewed the project will be assigned to review the report of noncompliance or apparent serious or continuing noncompliance and other additional submitted documentation in order to brief the convened IRB on the known facts. If the Primary Reviewer is unavailable, the Secondary Reviewer will perform this function or the VA Central IRB Co-Chair will assign another VA Central IRB member authorized to perform such reviews to the task.



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- 4.3.3 All VA Central IRB members will have access to the report of the allegation or apparent serious or continuing noncompliance and all other investigative materials on the SharePoint site. All members will also have access to the approved research file on SharePoint for reference as needed.
- 4.3.4 After discussion at the convened IRB meeting, the VA Central IRB will make a determination on whether the issue reported constitutes serious or continuing noncompliance based on the information available.
- 4.3.4.1 For reports of apparent serious noncompliance the Board will determine whether the issue meets one or both of the following criteria: 1) the issue involved substantive harm or the genuine risk of substantive harm to the safety, rights, or welfare of human subjects or others or 2) the issue substantively compromised the effectiveness of a facility's human research protection or human research oversight program.
- 4.3.4.2 For reports of continuing noncompliance, the Board will determine if the issue involves repeated failures to adhere to the laws, policies, and procedures regarding the conduct of human subjects' research and the findings, determinations, and requested corrective actions of the VA Central IRB.
- 4.3.4.3 If the Board cannot make a determination based on the information currently available, the Board can table making a determination in order to obtain additional information to supplement the VA Central IRB review. However, the VA Central IRB must reach a determination that serious or continuing noncompliance did or did not occur within 30 to 45 days after receiving the report of apparent serious or continuing noncompliance.
- 4.3.5 If the Board determined that the issue did involve serious or continuing noncompliance, the Board can also take one or more of the following actions.
- Require modifications to the project.
 - Require modifications to the information disclosed to participants during the consent process.
 - Require that additional information be provided to current participants that may relate to participants' willingness to continue to take part in the research.
 - Require that additional information be provided to past participants.
 - Require that current participants be re-consented to continue participation.
 - Alter the continuing review interval.
 - Observe and/or monitor the research or consent process.
 - Require additional training of the PI, LSI, and/or research team.



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- Require additional monitoring.
- Require or modify progress reporting or frequency of progress reports.
- Suspend the conduct of a specific research project until specified protections or corrective actions have been implemented. In this circumstance, research activities involving subjects already enrolled in the affected project may continue if the IRB determines it is in the best interests of the subjects to do so.
- Temporarily suspend or permanently remove the local site or an investigator from participation in specific projects.
- Notify scientific peer group of investigator non-compliance.
- Terminate the VA Central IRB approval (see SOP 119, Suspensions and Terminations).
- Refer the noncompliance to other organizational entities.
- Refer an investigator for evaluation of possible research misconduct.
- Refer an investigator for evaluation of possible debarment or suspension based on research impropriety in VA research.
- Take other actions as determined appropriate.

4.3.6 Even if the Board determined that the issue did not constitute serious or continuing noncompliance, the Board can still take some of the actions indicated above, such as requiring additional training or that additional information be provided to participants.

4.4. PI/SC or LSI Notification of the Results of the VA Central IRB Review: The PI/SC or LSI as applicable is notified in writing of the results of the review by the VA Central IRB. In addition, the applicable VA Central IRB Local Site Liaisons are also notified. If reporting to federal agencies and/or other applicable individuals or agencies is required due to a finding of serious or continuing noncompliance, the required reporting will be accomplished per VA Central IRB SOP 125, Reportable Action Reporting.

4.4.1 Any remedial actions required by the VA Central IRB involving a finding of serious or continuing noncompliance must be completed within 90 to 120 days after the VA Central IRB's determination.

4.3.5 Any remedial actions required by the VA Central IRB involving programmatic noncompliance must be completed within 120-180 days after the VA Central IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, legal negotiations, etc.



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5 DOCUMENTATION REQUIREMENTS

- 5.1 The VA Central IRB administrative staff file all documents relating to the report of an allegation, observation, or evidence of serious or continuing noncompliance in the appropriate VA Central IRB research project file. Copies of all correspondence to include responses to requests for remedial actions are also filed in the VA Central IRB research project file.
- 5.2 Copies of all documents are also kept on the VA Central IRB shared drive. Selected documents may be loaded to SharePoint for specified periods of time or while the project is active but are not kept permanently on that site

6 REFERENCES

- 6.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects
- 6.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research
- 6.3 VHA Handbook 1058.01, Research Compliance Reporting Requirements
- 6.4 VHA Handbook 1058.2, Research Misconduct
- 6.5 VHA Handbook 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research
- 6.6 Office for Human Research Protections Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, dated January 15, 2007
- 6.7 Office for Human Research Protections Policy, OHRP's Compliance Oversight Procedures for Evaluating Institutions, dated October 14, 2009
- 6.8 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards



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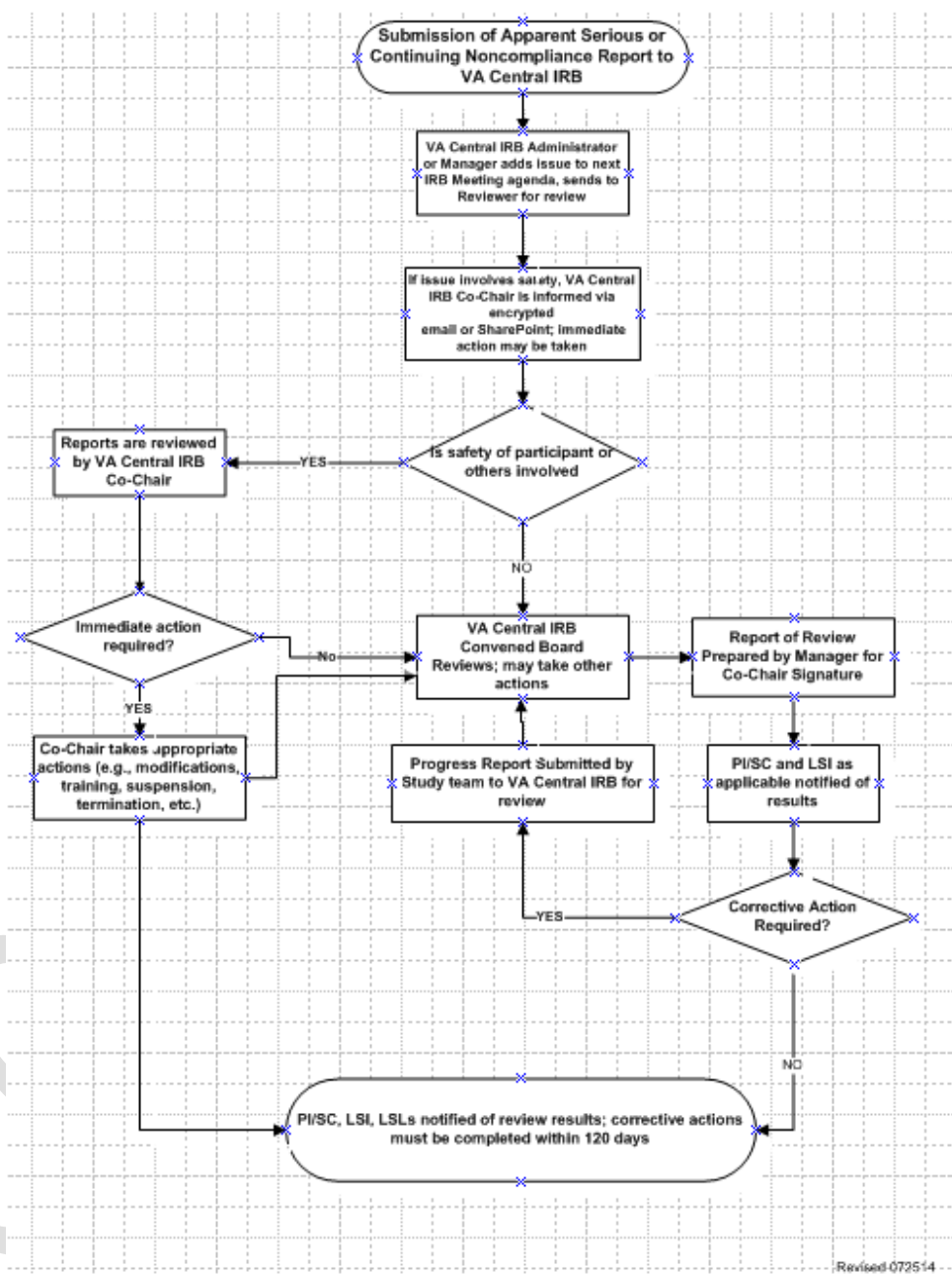
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Attachment 1: VA Central IRB SOP 118 Process Chart





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