



Reportable Action Reporting

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1 SCOPE AND APPLICABILITY

- 1.1 The scope and purpose of this standard operating procedure (SOP) is to describe the policies and procedures of the VA Central IRB for reporting to the applicable federal agencies, including the VA Office of Research Oversight (ORO), the Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP), as well as to VA facilities and other required individuals, any event that the VA Central IRB has determined to involve serious or continuing noncompliance; is an unanticipated serious adverse event (SAE) or a serious unanticipated problem (UAP) involving risks to participants or others; or a suspension or termination of a project previously approved by the VA Central IRB.
- 1.2 This SOP applies to all study team members, VA facility officials, and sponsors involved with human subjects research projects under the oversight of the VA Central IRB.
- 1.3 It is the policy of the VA Central IRB to comply with all applicable local, state, and federal requirements for the conduct of human research projects and to communicate certain actions to entities as required and/or if the entities have an interest in the status of the research being conducted.

2 DEFINITIONS

- 2.1 **Adverse Event.** An AE is defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research. (VHA Handbook 1200.05). In the context of a multi-center study, local or internal AEs are those AEs experienced by subjects, research staff, or others at the reporting individual's own VA facility or VA-approved research site.
- 2.2 **Continuing Noncompliance.** This refers to persistent failure to adhere to the laws, regulations or policies governing human research (VHA Handbook 1058.01).
- 2.3 **Serious Adverse Event.** A local SAE in human research is an AE that results in death, a life threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, or congenital anomaly or birth defect. An AE is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent such an outcome. (VHA Handbook 1200.05)
- 2.4 **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).
- 2.5 **Suspension of IRB Approval.** 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 entities and oversight bodies and provides all written communication with external departments, agencies and oversight bodies. The Principal Deputy Under Secretary for Health Affairs is the IO for VHA Central Office and VA facility Directors are the IOs for local VA facilities (VHA Handbook 1200.05)



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2.6 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)

2.7 Unanticipated Problems Involving Risks to Participants or Others. Any event or problem that meets all of the following criteria: (1) unexpected (in terms of nature, severity, or frequency) that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents, such as the IRB-approved research protocol and informed consent document; and the characteristics of the subjects population being studied, (2) related to participation in the research; and (3) suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, social, or legal harm) than was previously known or recognized.

2.8 Unexpected or Unanticipated Adverse Event. An AE that is new or greater than previously known in terms of nature, severity, or frequency of occurrence, as documented in the protocol or other materials approved by the IRB. Such materials may include but are not limited to: the informed consent form, clinical investigators' brochure, and product labeling. (VHA handbook 1058.01 and VHA Handbook 1200.05).

3 RESPONSIBILITY

3.1 The VA Central IRB is responsible for reporting all unanticipated serious adverse events that are related to the research, unanticipated problems involving risks to participants or others that are related to the research, serious or continuing noncompliance, and any suspension or termination of IRB approval for a study to applicable oversight agencies in accordance with VA and other federal requirements. It also must determine whether the reportable action involves all engaged sites or only the local reporting facility. Relevant determinations made during convened meetings are documented in the meeting minutes.

3.2 The VA Central IRB Co-Chairs are responsible for reporting any reportable action within 5 working days after a determination has been made by the VA Central IRB that an action is reportable, or a suspension or termination of IRB approval has taken place, to each affected participating facility Medical Center Director, as applicable, and to the VHA Central Office HRPP Institutional Official. The VA Central IRB Co-Chair is also responsible for notifying the investigator in writing of the determination.

3.3 Each affected Medical Center Director, as applicable, is responsible for reporting, within 5 working days of receiving the notification from the VA Central IRB Co-Chair, any reportable action to the Medical Center's ORO Regional Office, the Office of Human Research Protections (OHRP), and to the FDA, if the determination was serious or continuing noncompliance and if the study to which the action pertains involves an investigational product regulated by the FDA.

3.4 The sponsor is responsible for FDA reporting requirements if the reportable event is an Unanticipated SAE or UAP that is related to use of an FDA-regulated product.

3.5 The VHA Central Office HRPP IO is responsible for reporting the reportable action to the VA ORO Central Office within 5 working days of receipt of the notification from the VA Central IRB Co-Chair.



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3.6 The VA Central IRB Administrator and VA Central IRB Managers are responsible for coordinating the reporting of all actions with the various individuals involved to ensure that reporting requirements are met. The VA Central IRB Administrator and the Managers are also responsible for following up with the investigators and the study teams regarding progress being made in the specific remedial action plans for each reportable action, if any, and for ensuring that all documentation regarding the actions is filed in the applicable study folder and in accordance with VA Central IRB SOPs.

4 PROCEDURE

4.1 Preparation of Correspondence for Reportable Actions

- 4.1.1 Within 48 hours of a reportable determination being made the VA Central IRB Administrator sends an encrypted e-mail to ORO Central Office providing a preliminary description of the event and requesting assignment of an ORO case number.
- 4.1.2 The applicable VA Central IRB Manager for the study notifies the applicable investigator by phone or encrypted e-mail that the VA Central IRB has determined that there is a reportable action. The VA Central IRB Administrator then prepares a draft memorandum addressed to the PI/SC or LSI(s) as applicable that contains the following:
- The nature of the reportable action (an unanticipated problem involving risks to participants or others, serious or continuing non-compliance, or suspension or termination of VA Central IRB approval of research);
 - Title and VA Central IRB research project number of the research project in which the reportable action occurred, as well as the names of responsible investigators (PI/SC and/or LSIs); and the affected sites;
 - A detailed description of the problem including the determinations of the VA Central IRB and the reasons for them;
 - Any actions taken by the VA Central IRB in addition any corrective actions already taken by the study team (e.g., revise the protocol and/or informed consent, inform enrolled participants, increase monitoring, request an audit by the local RCO or other entity);
 - The requirement, if any, to submit a remedial action plan and/or send follow-up or progress reports, or a final report by either a specific date or when an investigation is completed or a corrective action plan implemented; and
 - That the action is reportable by the local VA participating facility IO to the facility's ORO Regional Office, to OHRP, and to the FDA if applicable.
- 4.1.2 The VA Central IRB Administrator also prepares a draft memorandum to the applicable Medical Center Director(s) notifying the Medical Center Director of the reportable action and indicating that the Medical Center Director must further report the action to the facility's ORO Regional Office within 5 working days of receipt of the notification and to OHRP and, if applicable, FDA.



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- 4.1.3 A draft memorandum is also prepared by the VA Central IRB Administrator to the VHA Central Office HRPP IO containing the same information as detailed above except asking the IO to report the event to ORO Central Office.
- 4.1.4 One of the VA Central IRB Co-Chairs reviews the draft of the memoranda, makes any changes as necessary, signs the memoranda, and forwards them back to the VA Central IRB Administrator for distribution.
- 4.1.5 Immediately upon receipt of the signed memoranda from the VA Central IRB Co-Chair, the VA Central IRB Administrator takes the following actions:
- 4.1.5.1 Forward copies of the Letter to the Investigator and to the Medical Center Director to the applicable VA Central IRB Manager. The VA Central IRB Manager will then perform the following actions:
- 4.1.5.1.1 Forward the letter to the LSI or to the PI/SC if applicable via encrypted e-mail or by uploading them to SharePoint and sending the link via regular e-mail. Copies will also be forwarded to the sponsor, to include any Coordinating Center Program Manager, and to the PI/SC if not the original addressee, as well as to the National Program Manager if applicable.
- 4.1.5.1.2 Forward the letter to the Medical Central Director to the VA Central IRB Local Site Liaison(s) of the affected site(s) via encrypted e-mail or by uploading them to SharePoint and sending the link via regular e-mail and asking that immediate attention is given to the distribution of the letter. The VA Central IRB Local Site Liaison will then ensure that the letter is immediately distributed to the following individuals at the facility:
- Institutional Official;
 - Associate Chief of Staff for Research (ACOS/R&D);
 - R&D Committee Chair;
 - Chief of Staff;
 - Local RCO;
 - Local VA Privacy Officer if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information; and
 - Local VA Information Security Officer if the event involved violations of information security requirements.
- 4.1.5.2 The VA Central IRB Administrator will then draft a letter from the VA Central Office HRPP IO to ORO Central Office reporting the action and attaching a copy of the letter from the VA Central IRB Co-Chair that details the incident and required corrective actions. The ORO case number, if available, will also be referenced. The VA Central IRB Administrator will then send an encrypted e-mail to the VHA Central Office HRPP IO, currently the Principal Deputy Under Secretary for Health (PDUSH), regarding the reportable action and attach a copy of the VA Central IRB Co-Chair's notification letter and the draft letter to ORO Central Office. The Deputy Under Secretary for Health for Policy and Services (DUSHPS), the Deputy DUSHPS, the VHA Central Office HPA, and

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the CRADO will be copied on the e-mail, as will the correspondence section for 10A. At the same time, the draft letter will be entered into the VAIQ concurrence system to the PDUSH for signature. The VAIQ number will be cited in the e-mail message to the IO for reference.

- 4.1.5. 3 The IO will sign the letter and return it via encrypted e-mail either directly or through one of the Executive Assistants within 5 work days of receipt to the VA Central IRB Administrator. Upon receipt of the signed letter from the PDUSH, the VA Central IRB Administrator will forward it via encrypted e-mail to the ORO Central Office and will also include a copy as part of the VAIQ action. Copies will also be filed with the project folder.

Note: in the event the VA Central IRB Administrator is unavailable, the VA Central IRB Manager assigned to the study will prepare and process the memorandum to the LSI, MCD, and IO in order to ensure the 5 day reporting requirement is met.

4.2. Submission of Interim and Follow-up Reports. Interim reports will be submitted to ORO as follows:

- 4.2.1 Upon receipt of the notification from the VHA Central Office HRPP IO of the reportable event, ORO Central Office may require that an interim or remedial action progress report be submitted by a specific date. These interim and progress reports will be submitted by the VA Central IRB Administrator via encrypted e-mail.
- 4.2.2 The VA Central IRB Manager for an assigned study will follow up with the study teams as directed by the VA Central IRB and forward progress reports for review by the Primary Reviewer of the study and the VA Central IRB Co-Chair overseeing the action as the reports are received. The progress reports will also be reviewed at the next convened meeting of the VA Central IRB.
- 4.2.3 The VA Central IRB Manager will inform the investigator in writing if progress was deemed to be acceptable or if additional actions or explanations are required. If the progress was determined to be acceptable but all remedial actions have not yet been completed, an encrypted e-mail by the VA Central IRB Manager can be forwarded to the investigator. If additional actions or explanations are being requested, a letter will be prepared by the VA Central IRB Manager to the investigator detailing the additional requirements and will be forwarded to a VA Central IRB Co-Chair for signature. Upon signature, the letter will be sent to the investigator via encrypted e-mail or loaded to the VA Central IRB SharePoint site.
- 4.2.4 Once the VA Central IRB has determined that all remedial action has been completed and no further action is required, the VA Central IRB Manager will prepare notification letters for signature of a VA Central IRB Co-Chair to the investigator notifying them that the VA Central IRB determined that all corrective action was accomplished and the action is now closed and, if the study or part of the study was suspended, that the suspension is being lifted:
- 4.2.4.1 Upon signature of the Co-Chair, the letter will be forwarded to the investigator via encrypted e-mail or uploaded to the secure SharePoint site. The VA Central IRB manager will also ensure copies are forwarded to the applicable Coordinating Center, ORD funding service, the Local Site Liaison for the Medical Center Director, and to the PI/SC as applicable.



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- 4.2.4.2 The VA Central IRB Administrator will then prepare a final report to ORO Central Office and send it via encrypted e-mail closing out the action. If ORO agrees that the action can be closed, a letter will be prepared by ORO and sent to the IO indicating concurrence with closing the action and a copy will also be forwarded to the VA Central IRB Administrator.

5 DOCUMENTATION REQUIREMENTS

- 5.1 All reportable actions will be documented in a notification letter prepared by the VA Central IRB for signature by the VA Central IRB Co-Chair.
- 5.2 If required by ORO Central Office, interim or remedial action progress is documented in reports prepared by the VA Central IRB Manager or Administrator.
- 5.3 Copies of notification letters, progress reports, memoranda, and any other correspondence regarding the reportable action will be maintained in VA Central IRB research project files, uploaded to the secure SharePoint site as applicable, and/or stored on the VA Central IRB shared drive.

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 1058.03, Assurance of Protection for Human Subjects Research
- 6.5 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards



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Attachment 1: VA Central IRB SOP 125 Process Chart

