Written/Revised By:

Author	**Author**	**Author**
Print Name: Annette R. Anderson, MS, CIP	Print Name: N/A	Print Name: N/A
Signature: Signature on File	Signature: N/A	Signature: N/A
Date: 7/17/2014	Date: N/A	Date: N/A

Approved By:

Program Manager	**Deputy CRADO**
Print Name: Annette R. Anderson, MS,CIP	Print Name: Holly Birdsall, M.D.
Signature: Signature on File	Signature: Signature on File
Date: 7/17/2014	Date: 7/21/2014

Issued By:

Quality Manager	**Designee Title (if applicable):**
Print Name: Avis Bullard, M.S., CQA(ASQ)	Print Name: N/A
Signature: Signature on File	Signature: N/A
Date: 7/21/2014	Date: N/A

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 the reporting and review of protocol deviations and violations. It includes reporting responsibilities of Principal Investigators/Study Chairs (PI/SC), Local Site Investigators (LSIs), and Coordinating Centers, and any other person who observes or identifies a deviation or violation. This SOP also includes the review procedures of the VA Central IRB when receiving a report of a protocol deviation or violation.

1.2 This SOP applies to all study teams, and Research Office personnel at local sites, participating in a project overseen by the VA Central IRB. It also applies to VA Central IRB members and staff.

1.3 Deviations from the VA Central IRB-approved protocol are considered noncompliance. The terms *protocol deviations* and *protocol violations* are synonymous for the purposes of this SOP.

1.4 Principal Investigators/Study Chairs (PI/SC) and Local Site Investigators (LSI) are required to follow the policies and procedures outlined in the project application package that was reviewed and approved by the VA Central IRB. Changes in any aspect of the VA Central IRB-approved research project initiated without VA Central IRB approval are considered to be protocol deviations or violations.

1.5 Protocol deviations or protocol violations must be reported no later than 5 business days after being made aware of the occurrence if the deviation or violation is likely to substantially adversely affect (a) the rights, safety, or welfare of the research participant, (b) the participant's willingness to continue participation, or (c) the integrity of the research data, including VA information security requirements.

2 DEFINITIONS

2.1 **Continuing Noncompliance.** This refers to 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 entities and oversight bodies and provides all written communication with external departments, agencies and oversight bodies. The Principal Deputy Undersecretary 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).

2.3 **Local Site Liaison.** An individual who serves as the main point of contact between the VA Central IRB and the local facility Research and Development Service regarding studies that are being reviewed and overseen by the VA Central IRB.

2.4 **Related AE or a Related Problem.** A related AE or a related problem in VA research is an AE or problem that may reasonably be regarded as caused by, or probably caused by, the research (see 21 CFR 312.64).

2.5 **Reportable.** The term reportable refers to an incident, event, or situation that must be reported under the requirements of an applicable regulatory or oversight entity.
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2.6 **Serious Noncompliance.** Serious noncompliance is a 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 research subjects, research staff, or others; or (2) Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

2.7 **Serious Problem.** A serious problem is a problem in 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 research subjects, research staff, or others; or (2) Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

2.8 **Suspension or Termination of Research.** Refers to the suspension or termination of research as it relates to VA research and are described as follows: (1) Suspension refers to a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities; (2) Termination refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities; (3) Suspension and termination also apply to interruptions related to concerns regarding the safety, rights, or welfare of human subjects, research investigators, research staff, or others or the safety, health, or welfare of laboratory animals. (4) Suspension and termination does not include interruptions in research resulting solely from the expiration of a project approval period (VHA Handbook 1058.01).

2.9 **VA Facility Director.** A facility Director is the Director of a VA Medical facility or a VA Health Care System. The terms facility Director and Medical facility Director are considered synonymous. The facility Director serves as the Institutional Official (IO) for VA research facilities and programs.

3 RESPONSIBILITY

3.1 The PI/SC and LSIs are responsible for obtaining VA Central IRB review and approval prior to initiating changes in the VA Central IRB-approved research project except when necessary to eliminate apparent immediate hazard to participants. They are also responsible for promptly notifying the VA Central IRB of protocol deviations or violations for which the VA Central IRB serves as the IRB of Record for the research project as per Section 4.1.

3.2 If a Coordinating Center is participating in a VA Central IRB-approved project, the PI/SC is responsible for reporting protocol deviations or violations concerning the operations of the Coordinating Center. Coordinating Center may also submit such reports with the knowledge of the PI/SC.

3.3 The VA Central IRB is responsible for reviewing reported protocol deviations or violations and determining what, if any, action must be taken to safeguard the health and welfare of human research participants and/or the integrity of the research data.

4 PROCEDURE

4.1 Principal Investigator/Study Chair and Local Site Investigator Reporting Procedures

4.1.1 The PI/SC and LSI must report the following protocol deviations or violations to the VA Central IRB **within 5 business days** after being made aware of the occurrence:

4.1.1.1 Any protocol deviation or violation initiated to prevent or eliminate immediate hazards to participants;

4.1.1.2 Any protocol deviation or violation that is likely to substantially adversely affect any of the following:

- The rights, safety, or welfare of the research participant,
- The participant's willingness to continue participation, or
- The integrity of the research data, including VA information security requirements.

4.1.2 The reporting individual must submit VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (U-SAE), Unanticipated Adverse Device Defect (U-ADE), and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others, to report any protocol deviation or violation initiated to prevent or eliminate immediate hazards to participants.

4.1.3 The reporting individual must submit VA Central IRB Form 129, Report of Protocol Deviations, Violations, and/or Noncompliance (Attachment 2), to report a protocol deviation or violation that is substantially likely to have an adverse effect on (a) the rights, safety, or welfare of the research participant, (b) the participant's willingness to continue participation, or (c) the integrity of the research data, including VA information security requirements.

4.1.4 All reports can be submitted through the VA Central IRB secure SharePoint reporting system. This system is monitored on a daily basis during the duty day and reports are logged into the VA Central IRB tracking log or database and downloaded from the system for processing upon receipt.

4.2 VA Central IRB Administrative Staff and IRB Reviewer Procedures

4.2.1 If the protocol deviation or violation is reported on VA Central IRB Form 119, it is processed per VA Central IRB SOP 114, Reportable Adverse Events and Unanticipated Problems in Research.

4.2.2 Upon receipt of a notification through the VA Central IRB SharePoint system that a report has been uploaded, a copy of the report is downloaded to the applicable project and site Reports folder on the PRIDE shared drive. An email is sent to the reporting individual by the VA Central IRB administrative staff acknowledging receipt of the VA Central IRB Form 129. If the VA Central IRB Form 129 is incomplete, the VA Central IRB administrative staff contacts the reporting individual for the missing information. Upon receipt of the missing information, the report is logged into VA Central IRB Form 132, VA Central IRB Protocol Deviation/Violation Tracking Log (Attachment 3) or entered into the ACCESS tracking database, and assigned a tracking number in chronological order based on the calendar year preceded by the letter "D." *Note: The log is in the process of being converted to an ACCESS database.*

4.2.3 The VA Central IRB administrative staff makes the completed VA Central IRB Form 129, along with any included supplemental materials, available to the assigned Reviewer for that specific project on the secure VA Central IRB SharePoint site and uses the Task Manager function to inform the Reviewer of the assigned task. A copy of the most current, approved protocol is also made available if applicable. In addition, the VA Central IRB Administrative staff will prepare VA Central IRB Form 146, Checklist for Review of Protocol Deviations, Violations, and Noncompliance (Attachment 4), for use by the assigned Reviewer. In the absence of the assigned Reviewer, a VA Central IRB Co-Chair or the Secondary Reviewer, if applicable, can serve in the place of the assigned Reviewer in order to perform the review within the required timeframe.

4.2.4 The assigned Reviewer takes one or more of the following actions upon completion of their review, signs the VA Central IRB Form 146, and returns it to the VA Central IRB Administration Office:

- Request additional information. Additional information should only be requested if it is necessary in order for the Reviewer to make a determination.
- Determine that the report represents an unanticipated problem involving risks to participants or others and should be processed as per VA Central IRB SOP 114: Reportable Adverse Events and Unanticipated Problems in Research.
- Determine that apparent serious noncompliance may be involved and the report should be processed as per VA Central IRB SOP 118, Serious and Continuing Non-Compliance.
- Recommend Suspension of approval of the research as per VA SOP 119, Suspensions and Terminations.
- Refer the report to the convened IRB for further review.
- Indicate no further action is needed and that any corrective action already taken was adequate
- Take other actions as appropriate such as requiring additional training for the study team; requiring minor modifications in the protocol, informed consent process, or other study documents; requesting a third party observe the informed consent process or perform a compliance audit; and altering the continuing review period to name a few.

4.2.5 The assigned Reviewer has an initial 5 business day to make a determination. If additional information is needed to make a determination, the VA Central IRB staff will be notified within the 5 business days via the Reviewer responding via the Task Manager function or via email and will then send the request for the additional information to the study team or reporting individual.

4.2.5.1 The Reviewer has a total of 30 calendar days from day of receipt of the initial report to receive the additional information and make a determination. If a determination still cannot be made at the end of the 30 days, the issue will be forwarded to either the convened IRB or to one of the VA Central IRB Co-Chairs for further review.

4.2.5.2 The VA Central IRB Administrative staff will follow-up with the study team or reporting individual to ensure the required additional information is received in sufficient time for a determination to be made within the 30 days. If the study team or reporting individual are non-responsive or request additional time, the issue will be forwarded to one of the VA Central IRB Co-Chairs for further review.

4.2.5.3 The VA Central IRB Co-Chair can take one or more of the actions as described in paragraph 4.2.4.

4.2.5.4 The review should take no more than 45 days from initial receipt of report unless there are extenuating circumstances. If this is the case, justification for the delay will be documented in the tracking log or ACCESS database.

4.2.6 If no further action is needed upon initial review or after additional information is received, the VA Central IRB Administrative staff will notify the reporting individual in writing via encrypted email with copies also sent to the PI/SC, LSI if applicable, Coordinating Center if applicable, national and local study coordinators as applicable and the reporting individual's VA Central IRB Local Site Liaison. All reports and correspondence will be filed in the VA Central IRB research project file.

4.3 VA Central IRB Convened Meeting Review Procedures

4.3.1 The VA Central IRB reviews protocol deviations or violations reported on VA CIRB Form 129, at a convened meeting as follows:

4.3.1.1 The Primary Reviewer is given access on the secure VA Central IRB SharePoint site to the VA Central IRB Form 129, any included supplemental materials, and the complete VA Central IRB approved research project file if applicable.

4.3.1.2 All other VA Central IRB members are given access to the VA Central IRB Form 129, any included supplemental materials, and the current VA Central IRB-approved informed consent form (if applicable). Members may request access to the other materials as needed or the Reviewer may request that certain materials be uploaded for the Board's review.

4.3.2 Upon completion of its review, the VA Central IRB may take one or more of the following actions:

- Obtain additional information to supplement the VA Central IRB review,
- Determine whether the protocol deviation or violation represents serious or continuing non-compliance as per VA Central IRB SOP 118, Serious and Continuing Non-Compliance,

- Determine whether the protocol deviation or violation represents an unanticipated problem involving risks to subjects or others as per VA Central IRB SOP 114, Reportable Adverse Events and Unanticipated Problems in Research,
- Require modifications to the protocol,
- Alter the continuing review interval,
- Observe the research or consent process,
- Require additional training of the investigator,
- Suspend approval of the research as per VA SOP 119, Suspensions and Terminations,
- Terminate approval of the research as per VA SOP 119, Suspensions and Terminations,
- Determine that no further action is required, or
- Take other actions as appropriate, such as request a compliance audit at a later future date.

4.3.3 The reporting individual and LSI, as applicable, are notified in writing of the results of the review via letter signed by one of the VA Central IRB Co-Chairs. The letter is sent via encrypted email or loaded to SharePoint with a non-encrypted email. The PI/SC, Coordinating Center as applicable, national and local study coordinators as applicable, and the VA Central IRB Local Site Liaison are also copied on the email message.

4.3.4 The VA Central IRB administrative staff follow-up with the applicable investigator to ensure that the requirements of the VA Central IRB are carried out, particularly if changes or modifications are required to an approved project that require submission of an amendment.

4.5 VA Central IRB Record Keeping. All documentation pertaining to the reporting of protocol deviations , violations, or noncompliance and the reporting of the results of the VA Central IRB review are filed in the appropriate VA Central IRB research project file by the VA Central IRB administrative staff. The VA Central IRB Form 132 tracking log and/or the ACCESS tracking database is kept up to date with the actions taken.

5 DOCUMENTATION REQUIREMENTS

5.1 All protocol deviations or violations identified by study team members are submitted on VA Central IRB Form 129 and VA Central IRB Form 119 as applicable. Documentation of reports submitted will be maintained in the VA Central IRB Protocol Deviation tracking system either through use of the VA Central IRB Form 132 or through the ACCESS database.

5.2 Copies of all submitted VA Central IRB Forms 119 and 129, as well as any supplementary and follow-up information, as well as VA Central IRB review results and related correspondence will be documented in writing, uploaded to the secure SharePoint site and PRIDE shared drive as applicable, and maintained in the VA Central IRB research project files.

6 REFERENCES

6.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

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

6.3 VHA Handbook 1058.01, Research Compliance Reporting Requirements

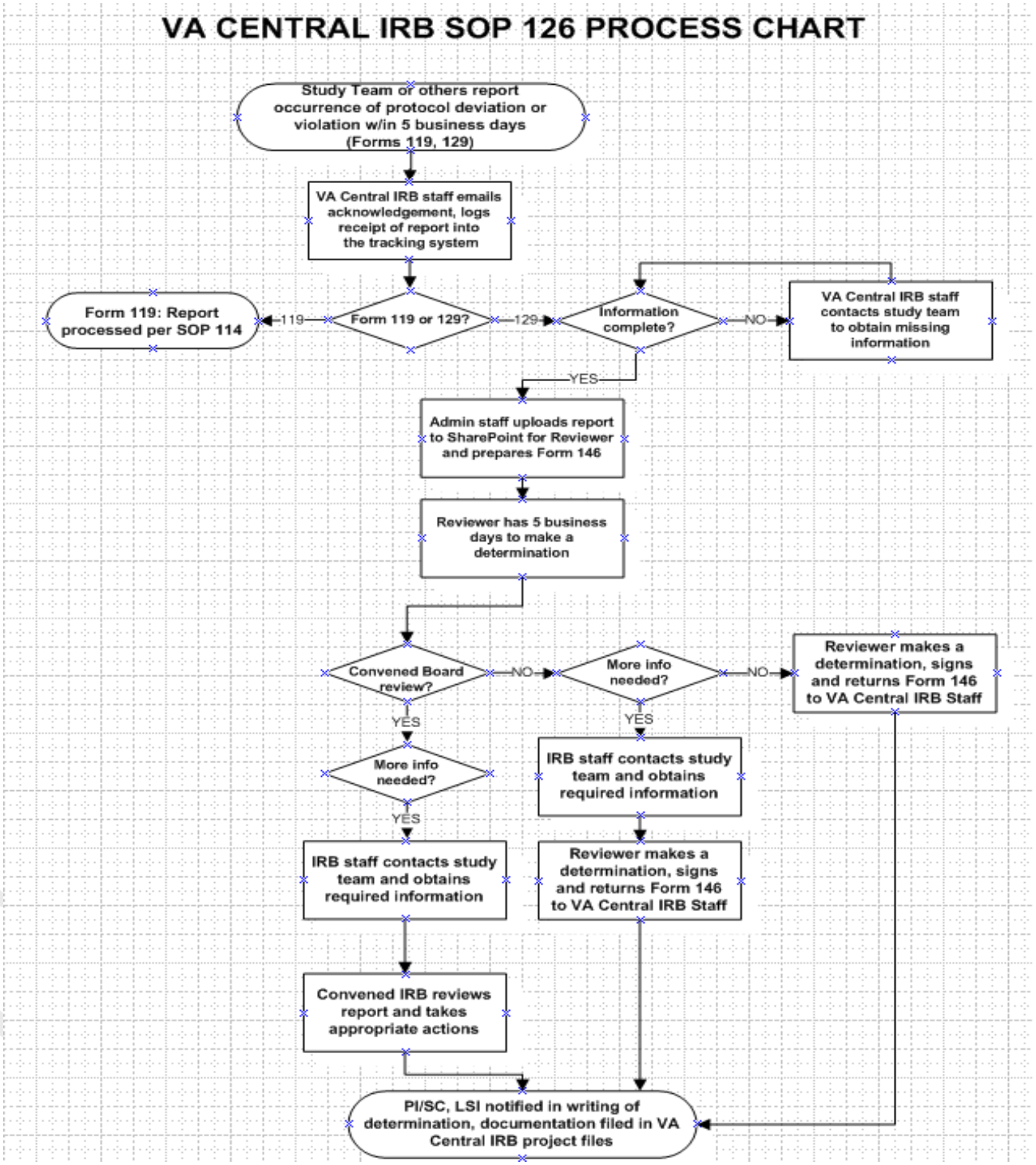
6.4 Office for Human Research Protections Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, dated January 15, 2007

6.5 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

Revision History

Revision:	Description:	Date:
00	New Document	7/21/2014

Attachment 1: VA Central IRB SOP 126 Process Chart



Attachments (continued):

2. **VA Central IRB Form 129, Report of Protocol Deviation or Violation**
   http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx

3. **VA Central IRB Form 132, VA Central IRB Protocol Deviation Tracking Log**
   http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx

4. **VA Central IRB Form 146, Checklist for Review of Protocol Deviations or Violations**
   http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx

Report of Protocol Deviations, Violations, and/or Noncompliance

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form is to be used to report local protocol deviations, violations, or noncompliance reports to the VA Central IRB. These protocol deviations, violations, or noncompliance must be submitted to the VA Central IRB within 5 business days of the reporting individual becoming aware of the occurrence.

Reportable events are those that are likely to substantially adversely affect any of the following:

- ***the rights, safety, or welfare of the research participant,***
- ***the participant's willingness to continue participation, or***
- ***the integrity of the research data, including VA information security requirements.***

DO NOT USE THIS FORM to report any protocol deviation or violation that occurred in order to prevent or eliminate immediate hazards to participants. Instead, use VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Unanticipated Problem Involving Risks to Participants or Others.

Check one:

New Report ☐
or
Follow-up ☐

If follow-up, cite previous VA Central IRB Report #:

For VA Central IRB Use Only

VA Central IRB Report Number:

Date Received:

I. Project and Reporting Individual General Information:

VA Central IRB Project #:	
Title of Project:	
Name of Individual Submitting Report:	**Name of LSI or PI if not individual submitting the report:**
Role of Individual Submitting Report: *(Please check one)* ☐ Principal Investigator/Study Chair ☐ Local Site Investigator ☐ Other (specify): ☐ National Program Manager or Study Coordinator ☐ Local Study Coordinator	
Reporting Individual E-mail: @va.gov	**Telephone Number:**
VA Facility Name: **VA Facility City:**	**Does this deviation involve multiple sites?** ☐ Yes ☐ No **If yes, are other sites also submitting reports?** ☐ Yes ☐ No

II. Description of Protocol Deviation, Violation, or Noncompliance

1. **Indicate which of the following criteria for reportable protocol deviation, violation or noncompliance does this event meet: (check all that apply)**

☐ the rights, safety, or welfare of the research participant,
☐ the participant's willingness to continue participation,
☐ the integrity of the research data, including VA information security requirements,

and/or

☐ compliance with regulatory requirements (VHA Handbooks, Federal regulations, etc.)

2. **Is this being reported as Apparent Serious or Continuing Noncompliance?**
(Note: Refer to VHA Handbook 1058.01)

☐ Yes ☐ No

3. **What is the date the deviation, violation or noncompliance occurred?**

4. **What is the date the reporting individual was made aware of the reported event?**

a. Is this date more than 5 business days after the event occurred? ☐ Yes ☐ No

If yes, provide the reason for the delay in becoming aware of the event:

b. Is the reporting date for this event more than 5 business days after discovery of the event?

☐ Yes ☐ No

If yes, provide the reason for the delay in reporting:

5. **Indicate what the event involves (check all that apply):**

☐ ICF/HIPAA ☐ Inclusion/exclusion criteria ☐ Protocol procedure

☐ Late reporting to the IRB ☐ Missed visit(s)/labs ☐ Study team member

☐ Other, describe *(40 characters maximum)* :

6. **Provide a detailed description of the event**:

a. Include pertinent dates, ***who*** was involved, ***what*** happened, and ***why.***

b. Describe ***how*** the event substantially adversely affected the items checked in Question 1 of this section:

c. Provide the following information for the involved participants. ☐ N/A

Age: Gender:

Participant history:

7. **If the protocol deviation involved the failure to obtain documented informed consent and/or an appropriate signature and/or date on the informed consent or HIPAA authorization, indicate if these have now been obtained and/or what efforts are being made to obtain them:** ☐ N/A

8. **Was the participant withdrawn from the project**? ☐ N/A

☐ Yes, on date:

☐ No. If no, why?

III. Actions Taken

1. **What actions have been taken to correct the deviation, violation, or noncompliance to ensure it does not happen again?**

2. **Are changes being recommended to the project** (e.g., protocol, informed consent form)?

☐ Yes (*If yes, please submit VA Central IRB Form 116, "Request to Amend or Modify an Approved Project", with the modified documents.)*

☐ No

3. **Has the sponsor and/or Principal Investigator/Study Chair been notified of the protocol deviation, violation, or noncompliance?**

☐ Yes, on date:

☐ No -- *If no*, why?

☐ N/A -- If this box is checked, indicate: ☐ PI/SC is making the report, *or*

☐ PI/SC is blinded

4. **If this deviation, violation, or noncompliance involves a breach of information security and/or the HIPAA Privacy Rule, indicate if the following individuals have been notified and when**:

☐ N/A

☐ Local ISO Date Notified:

☐ Local Privacy Officer Date Notified:

a. Were the above notifications made within one hour of discovery of the deviation, violation, or noncompliance?

☐ Yes ☐ No If no, why:

b. Indicate below what, if any, other notifications have been made and when they were made: ☐ N/A

IV. Signature of Reporting Individual

_____ _____
Signature Date

_____
Printed Name

Submission Instructions

The VA Central IRB currently uses a secure SharePoint site for submission of reportable events.

This is a separate SharePoint site from the site used to load study documents and it is monitored throughout the day. **DO NOT** load these reports to the regular study submission folder on SharePoint as this folder may not be monitored on a daily basis.

Since this is also a limited access site, if access is not already authorized and a report needs to be submitted, please contact the PRIDE SharePoint Manager at 202-443-5653 or the VA Central IRB Administrator at 202-443-5649 to obtain access and further instructions. The PRIDE toll free number at 1-877-254-3130 may also be contacted.

For any other questions, please contact the VA Central IRB staff by e-mail at va.central.irb@va.gov or at the above toll-free number.

VA Central IRB Report of Protocol Deviation/Violation Tracking Log

Date Received	Processed By	Report Number	Project Number	Site ID	Nature of Problem	Reviewer Assigned	Date to Reviewer	Date Returned	Referred to IRB for Noncompliance?	Date of IRB Action	Meeting Date to Report
VA Central IRB Form 132											
Updated: June 30, 2014											

Other
Comments

Checklist for Review of Protocol Deviations, Violations and Noncompliance

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form is used to document review of a VA Central IRB Form 129, Report of Protocol Deviations, Violations, and/or Noncompliance by a VA Central IRB Reviewer. The Reviewer must make a determination within 5 business days.. If a determination cannot be made in 5 business days, the VA Central IRB Manager of the study should be notified.

Date Received by VA Central IRB:

Report Number:
(*Check if this is a follow-up report):* ☐

Date by Which a Determination or Interim Report Must be Made:

I. Project Information (*To be completed by VA Central IRB Manager)*

VA Central IRB Study Number	
Title of Project	
Reporting Site (Include city)	
Reviewer	

II. Report Evaluation

The reviewer is required to answer each of the following questions.	**YES**	**NO**
1. **Does the reviewer have a conflict of interest (COI)?** ***(If yes, <u>do not</u> proceed. Return the checklist without further review.)***	☐	☐
2. **Does the deviation or violation substantially involve one or more of the following examples from VHA Handbook 1058.01 of apparent serious or continuing noncompliance:** a) Initiation of research without applicable local or VA Central IRB approval, b) Initiation of research interventions without obtaining informed consent, c) Use of informed consent document not approved by VA Central IRB, d) Lack of required signed HIPAA or Informed Consent document, e) Failure to report one or more SAEs or UAPs, f) Participation of one or more study team members without appropriate credentialing, privileging, or approved Scope of Practice; g) Implementation of substantive changes without IRB approval, h) Continue of research interactions or interventions beyond IRB approval period, i) Failure to implement required changes in ongoing study in time specified by IRB, j) Deficiencies in informed consent or HIPAA authorization procedures for ten or more subjects, or k) Failure to maintain documentation required IRB or protocol for ten or more subjects?	☐	☐

The reviewer is required to answer each of the following questions.	YES	NO
3. **Does the protocol or violation involve other serious or continuing compliance not described above?**	☐	☐
4. **Were actions taken in response to deviation or violation?** *Answer one of the following as applicable:*	☐	☐
If yes, were the actions appropriate?	☐	☐
If no, does immediate action need to be taken to protect the health and welfare of participants or others?	☐	☐
5. **Does this project continue to meet criteria for IRB approval?**	☐	☐

III. Reviewer Recommendations

The reviewer is required to make a determination or recommendation for each of the following three items. (Check all that apply.)

1. **Does the protocol deviation or violation substantially adversely affect one or more of the following?**

   YES ☐ **NO** ☐

   If yes, check one or more of the following boxes. The report will need to be reviewed by the convened IRB.

   ☐ The rights, safety, and welfare of the research participants,

   ☐ The participant's willingness to continue participation, or

   ☐ The integrity of the research data, including VA information security requirements.

2. **Indicate whether Review by the Convened VA Central IRB is required.** ***Note: If apparent serious or continuing noncompliance is involved, review by the convened IRB is required.***

   ☐ Review by the convened VA Central IRB is not required.

   ☐ Review by the convened VA Central IRB is required. Immediate action must be taken to prevent immediate hazards to subjects *(Require immediate review by a VA Central IRB Co-Chair). Indicate in Reviewer Recommendations what immediate actions need to be taken.*

   ☐ Review by the convened VA Central IRB is required, but immediate action is not required to prevent an immediate hazard to subjects.

3. **Reviewer Recommendations**

   Based upon my review of this reported event (*check **one** of the following below*):

   ☐ No further action is required. *(If this is checked, also check one of the boxes below.)*

   ☐ Corrective action taken was adequate.

   ☐ No corrective action is required.

☐ The report represents an unanticipated problem involving risks to participants or others. *(Process under VA Central IRB SOP 114, Reportable Adverse Events and Unanticipated Problems in Research.)*

☐ Suspend IRB approval of the research. Immediate actions must be taken to prevent an immediate hazard to participants. Recommended actions are specified below:

Specify:

☐ Other (e.g., modify the protocol, observe informed consent process, alter continuing review schedule, require additional training of investigators, refer to other organizational entities):

Specify:

☐ Request additional information from study team. *(Specify below what questions you would like to be forwarded to the study team.)*

Comments and questions to be forwarded to study team: *(Phrase in the manner you would like for these to be sent to the study team.)*

Comments or requests for additional information from VA Central IRB Staff or other VA Central IRB members: *(If comments are for other than VA Central IRB staff, please specify, i.e., for ISO, Regulatory, Legal, Ethics, Privacy, or Co-Chairs.)*

_____ _____

Printed Name of Individual Submitting Report **Date Submitted**