

Checklist for Review of Protocol Deviations, Violations and Noncompliance



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

<i>The reviewer is required to answer each of the following questions.</i>	YES	NO
1. Does the reviewer have a conflict of interest (COI)? <i>(If yes, do not proceed. Return the checklist without further review.)</i>	<input type="checkbox"/>	<input type="checkbox"/>
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?	<input type="checkbox"/>	<input type="checkbox"/>

<i>The reviewer is required to answer each of the following questions.</i>	YES	NO
3. Does the protocol or violation involve other serious or continuing compliance not described above?	<input type="checkbox"/>	<input type="checkbox"/>
4. Were actions taken in response to deviation or violation? <i>Answer one of the following as applicable:</i> 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?	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5. Does this project continue to meet criteria for IRB approval?	<input type="checkbox"/>	<input type="checkbox"/>

III. Reviewer Recommendations

The reviewer is required to make a determination or recommendation for each of the following three items. (At least one box in each item must be checked.)

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