



# SAEs, UAPs, and Deviations: The What, When, Where, and How of Reporting Events to the VA Central IRB

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# Agenda

- Requirements for submitting Unanticipated Serious Adverse Events (U-SAEs), Unanticipated Adverse Device Effects (U-ADEs), Unanticipated Problems (UAPs), and Deviations to the VA Central IRB
- Review of the U-SAE/U-ADE/UAP and Deviation forms
- Submission instructions
- IRB review
- Serious and/or continuing noncompliance
- Q & A

# Events

During the course of a study, adverse events, deviations, and problems occur

Most events are reported in summary format at time of continuing review

A subset of these events must be submitted to the IRB within 5 business days

## Definitions – The key to reporting

**Adverse Event (AE)** – any untoward physical or psychological occurrence in a human subject participating in research. An AE can be an unfavorable and 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 a causal relationship with the research.

## Definitions - The key to reporting

**Serious Adverse Event (SAE)** - 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, 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.

## Definitions - The key to reporting

**Unanticipated SAE (U-SAE)** – An SAE that is new or greater than previously known in terms of nature, severity, or frequency given the procedures described in the protocol-related documents and the characteristics of the study population. Such materials may include but are not limited to: the informed consent form, clinical investigators' brochure, and product labeling. A U-SAE **must be promptly reported to the VA Central IRB.**

# Definitions - The key to reporting

**Serious Adverse Device Effect (ADE)**- any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device.

**Unanticipated ADE (U-ADE)**: not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a **device** that relates to the rights, safety, or welfare of participants.

# Investigator Responsibilities

Report all internal/local U-SAEs or U-ADEs, regardless of relatedness to the research, within 5 business days of becoming aware of the event

Use VA Central IRB form 119, "Report of Unanticipated Serious Adverse Event (U-SAE), Unanticipated Adverse Device Effect (U-ADE), and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others"

# Definitions – The key to reporting

**Serious Problem** - 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.

## Definitions – The key to reporting

**Unanticipated problem (UAP)** – a serious problem that is 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.

# Investigator Responsibilities

Report all internal/local UAPs, regardless of relatedness to the research, within 5 business days of becoming aware of the problem.

Use VA Central IRB Form 119, "Report of Unanticipated Serious Adverse Event (U-SAE), Unanticipated Adverse Device Effect (U-ADE), and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others"

**Report of Unanticipated Serious Adverse Event (U-SAE), Unanticipated Adverse Device Effect (U-ADE), and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others**



*This form is used to report local U-SAEs, U-ADE and UAPs involving risks to participants or others. Reports must be submitted to the VA Central IRB within 5 business days after the reporting individual becomes aware of the occurrence.*

+ Check one:		<u>For VA Central IRB Use Only</u>	
<b>New Report</b> <input type="checkbox"/>		VA Central IRB Report Number: <input type="text"/>	
or		Date Received: <input type="text"/>	
<b>Follow-up</b> <input type="checkbox"/>			
<i>If follow-up, cite previous          VA Central IRB Report #:</i> <input type="text"/>			

## I. Project and Reporting Individual General Information:

VA Central IRB Project #: [REDACTED]	
Title of Project: [REDACTED]	
Name of Individual Submitting Report: [REDACTED]	Name of LSI or PI if not individual submitting the report: [REDACTED]
Role of Individual Submitting Report: <i>(Please check one)</i> <input type="checkbox"/> Principal Investigator/Study Chair <input type="checkbox"/> Local Site Investigator <input type="checkbox"/> Other (specify): [REDACTED] <input type="checkbox"/> National Program Manager or Study Coordinator <input type="checkbox"/> Local Study Coordinator	
Reporting Individual E-mail: [REDACTED]@va.gov	Telephone: [REDACTED]
VA Facility Name: [REDACTED]	VA Facility City: [REDACTED]

## II. Type of Report and Location

1. Check all that apply to describe the reported event involving risks to participant or others:

- Unanticipated (Unexpected) Serious Adverse Event (U-SAE)
- Unanticipated Problem Involving Risks to Participants or Others (UAP)
- Unanticipated Adverse Device Effect (U-ADE)

2. Which of the following best describes the type of event being reported?

- Death
- A life-threatening experience
- Hospitalization (for a research participant not already hospitalized)
- Prolongation of Hospitalization (for a research participant already hospitalized)
- Persistent or significant disability or incapacity
- Need for medical, surgical, behavioral, social, or other intervention (to prevent outcomes such as the examples above)
- Privacy and/or security incident
- Other (specify):

**3. Where did the reported event occur?**

- Reporting individual's facility (local site)
- Other VA facility (Specify):
- Non-VA facility (Specify):
- Other (Specify):

**4. Has a Data Safety and Monitoring Board (DSMB) or Data Monitoring Committee (DMC) reviewed the reported event? (Choose one):**

- N/A; Project does not have a DSMB or DMC.
- No, a review has not yet been conducted by the DSMB or DMC.
- Yes, a review has been conducted by the DSMB or DMC.
  - Please check this box if the DSMB or DMC report is attached.*

**5. Check this box if the report pertains to a CSP study and also attach a copy of the CSP Adverse Event Form, in addition to providing the requested description:**

### III. Description

1. Participant Information  N/A

a. Participant ID Number:  Age:  Sex:

b. Date the participant was enrolled:

2. What is the date the reported event occurred?

3. What is the date the site became aware of the reported event?

*Please explain if the reporting date is more than five business days after the site became aware:*

4. Fully describe the event to include initial event, management, and outcome:

5. Does the project evaluate a drug or device?  Yes  No

If yes, Drug/Device Name(s):

Start Date  Stop Date  or  Continuing

6. **Is the study blinded?**  Yes  No

If **yes**, who is blinded? (select one):  Participants  PI  LSI  
 All study team members  Other

If **no**, or if the subject was unblinded due to the event, to what arm of the study was the participant randomized?   N/A

7. **What concomitant medications was the participant taking at the times indicated below?**

If any of these times are not applicable, please indicate N/A:

(1) Prior to study enrollment?   N/A

(2) At the time of the event?   N/A

Were concomitant medications changed due to the event?  Yes  No  N/A

If yes, list changes

8. **Provide diagnostic test results relevant to the event:**   N/A

9. **Were any changes (e.g., protocol change) initiated without IRB approval to eliminate any apparent immediate hazard to a participant?**

Yes *If yes, describe the change and indicate in Section IV if an amendment to the approved study is also being submitted: [REDACTED]*

No

10. **Is the reported event:** (check one):  Resolved, *or*  Ongoing?

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

Yes, on: [REDACTED] (Date)  No

12. **Assessment of the relationship of reported event to research participation**  
*(the IRB will make the final determination):*

Not Related  Possibly Related  Probably Related  Related

*Note: "Related" is defined as an event or problem that may reasonably be regarded as caused by, or probably caused by, the research. "Possibly related" indicates that it is unclear.*

#### IV. Actions Taken

1. Will changes in the project be made (e.g., protocol, informed consent form)?

- Yes *If yes, please attach VA Central IRB Form 116, Request to Amend an Approved Project, with the modified documents.*
- No

2. Will changes to the site's procedures be made?  N/A

- Yes If yes, what will change?
- No If no, why not?

3. Has the sponsor been notified of the reported event?  N/A

- Yes
- No If no, why not?

4. If the individual making this report is not the Principal Investigator/Study Chair, has the Principal Investigator/Study Chair received a copy of this report?

- N/A (If this box is checked,  PI/SC is making report *or*  PI/SC is blinded.)
- Yes, on date
- No

*Note: The PI/SC must receive a copy of this report unless it is not applicable or contraindicated by study design as described in the IRB-approved protocol (e.g., PI/SC is blinded).*

# IRB Responsibilities

Review all reported U-SAEs, U-ADEs, and UAPs.  
May ask for additional information within 5  
business days of receipt.

The IRB will determine and document:

Serious?

Anticipated?

Related?

Action Warranted?

# Definitions – The key to reporting

- **Deviations** – not defined in 38 CFR 16, 1200.05 or 1058.01. Referenced in 1200.05:
  - IRB records: reports of deviations
  - Investigator responsibilities: reporting deviations from the protocol...to IRB in a time frame specified in local SOPs
  - IRB study file: documentation of protocol deviations

## Definitions – The key to reporting

**Protocol Deviation** - For the purposes of the VA Central IRB, a protocol deviation is any change, divergence, or departure from the design or procedures of a research project as was approved by the VA Central IRB.

# Report to the VA Central IRB

- Any protocol deviation initiated to prevent or eliminate immediate hazards to participants (reported as a SAE/UAP);
- Any protocol deviation 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.

# Investigator Responsibilities

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

Use form 129, "Report of Protocol Deviations, Violations, and/or Noncompliance"

# Report of Protocol Deviations, Violations, and/or Noncompliance



*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:	
<b>New Report</b> <input type="checkbox"/>	<b>For VA Central IRB Use Only</b>
or	
<b>Follow-up</b> <input type="checkbox"/>	
<i>If follow-up, cite previous</i>	VA Central IRB Report Number: [ ]
VA Central IRB Report #: [ ]	Date Received: [ ]

## I. Project and Reporting Individual General Information:

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

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### 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

# IRB Responsibilities

- The VA Central IRB is responsible for reviewing reported protocol deviations and determining what, if any, action must be taken to safeguard the health and welfare of human research participants and determining if the deviation is a UAP or represents serious or continuing noncompliance
- Usually processed within 5 days but may take 30-45 days with additional requests for information

# Current submission instructions for Form 119 & 129

- 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
- This will change with the launch of SharePoint 2010. An e-mail message will be sent to all Site Liaison when the change occurs

# Definitions – The key to reporting

**Serious Noncompliance:** failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

- 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
- Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

If the noncompliance is not serious but is “persistent” then it is **continuing** noncompliance.

# Apparent Serious or Continuing Noncompliance

- All noncompliance that **appears** to meet the definition of serious or continuing must be reported. Reference VHA Handbook 1058.01, paragraphs 7 (f and g) for examples
- Report to the IRB within 5 business days
- The determination of serious or continuing noncompliance lies with the IRB

# Summary: Prompt Reporting to VA Central IRB

- All AEs and ADEs that are serious and unexpected
- All problems that are serious and unexpected
- All deviations that substantively adversely effect subjects or the data
- Any “Apparent” noncompliance that is serious or continuing.

Reminder: all other events are reported at time of continuing review.

# Reporting determinations by the VA Central IRB

- If the IRB determines that an event does not require additional reporting the submitting party(ies) and the VA Central IRB Site Liaison are notified via email that no further action is necessary and the report is closed.
- For events that are serious, unanticipated, and related, **or** for events that are determined to be serious or continuing noncompliance, the VA Central IRB submits reports to ORO and the applicable Medical Center Director (IO).

## Site and Study Team response

- The Medical Center Director must report the determination to the regional ORO office and other federal oversight agencies within 5 business days.
- Study teams must respond to additional questions or corrective actions by IRB established deadlines.

# Changes to research and/or corrective actions

- In addition to making these determinations, the board is also tasked with assessing whether or not changes to the research, up to and including suspension or termination of the study are warranted
- Possible changes include:
  - Retraining/staff changes
  - Protocol amendments/ICF changes
  - Audits/CAPAs
  - Observation of consenting process

# Contact Information

VA Central Administrator

Annette Anderson

202-443-5649

annette.anderson3@va.gov

SharePoint Manager

Lindsey Martin

202-443-5653

lindsey.martin2@va.gov

For specific projects: Assigned IRB Manager (see next slide)

All other questions: [vacentralirb@va.gov](mailto:vacentralirb@va.gov)

# Contact Information

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202-443-5656  
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Nikia Morris  
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[nikia.morris@va.gov](mailto:nikia.morris@va.gov)

# References

- VHA Handbook 1058.01, "Research Compliance Reporting Requirements"
- VHA Handbook 1200.05, "Requirements for the Protection of Human Subjects in Research"
- VA Central IRB SOPs and Forms:  
<http://www.research.va.gov/vacentralirb/sop/default.cfm>



Questions?

# Report of Protocol Deviations, Violations, and/or Noncompliance



*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:

<b>VA Central IRB Project #:</b>	
<b>Title of Project:</b>	
<b>Name of Individual Submitting Report:</b>	<b>Name of LSI or PI if not individual submitting the report:</b>
<b>Role of Individual Submitting Report:</b> <i>(Please check one)</i>	
<input type="checkbox"/> Principal Investigator/Study Chair <input type="checkbox"/> Local Site Investigator <input type="checkbox"/> Other (specify):	
<input type="checkbox"/> National Program Manager or Study Coordinator <input type="checkbox"/> Local Study Coordinator	
<b>Reporting Individual E-mail:</b> @va.gov	<b>Telephone Number:</b>
<b>VA Facility Name:</b>	<b>Does this deviation involve multiple sites?</b>
	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>VA Facility City:</b>	<b>If yes, are other sites also submitting reports?</b>
	<input type="checkbox"/> Yes <input type="checkbox"/> 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](mailto:va.central.irb@va.gov) or at the above toll-free number.

**Report of Unanticipated Serious Adverse Event (U-SAE), Unanticipated Adverse Device Effect (U-ADE), and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others**



## What and When to Report on this Form

All Unanticipated Serious Adverse Events (U-SAEs), Unanticipated Adverse Device Effects (U-ADE), and all Unanticipated Serious Problems (UAPs) occurring on a study overseen by the VA Central IRB must be reported within **five** business days and in accordance with your IRB approved protocol.

### Definitions

I. An Adverse Event (AE) is **Serious** when the event occurs in research and results in:

- Death
- A life-threatening experience
- Hospitalization (for a research participant not already hospitalized)
- Prolongation of Hospitalization (for a research participant already hospitalized)
- Persistent or significant disability or incapacity
- Congenital anomaly
- Birth defect, or
- Need for medical, surgical, behavioral, social, or other intervention to prevent outcomes such as the above

These events are reported to the VA Central IRB within five business days when they are **Unanticipated** or **Unexpected**, defined as new or greater than previously known in terms of nature, severity, or frequency given the procedures *as described in protocol-related documents* and the characteristics of the study population. These documents must be provided to the VA Central IRB.

U-SAEs are reported to the VA Central IRB regardless of relationship to the research.

II. Serious Adverse Device Effects (ADEs) are any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device.

Serious ADEs are reported to the VA Central IRB when they are **Unanticipated** or **Unexpected**, defined as not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.

U-ADEs are reported to the VA Central IRB regardless of relationship to the research.

## Delete Instructions Prior to Submission

III. Problems Involving Risks to Participants or others are **Serious** when the problem:

- Involves substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research participants, research staff, or others; or
- Substantively compromises the effectiveness of a facility's human research protection or human research oversight programs.

Serious Problems are reported to the VA Central IRB in 5 business days when they are **Unanticipated**, defined as unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved protocol and informed consent document; and the characteristics of the participant population being studied.

UAPs are reported to the VA Central IRB regardless of relationship to the research.

Refer to VHA Handbooks 1058.01 and 1200.05, and VA Central IRB SOP 114, "Reportable Adverse Events and Unanticipated Problems in Research" for more information on event reporting.

## Submission Procedures

Submit this form to the VA Central IRB SharePoint site for submission of U-SAEs, U-ADEs, and UAPs. 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.

If you need access to submit a report or have any questions, please contact the VA Central IRB SharePoint Administrator or the VA Central IRB Study Manager assigned to your project at 1-877-254-3130 or by e-mail at [va.central.irb@va.gov](mailto:va.central.irb@va.gov).

## Delete Instructions Prior to Submission

**Report of Unanticipated Serious Adverse Event (U-SAE), Unanticipated Adverse Device Effect (U-ADE), and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others**



*This form is used to report local U-SAEs, U-ADE and UAPs involving risks to participants or others. Reports must be submitted to the VA Central IRB within **5 business days** after the reporting individual becomes aware of the occurrence.*

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:**

<b>VA Central IRB Project #:</b>	
<b>Title of Project:</b>	
<b>Name of Individual Submitting Report:</b>	<b>Name of LSI or PI if not individual submitting the report:</b>
<b>Role of Individual Submitting Report:</b> <i>(Please check one)</i> <input type="checkbox"/> Principal Investigator/Study Chair <input type="checkbox"/> Local Site Investigator <input type="checkbox"/> Other (specify): <input type="checkbox"/> National Program Manager or Study Coordinator <input type="checkbox"/> Local Study Coordinator	
<b>Reporting Individual E-mail:</b> @va.gov	<b>Telephone:</b>
<b>VA Facility Name:</b>	<b>VA Facility City:</b>

## II. Type of Report and Location

**1. Check all that apply to describe the reported event involving risks to participant or others:**

- Unanticipated (Unexpected) Serious Adverse Event (U-SAE)
- Unanticipated Problem Involving Risks to Participants or Others (UAP)
- Unanticipated Adverse Device Effect (U-ADE)

**2. Which of the following best describes the type of event being reported?**

- Death
- A life-threatening experience
- Hospitalization (for a research participant not already hospitalized)
- Prolongation of Hospitalization (for a research participant already hospitalized)
- Persistent or significant disability or incapacity
- Need for medical, surgical, behavioral, social, or other intervention (to prevent outcomes such as the examples above)
- Privacy and/or security incident
- Other (specify):

**3. Where did the reported event occur?**

- Reporting individual's facility (local site)
- Other VA facility (Specify):
- Non-VA facility (Specify):
- Other (Specify):

**4. Has a Data Safety and Monitoring Board (DSMB) or Data Monitoring Committee (DMC) reviewed the reported event? (Choose one):**

- N/A; Project does not have a DSMB or DMC.
- No, a review has not yet been conducted by the DSMB or DMC.
- Yes, a review has been conducted by the DSMB or DMC.
  - Please check this box if the DSMB or DMC report is attached.*

**5. Check this box if the report pertains to a CSP study and also attach a copy of the CSP Adverse Event Form, in addition to providing the requested description:**

### III. Description

1. **Participant Information**  N/A

a. Participant ID Number: Age: Sex:

b. Date the participant was enrolled:

2. **What is the date the reported event occurred?**

3. **What is the date the site became aware of the reported event?**

*Please explain if the reporting date is more than five business days after the site became aware:*

4. **Fully describe the event to include initial event, management, and outcome:**

5. **Does the project evaluate a drug or device?**  Yes  No

If **yes**, Drug/Device Name(s):

Start Date Stop Date or  Continuing

6. **Is the study blinded?**  Yes  No

If **yes**, who is blinded? (select one):  Participants  PI  LSI

All study team members  Other

If **no**, or if the subject was unblinded due to the event, to what arm of the study was the participant randomized?  N/A

7. **What concomitant medications was the participant taking at the times indicated below?**

If any of these times are not applicable, please indicate N/A:

(1) Prior to study enrollment?  N/A

(2) At the time of the event?  N/A

Were concomitant medications changed due to the event?  Yes  No  N/A

If yes, list changes

8. **Provide diagnostic test results relevant to the event:**  N/A

9. **Were any changes (e.g., protocol change) initiated without IRB approval to eliminate any apparent immediate hazard to a participant?**

Yes *If yes, describe the change and indicate in Section IV if an amendment to the approved study is also being submitted:*

No

10. **Is the reported event:** (check one):  Resolved, **or**  Ongoing?

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

Yes, on: (Date)  No

12. **Assessment of the relationship of reported event to research participation (the IRB will make the final determination):**

Not Related  Possibly Related  Probably Related  Related

**Note:** *“Related” is defined as an event or problem that may reasonably be regarded as caused by, or probably caused by, the research. “Possibly related” indicates that it is unclear.*

#### IV. Actions Taken

1. **Will changes in the project be made (e.g., protocol, informed consent form)?**

Yes *If yes, please attach VA Central IRB Form 116, Request to Amend an Approved Project, with the modified documents.*

No

2. **Will changes to the site’s procedures be made?**  N/A

Yes If yes, what will change?

No If no, why not?

3. **Has the sponsor been notified of the reported event?**  N/A

Yes

No If no, why not?

4. **If the individual making this report is not the Principal Investigator/Study Chair, has the Principal Investigator/Study Chair received a copy of this report?**

N/A (If this box is checked,  PI/SC is making report **or**  PI/SC is blinded.)

Yes, on date

No

***Note: The PI/SC must receive a copy of this report unless it is not applicable or contraindicated by study design as described in the IRB-approved protocol (e.g., PI/SC is blinded).***

## V. Attestation of Reporting Individual

**I certify that this report is accurate and complete to the best of my knowledge.**

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date