

Table of Reporting Requirements

Principal Investigators, Local Site Investigators, and

Local VA Facility Research Compliance Officers



Investigator Reporting Requirements

INSTRUCTIONS:

- Local Site Investigators (LSIs) should only submit Reportable Events under their project in IRBNet if the event occurred locally at their site. If the event occurred at another facility participating in the multi-site study, the LSI should not submit a Reportable Event.
- The Principal Investigator (PI) should not duplicate submission of Reportable Events if the Reportable Events was previously reported to the VA Central IRB by the LSI and no new additional information is being conveyed.
- Please refer to the following important definitions as they pertain to reporting requirements of certain Reportable Event types:
 - **“Unanticipated”** and **“unexpected”** are synonymous terms that refer to an incident, experience, or outcome that is new, or is greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.
 - **“Related”** a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome.
 - **“Possibly related”** implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest there might be a causal relationship between study procedures and the incident, experience, or outcome.

Type of Report	Description	VA CIRB Form	Reporting
Research Death that is <u>both unanticipated and related or possibly related</u>	<p>A report by oral notification to the VA Central IRB immediately (e.g., within one hour) upon becoming aware of any local research death of a human subject that is believed to be both unexpected and related or possibly related to participation in a VA non-exempt human subjects research study. VA personnel must also ensure that the VA Central IRB is notified in writing within one business day of becoming aware of such a death.</p> <p>NOTE: Refer to definitions of “unexpected”, “related” and “possibly related” in the instructions.</p>	Form 124 Reportable Events	<p>Research deaths that are <u>both unanticipated and related</u> to the research must be immediately reported using our toll free number 877-254-3130.</p> <p>Additionally, Form 124 must be submitted in IRBNet by the Investigator within 1 business day of becoming aware of the death.</p>

<p>Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) that is <u>both</u> unanticipated <u>and</u> related or possibly related</p>	<p>An UPIRTSO is an incident, experience or outcome that is:</p> <ul style="list-style-type: none"> • Unexpected • Related or possibly related to participation in the research; and • Indicative of the research possibly placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized (e.g., in the protocol or informed consent documents). <p>Apparent UPIRTSOs need to be reported to the VA Central IRB promptly (within 5 business days). An unexpected Serious Adverse Event (SAE) that is related or possibly related to participation in human subjects research constitutes a UPIRTSO. SAE in human subjects research is an untoward occurrence, whether or not considered related to a subject's participation in research, that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or that requires medical, surgical, behavioral, social or other intervention to prevent such an outcome. Anticipated Adverse Events (serious or not) do not need to be promptly reported to the IRB. Anticipated means they are included in the protocol and/or informed consent documents as anticipated risks of the research and have not exceeded anticipated probability or magnitude of harm.</p> <p>NOTE: Refer to definitions of “unexpected”, “related” and “possibly related” in the instructions.</p>	<p>Form 124 Reportable Events</p>	<p>Apparent UPIRTSO that are <u>both</u> unanticipated <u>and</u> related or possibly related to the research must be reported.</p> <p>Form 124 must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of the occurrence.</p>
<p>Unanticipated Adverse Device Effect (UADE)</p>	<p>UADE means any serious adverse effect on health or safety, or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was 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 subjects.</p>	<p>Form 124 Reportable Events</p>	<p>Form 124 must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of the occurrence.</p>

Noncompliance (Meets criteria for reporting within 5 business days under VHA Directive 1058.01)	In accordance with VHA Directive 1058.01, apparent serious and/or continuing noncompliance must be reported if the noncompliance was initiated to prevent or eliminate immediate hazards to participants or it is likely to substantially adversely affect any of the following: <ul style="list-style-type: none"> the rights, safety, or welfare of the research subjects or others the participant's willingness to continue participation; or the integrity of the research data VA's reputation A medical facility's Human Research Protection Program 	Form 124 Reportable Events	Form 124 must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of the occurrence.
Protocol Deviation (Does not meet criteria for reporting within a specified timeframe under VHA Directive 1058.01)	Deviation from the VA Central IRB-approved protocol by the Investigator or study team is considered non-serious noncompliance. The terms protocol deviation and protocol violation are synonymous. Deviations arising in studies that require Continuing Review approval need to be logged and reported in summary to the VA Central IRB at the time of Continuing Review. Non-serious deviations arising in minimal risk studies that do not require Continuing Review do not need to be reported to the VA Central IRB.	Form 115d Protocol Deviation Log	Form 115d must be submitted by the Investigator at the time of Continuing Review only.
Adverse Event (Does not meet criteria for reporting within a specified timeframe under VHA Directive 1058.01)	An Adverse Event (AE) is any untoward physical or psychological occurrence in a human subject participating in research, whether or not considered related to the subject's participation in research. AEs arising in studies that require Continuing Review approval and do not have a Data Safety and Monitoring committee review need to be logged and reported in summary to the VA Central IRB at the time of Continuing Review. AEs arising in minimal risk studies that do not require Continuing Review do not need to be reported to the VA Central IRB.	Form 115e Adverse Event Log	Form 115e must be submitted by the Investigator at the time of Continuing Review only.

Complaint	<p>Complaints from a site or participant that indicate a research subject's rights, safety or welfare may have been or are at risk of being substantially adversely affected must be reported within 5 business days after becoming aware of the complaint.</p> <p>NOTE: Complaints that do not substantially adversely affect participants should be logged and reported in summary to the VA Central IRB at the time of Continuing Review.</p>	Form 124 Reportable Events	Form 124 must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of a complaint that substantially and adversely affects participants rights or welfare.
Incarceration of a Participant	If prisoners are not approved to be included in the research and a participant becomes incarcerated, it must be reported to the VA Central IRB.	Form 124 Reportable Events	Form 124 must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of the incarceration.
New Information that Indicates a Change in Risk (From other sites, or information from the Sponsor, or from published literature)	New information has been received by the Investigator (as distinct from a UPIRTSO occurring in the local study) that indicates an increased risk in the frequency or magnitude of a previously known risk or uncovers a new risk or safety issue (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, investigator finding, etc.).	Form 124 Reportable Events	Form 124 must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of the new information.
Termination or Suspension of Research	A termination or suspension of research activities of a VA Central IRB approved project by a VA research oversight committee, ACOS for Research, other VA Facility official, or by an external entity due to the study not being conducted in accordance with applicable regulations, policies, agreements, or IRB requirements or related to concerns about the safety, rights, or welfare of human research subjects, research staff, or others must be reported to the VA Central IRB.	Form 124 Reportable Events	Form 124 must be submitted in IRBNet by the Investigator within 5 business day after the termination or suspension occurs.
Violation or Breach of Confidentiality, Privacy, or Information Security (Meets criteria for reporting within 5 business days under VHA Directive 1058.01)	<p>Incidents involving a violation or breach of Information Security and/or the HIPAA Privacy Rule must be reported. This includes but is not limited to:</p> <ul style="list-style-type: none"> Protected Health Information (PHI) disclosed in an unauthorized manner and/or to unauthorized personnel Lost or missing documents containing PHI Mix-up of documents containing PHI Any other incident that has the potential for an unauthorized disclosure of PHI 	Form 124 Reportable Events	Form 124 must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of the occurrence.

<p>Notification from an RCO of an Audit with Findings of Apparent Serious/Continuing Noncompliance or UPIRTSO</p> <p>(Meets criteria for reporting within 5 business days under VHA Directive 1058.01)</p>	<p>The responsible Investigator will be informed by an RCO when a completed audit has findings of Apparent Serious/Continuing Noncompliance or UPIRTSO. The responsible Investigator must submit to the VA Central IRB an IRBNet Reportable Events Package within 5 business days of becoming aware of the findings according to the reporting timeframes required by VHA Directive 1058.01.</p> <p>NOTE: The VA Central IRB convened board will review the findings in the package submitted by the responsible Investigator and make a determination. The Board's official determination and documentation (e.g., letters) will be published in the package submitted by the Investigator. The Investigator should share with the RCO the determination of the board.</p> <p><i>See RCO Reporting in the next table for additional guidance.</i></p>	<p>Form 124 Reportable Events</p> <p>and</p> <p>RCO Audit Report</p>	<p>Form 124 and the corresponding audit report must be submitted in IRBNet by the Investigator within 5 business days of becoming aware of the findings of Apparent Serious/Continuing Noncompliance or UPIRTSO.</p>
<p>Notification from an RCO of an Audit with No Findings <u>or</u> Findings not required to be reported within a specified timeframe under VHA Directive 1058.01</p>	<p>The responsible Investigator will be informed by an RCO when a completed audit has no findings or findings not required to be reported within a specified timeframe under VHA Directive 1058.01. The responsible Investigator will submit the completed audit report at time of Continuing Review, Annual Status Report or Project Closure.</p> <p>However, please note audit reports that were submitted directly by an RCO to the VA Central IRB should not be resubmitted again by the Investigator at the time of Continuing Review, Annual Status Report or Project Closure if it was already reviewed by the VA Central IRB.</p> <p>Audit reports completed in minimal risk LSI studies that do not require Continuing Review or Annual Status Report can be submitted directly by the RCO.</p> <p><i>See RCO Reporting in the next table for additional guidance.</i></p>	<p>Use the following Form as applicable:</p> <p>Continuing Review:</p> <ul style="list-style-type: none"> • Form 115a PI • Form 115b LSI <p>Annual Status Report:</p> <ul style="list-style-type: none"> • Form 130 <p>Project Closure:</p> <ul style="list-style-type: none"> • Form 117a PI • Form 117b LSI 	<p>Applicable VA Central IRB Form should be submitted at the time of Continuing Review, Annual Status Report or Project Closure.</p>

Research Compliance Officer (RCO) Reporting

INSTRUCTIONS:

- RCO Audit Reports should be submitted to the VA Central IRB as instructed in the below table. Additional instructions for the responsible Investigator are in the above table.
- Reports emailed directly to an individual at the VA Central IRB **will not be accepted** and RCOs will be instructed to submit in one of the pathways noted below.
- The VA Central IRB will not review an RCO Audit Tool. A report or summary should be submitted that clearly states the findings being reported.

Type of Report	Description	Reporting	Follow Up Actions
Audit Report with Findings of Apparent Serious/Continuing Noncompliance or UPIRTSO	<p>Per VHA Directive 1058.01, apparent serious or continuing noncompliance or apparent UPIRTSOs identified by an RCO through the course of conducting study audits or by other means must be reported to the VA Central IRB within 5 business days of becoming aware of such apparent noncompliance or apparent UPIRTSO.</p> <p>The RCO must verify that the report has been submitted by the responsible Investigator and received by the VA Central IRB within the timeframes required by VHA Directive 1058.01 or local policies.</p>	<p>RCO provides the responsible Investigator with the audit report and the Investigator will in turn submit the report to the VA Central IRB as part of a Reportable Events Package in IRBNet using Form 124 Reportable Events.</p> <p>Alternatively, RCO may submit findings by email to the Investigator and the VA Central IRB using vacentralirb@va.gov. In the email, the RCO will clearly indicate that there is a finding of Apparent Serious/Continuing Noncompliance or UPIRTSO and inform the Investigator of the prompt reporting timeframe to submit the findings as a Reportable Event Package in IRBNet with Form 124 Reportable Events.</p> <p>NOTE: The VA Central IRB will not review or make a determination on an audit report with findings of Apparent Serious/Continuing Noncompliance or UPIRTSO submitted in the IRBNet RCO Audit Workspace.</p>	<p>The VA Central IRB convened board will review the audit findings in the Reportable Events package submitted by the responsible Investigator and make a determination. The Board's official determination and documentation (e.g., letters) will be published in the package submitted by the Investigator.</p>

Audit Report with No Findings or Findings not required to be reported within a specified timeframe under VHA Directive 1058.01	<p>VA Central IRB committee members must be notified of RCO audit reports that contain no findings or findings that are not required to be reported within a specified timeframe under VHA Directive 1058.01.</p> <p>NOTE: Audit reports completed for minimal risk LSI studies that do not require Continuing Review or Annual Status Report can be submitted directly by the RCO.</p>	<p>Reporting can be done in one of the following two ways:</p> <ol style="list-style-type: none"> (1) RCO will provide the responsible Investigator with the audit report who will in turn submit the RCO Audit Report at Continuing Review, Annual Status Report or Project Closure. or (2) RCO can submit the audit report directly to the VA Central IRB through the IRBNet RCO Audit Workspace. 	<p>When the Investigator submits an audit report at Continuing Review, Annual Status Report or Project Closure the VA Central IRB will review the report submitted within that package.</p> <p>If the RCO submits a report directly in the IRBNet RCO Audit Workspace, the VA Central IRB will record the Board's acknowledgement of the report within that record and the Audit Report will be listed on a VA Central IRB convened board agenda for notification to committee members.</p>
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If you are unsure whether a Reportable Event requires submission or need guidance on how to submit, please contact the responsible VA Central IRB Manager for the project or send a request to the VA Central IRB mailbox at vacentralirb@va.gov. Additional instructions can be found in the VA Central IRB IRBNet Forms and Templates library (VA Central IRB Administration, Washington, DC – Documents for Researchers).

References:

- [ORO Publications and Guidance - Office of Research Oversight \(va.gov\)](#)
- [VHA Directive 1058.01 Research Compliance Reporting Requirements](#)
- [Guidance for Research Compliance Officers \(RCOs\) and Research Review Committees \(RRCs\) on Reporting and Reviewing All Audit Results](#)