Table of Reporting Requirements to the VA Central IRB for Principal Investigators/Study Chairs, Local Site Investigators, and Local VA Facility Research Compliance Officers

VA Central IRB
VA Institutional Review Board for Multisite Studies

Type of Report	Description	Form	Time Frame
Local* Research Deaths that are both unanticipated and related *reporting individual's facility (local site)	"Unanticipated" and "unexpected" are synonymous terms that refer to an event or problem in human research 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. "Related deaths" are deaths that may reasonably be regarded as caused by, or probably caused by, the research.	VA Central IRB Form 119: Report of Serious Adverse Event (SAE) and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others *Please note: There is also an oral reporting requirement.*	Local research deaths that are **both** unanticipated **and** related to the research must be immediately reported orally using our toll free number 877-354-3130. Written notification must follow within 5 business days of becoming aware of the death.
Local* Unanticipated (Unexpected) Serious Adverse Events that are both unanticipated and related *reporting individual's facility (local site)	"Unanticipated" and "unexpected" are synonymous terms that refer to an event or problem in human research 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. "Serious adverse events" (SAEs) are adverse events in human research that result 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 or Birth defect • The need for medical, surgical, behavioral, social, or other intervention to prevent outcomes such as the above. Related SAEs are SAEs that may reasonably be regarded as caused by, or probably caused by, the research.	VA Central IRB Form 119: Report of Serious Adverse Event (SAE) and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others	Serious adverse events that are **both** unanticipated **and** related to the research must be reported, in writing, within 5 business days of becoming aware of the occurrence

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Unanticipated Problems Involving Risks to Participants or Others that are serious and unanticipated and related	"Unanticipated" and "unexpected" are synonymous terms that refer to an event or problem in human research 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. "Serious problems" are problems in human research or research information security that may reasonably be regarded as (1) presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or (2) Substantively compromising a facility's HRPP or research information security program. Possibly reportable serious problems can include but are not limited to: • Any situation that requires action to prevent an immediate hazard to subjects or others • Any serious research-related injury to human research subjects, research personnel, or others • Any problem described in a VA Pharmacy Benefits Management alert relevant to local human subjects • Any problem described in a Data Monitoring Committee report • Any combination of problems that collectively present a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, or substantively compromise a facility's HRPP • Inappropriate access, loss, or theft of documents containing PHI (e.g. informed consent forms, HIPAA authorization forms, case report forms) • Unauthorized destruction (accidentally or intentionally) of research records • Loss, theft, or unauthorized destruction of equipment (e.g., laptops, other mobile devices, external storage media) containing VA research-related PHI • Transmission of VA research-related PHI not encrypted according to VA standards • Use or connection of unauthorized equipment (e.g., non-VA thumb drive, unauthorized personally owned equipment) to store, process, or transmit VA research-related PHI • Malicious attack on or unauthorized access to VA information system containing VA research-related PHI "Related Problems" are problems that may reasonably be regarded as caused by, or probably caused by, the research	VA Central IRB Form 119: Report of Serious Adverse Event (SAE) and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others	Serious Problems that are **both** unanticipated **and** related to the research must be reported, in writing, within 5 business days of becoming aware of the occurrence ***Local Site Investigators (LSIs)*** *should not report serious adverse events or unanticipated problems involving risks to participants or others if the reportable problem or event did not occur locally, i.e., if the event occurred at another facility participating in the trial.*

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Apparent Serious or Continuing Noncompliance Note: The determination that noncompliance is "serious" or "continuing" rests with the IRB; hence, reporting of *apparent* serious or continuing noncompliance is required.	Serious noncompliance is a failure to adhere to requirements for conducting human research that may reasonably be regarded as: • Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others; including their rights to privacy and confidentiality of identifiable private information; or • Substantively compromising a facility's human research protection or human research oversight programs. Examples of possibly reportable serious noncompliance in human research can be found at: http://www.va.gov/ORO/Docs/Guidance/1058_01_Examples_Serious_Problems_and_NonComp_06_15_2015.pdf	No VA Central IRB form required. Report must be in writing. VA Central IRB Form 129: Report of Protocol Deviations, Violations, and/or Noncompliance can also be used.	Written notification within 5 business days of becoming aware of any apparent serious or continuing noncompliance
Protocol Deviations, Violations, and/or Noncompliance	Deviation from the VA Central IRB-approved protocol is considered an act of noncompliance. The terms protocol deviation and protocol violation are synonymous. They must be reported within the specified time frame if they 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	VA Central IRB Form 129: Report of Protocol Deviations, Violations, and/or Noncompliance	Within 5 business days of being made aware of the occurrence
Unanticipated Adverse Device Effect (UADE)	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.	VA Central IRB Form 119: Report of Serious Adverse Event (SAE) and/or Serious Unanticipated Problem (UAP) Involving Risks to Participants and Others	Within 5 business days of being made aware of occurrence

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Adverse Events (AEs that do not meet criteria for reporting within five days in accordance with VHA Handbook 1058.01)	An AE is any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any 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 to have a causal relationship with the research. Please Note: In the context of a multi-center study, local or internal AEs are those AEs experienced by subjects, research staff or others at the reporting individual's own VA facility or VA approved research site. ***The Principal Investigator/Study Chair*** *(P/SC) should not duplicate reporting of serious adverse events or unanticipated problems involving risks to participants or others if the reportable event or problem was previously reported to the VA Central IRB by the LSI and no additional information is conveyed.*	VA Central IRB Form 115a: Application for Continuing Review Local Site Investigator; Form 115b: Application for Continuing Review Principal Investigator/Study Chair as applicable; VA Central IRB Form 117a:Project Closure Report; or Form 117b, Local Site Project Participation Closure Report as applicable	At Continuing Review (overall total and summary of types of events that occurred) At project closure (VA Central IRB Form 119 or overall total and summary as applicable)
Modifications or Amendments	Amendments or modifications to approved projects must be submitted to the VA Central IRB for review and approval prior to implementation, except when necessary to eliminate apparent immediate hazard to human participants. Examples of modifications or amendments include protocol amendments, investigator's brochures, informed consent form changes, and addition or change of recruitment materials, and other changes in IRB-approved documents.	VA Central IRB Form 116: Request to Amend or Modify an Approved Project	Variable depending upon the modification or amendment but prior to implementation
Change in Principal Investigator/Study Chair (PI/SC)	A change in the Principal Investigator/Study Chair for a VA Central IRB-approved project must be submitted to the VA Central IRB.	VA Central IRB Form 134a: Change in Principal Investigator/Study Chair	Prior to initiating change
Change in Local Site Investigator (LSI)	Changes in local site investigators for a research project conducted at multiple sites with a PI/SC currently approved by the VA Central IRB must be submitted to the VA Central IRB.	VA Central IRB Form 134b: Change in Local Site Investigator	Prior to initiating change
Addition of New Local Sites	Addition of new local sites must be approved by the VA Central IRB prior to initiating the research project at the site.	VA Central IRB Form 104: Local Site Investigator Application	Prior to initiation of addition
Changes in Study Team Members or Study Personnel	VA Central IRB approval is not required for changes in study personnel (other than the PI/SC, LSI, co-PI/SC, or co-LSI) unless that individual is identified by name in the protocol, informed consent form, or recruitment materials. If the individual is identified by name in the protocol, informed consent form, or recruitment materials VA Central IRB approval of an amended protocol, informed consent form, or recruitment material is required. Otherwise, changes in study personnel can be reported as a notification to the VA Central IRB at continuing review.	If identified by name in protocol, use VA Central IRB Form 116: Request to Amend or Modify an Approved Project	Prior to initiation or inclusion if individual is identified by name in the VA Central IRB-approved protocol

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Complaints	Complaints received about a study approved by the VA Central IRB must be reported to the VA Central IRB. Complaints will be summarized in the continuing review application sent to the VA Central IRB. However, complaints indicating that a research subject's rights, safety or welfare may have been or were at risk of being substantially adversely affected (e.g., complaint about being inappropriately consented) must be reported within 5 business days after the individual making the report is aware of the complaint.	No VA Central IRB Form required	Within 5 business days of being made aware of a complaint substantially adversely affecting participants
Termination or Suspensions of Research or Administrative Hold	A change in status of research activities of a VA Central IRB-approved project, such as termination, suspension of research or administrative hold. Any termination or suspension of a VA Central IRB-approved project (e.g., by the IRB or other research committee, or by the ACOS for Research or other facility official, or by an external entity) related to concerns about the safety, rights, or welfare of human research subjects, research staff, or others must be reported directly (without intermediaries) to the facility director within 5 business days after the termination or suspension occurs. The report must be made in writing with simultaneous copies, as applicable, to the ACOS for Research, the facility RCO; the R&D Committee, the VA Central IRB, and any other relevant research review committee. An administrative hold is a voluntary interruption of research enrollments and ongoing research activities by an appropriate facility official, research investigator, or sponsor (including the VHA ORD when ORD is the sponsor).	No VA Central IRB Form required. Report must be in writing.	Within 5 business days of occurrence
Incarceration of the Participant	Incarceration of participants must be reported to the VA Central IRB.	No VA Central IRB Form required	Within 5 business days of being made aware of the incarceration
New Information that Indicates a Change to the Risks or Potential Benefits of the Project	New information that indicates a change to the risks or potential benefits of the project must be reported to the VA Central IRB.	No VA Central IRB Form required	Within 5 business days after being made aware of the new information
Informed Consent, Regulatory Audit, or other Audit Activity	If an informed consent audit, regulatory audit, or other type of audit activity is conducted by the RCO of a VA Central IRB-approved protocol, the VA Central IRB must receive a copy of the findings. The VA Central IRB must be notified within 5 business days by the RCO if the RCO identifies apparent serious or continuing noncompliance as a result of the audit activity. Otherwise, the audit activity can be submitted with the continuing review application materials for the VA Central IRB-approved protocol.	No VA Central IRB Form required	Submit by encrypted email to VA Central IRB Administrator within 5 business days if the audit activity involves identification of apparent serious or continuing noncompliance.
Miscellaneous	If you are unsure whether a document requires submission or reporting, please contact the VA Central IRB via the PRIDE toll free number 877-354-3130 or va.central.irb@va.gov.		