Required Reports in Human Research at PVAMC
per VHA ORO Handbook 1058.01, OHRP, FDA and local policies

What to Report for Human Research *(see also "Definitions" below)*	Reporting - Who should report to whom and when *(*see Definitions below)*	Other Notes
Research information security incidents – includes: any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI	▪ **VA personnel*** → report immediately to ACOS/R, ISO, and PO ▪ **ACOS/R** → report immediately to relevant subcommittee(s) (or, if none, R&DC) and, if official VA records were destroyed, the records management official ▪ **Sub-committee(s) or R&DC** → must be reviewed by each relevant research review committee at its earliest practicable convened meeting, not to exceed 30 business days from date of notification → Each committee must determine: whether or not the incident constitutes a serious problem; and (with the ISO and/or PO, as applicable) whether and what remedial actions are warranted If a committee determines that the incident constitutes a serious problem: ▪ **Committee** → notify the facility Director and ACOS/R&D within 5 business days after determination ▪ **Facility Director** → report the determination to ORO RISP within 5 business days of their notification	Additional Reporting Requirements: Facility Director must report the following to ORO within 5 business days of their awareness, regardless of other determinations: (1) Provision of an Issue Brief for VACO regarding the incident; (2) Any notification to individual(s) of an information breach or provision of credit monitoring as required by the NSOC; (3) Any breach notification required under the HITECH Act; (4) Any notification to or from the OIG regarding the incident
Local research deaths - unanticipated and related	▪ **VA personnel*** → oral report to IRB immediately → written report to IRB within 5 business days of awareness ▪ **IRB** → report (via email or phone) to ORO within 2 business days of notification from PI *(unless report is determined to be in error)* → must review report at next convened IRB meeting → must determine and document that: (a) the death was unanticipated and related to the research; or (b) there is insufficient information to determine whether the death was unanticipated and related to the research; or (c) the death was not unanticipated and/or was not related to the research → regardless of the determination, the IRB must also determine and document whether any protocol or informed consent modifications are warranted → if such modifications are warranted, the IRB must determine and document whether or not investigators must notify or solicit renewed/revised consent from previously enrolled subjects (and if so, when such notification or consent must take place and how it must be documented)	For FDA-regulated studies: If the IRB determines that the death is unanticipated and has implications for conduct of the study (e.g. related modifications are needed), it must also be reported to the FDA promptly

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	If the convened IRB determines the local death to be either (a) or (b) above: ▪ **IRB Chair or Designee** → notify Facility Director and ACOS within 5 business days ▪ **Facility Director** → report to ORO RO within 5 business days of their notification → for deaths determined to be (a), also written report to OHRP promptly*	
Serious problems or local SAEs - unanticipated and related	▪ **VA personnel*** → written report to IRB within 5 business days of awareness ▪ **IRB Reviewer** → reviews report within 5 business days; determines and documents whether any actions are warranted to eliminate apparent immediate hazards to subjects ▪ **IRB** → must review the incident and the IRB reviewer's determination at its next convened meeting → must determine and document that: (a) The incident was serious and unanticipated and related to the research; or (b) There is insufficient information to determine whether the incident was serious and unanticipated and related to the research; or (c) The incident was not serious, and/or the incident was not unanticipated, and/or the incident was not related to the research → regardless of the determination, the IRB must also determine and document whether any protocol or informed consent modifications are warranted → if modifications are warranted, the IRB must determine and document whether or not investigators must notify or solicit renewed/revised consent from previously enrolled subjects (and if so, when such notification or consent must take place and how it must be documented) ▪ **IRB Chair or Designee** → notify Facility Director and ACOS/R&D within 5 business days if: (a) actions were taken to eliminate apparent immediate hazards to subjects; or (b) the incident was determined to be serious and unanticipated and related to the research, or there was insufficient information to make the determination; or (c) protocol or informed consent modifications were warranted ▪ **Facility Director** → report to ORO RO within 5 business days of their notification	For FDA-regulated studies: If the IRB determines that the event is serious, unanticipated and has implications for conduct of the study (e.g. related modifications are needed), it must also be reported to the FDA promptly

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	→ for incidents determined to be (a), also written report to OHRP promptly*	
Apparent serious or continuing noncompliance	▪ **VA personnel*** → written report to IRB within 5 business days of awareness ▪ **IRB** → must review at next convened meeting, not to exceed 30 business days after notification → must determine and document whether or not serious or continuing noncompliance actually occurred → if the noncompliance was identified by the RCO, notify RCO of determination (regardless of outcome) within 5 business days of determination If IRB determines that the noncompliance is serious and/or continuing: ▪ **IRB** → must determine whether remedial actions are needed to ensure present and/or future compliance ▪ **IRB Chair or Designee** → notify Facility Director and ACOS/R&D within 5 business days of determination ▪ **Facility Director** → report to ORO RO within 5 business days of their notification, and to OHRP and (if FDA-regulated) to FDA promptly*	
Suspension or Termination of research by an external entity	▪ **VA personnel*** → written report to IRB within 5 business days of awareness ▪ **IRB** → must review at next convened meeting, not to exceed 30 business days after notification → must determine whether the suspension or termination: (a) resulted from a local AE(s), local noncompliance, or other local issue(s); or (b) requires additional local action to ensure the safety, rights, or welfare of local human research subjects, personnel or othersm or the effectiveness of the local HRPP. If IRB determines that either (a) or (b) applies: ▪ **IRB Chair or Designee** → notify Facility Director and ACOS/R&D within 5 business days of determination ▪ **Facility Director** → report to ORO RO within 5 business days of their notification, and to OHRP and (if FDA-regulated) to FDA promptly*	
Any suspension or termination of IRB approval	▪ **IRB Chair or Designee** → notify Facility Director, ACOS/R&D and RCO within 5 business days of suspension or termination ▪ **Facility Director** → report to ORO RO within 5 business days of their	

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	notification, and to OHRP and (if FDA-regulated) to FDA promptly*	
Program Changes	▪ **Facility Director →** report to ORO RO the following program changes: o Any change in the status (e.g., expiration, restriction, suspension, or termination) of the facility's FWA – within 5 business days o Any proposed changes to the FWA, including changes in designated IRB(s) and changes in IRB membership – prior to submission to the OHRP o New or substantially revised MOUs related to human research protections or oversight– within 5 business days after final concurrence/signature o Failure to achieve or maintain required HRPP accreditation – within 5 business days	

DEFINITIONS:

Continuing Noncompliance: A persistent failure to adhere to the legal and policy requirements governing human research.

Local: occurring in participants, personnel and/or other individuals involved in VAPORHCS research activities.

Promptly: As per OHRP guidance, "For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient."

Related: An AE, death, or problem that may reasonably be regarded as caused by, or probably caused by, the research.

Serious Adverse Event (SAE): 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; or the need for medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

Serious Noncompliance: Failure to adhere to requirements for conducting human research 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.

Serious Problem: A problem 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.

Unanticipated: 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 protocol documents and the characteristics of the study population.

VA personnel: Includes VA-paid employees, as well as WOC and IPA appointees.

For further reporting guidance, see:

Decision Chart for Reporting SAEs and Problems Involving Risk in Research

Examples of Apparently Serious or Apparently Continuing Noncompliance in VA Human Research

Examples of Apparently Serious Problems in VA Research Information Security

Summary of Requirements for Reporting Research Incidents

VHA Handbook 1058.01 – Research Compliance Reporting Requirements