

SUMMARY OF REQUIREMENTS FOR REPORTING RESEARCH INCIDENTS UNDER VHA HANDBOOK 1058.01

Reports should be directed to ORO as specified on the ORO SharePoint and Web sites at <https://vawww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx> and <http://www1.va.gov/oro/>

Note: This Table provides a CONDENSED SUMMARY of reporting requirements. See VHA Handbook 1058.01 for complete details.

Unless otherwise indicated, #1. VA employees (including WOC and IPA employees) must notify the relevant research review committee in writing within 5 BUSINESS DAYS (BD) after becoming aware of reportable incidents. #2. Research review committee must notify the Facility Director (FD) and Associate Chief of Staff for Research (ACOS/R) within 5 BUSINESS after making certain required determinations (DTMs). #3. FD must report to ORO within 5 BUSINESS DAYS after receiving notification.				
HUMAN RESEARCH – Report to ORO Regional Office (or ORO RCEP ¹ where indicated)	LABORATORY ANIMAL WELFARE – Report to ORO RSAW ²	RESEARCH SAFETY – Report to ORO RSAW ²	RESEARCH LABORATORY SECURITY – Report to ORO RSAW ²	RESEARCH INFORMATION SECURITY – Report to ORO RISP ³
<p>§6a. Local Research Deaths that are unanticipated and related to the research.</p> <ul style="list-style-type: none"> ● Immediate oral notice to IRB. ● IRB alert to ORO, FD, and ACOS/R within 2 BD. ● Written notice to IRB per #1. ● IRB Chair DTMs within 5 BD of written notice. ● Convened IRB DTMs. ● IRB notice of <u>all</u> DTMs to FD and ACOS/R per #2. ● FD report to ORO per #3. <p>§6b-d. Local SAEs and Serious Problems that are both unanticipated and related to the research.</p> <ul style="list-style-type: none"> ● Written notice to IRB per #1. ● IRB Chair DTMs within 5 BD of written notice. ● Convened IRB DTMs. ● IRB notice of DTMs to FD and ACOS/R per #2. ● FD report to ORO per #3. <p>§6f. Apparent Serious or Continuing Noncompliance.</p> <ul style="list-style-type: none"> ● Written notice to IRB per #1. ● Convened IRB DTMs. ● IRB notice of DTMs to FD AND ACOS/R per #2. ● FD report to ORO per #3. ● Notification of, and tracking by RCO, if from RCO audit. ● IRB tracking for Facility Director Certification. <p>§6h. Suspension/Termination by VA.</p> <ul style="list-style-type: none"> ● Notice to FD, ACOS/R, & RCO within 5 BD. ● FD report to ORO per #3. <p>§6i. Suspension/Termination by External Entity.</p> <ul style="list-style-type: none"> ● Written notice to IRB per #1. ● Convened IRB DTMs. ● IRB notice of DTMs to FD AND ACOS/R per #2. ● FD report to ORO per #3. <p>§6j. Program Changes.</p> <ul style="list-style-type: none"> ● FD report to ORO per #3. 	<p>§7c. Human Deaths.</p> <ul style="list-style-type: none"> ● Immediate oral notice to IACUC. ● IACUC alert to ORO, FD, and ACOS/R within 2 BD. ● Written notice to IACUC per #1. <p>§7a. Unanticipated Deaths of Research Animals.</p> <p>§7b. Animal Theft, Escape, or Unexplained Disappearance.</p> <p>§7d. Human Accident, Injury, Illness, or Exposure.</p> <p>§7e. Reportable Incidents Under Federal Standards.</p> <ul style="list-style-type: none"> ● Written notice to IACUC per #1. <p>§7f. IACUC Review of Incidents Reported under §§7a-7e.</p> <ul style="list-style-type: none"> ● DTMs by convened IACUC. ● Notice of IACUC DTMs to FD AND ACOS/R per #2. ● Notice to FD of DTMs by other officials of a reportable event. ● FD report to ORO per #3. <p>§7h. Delayed Determinations.</p> <p>§7i. Memoranda of Understanding.</p> <p>§7j. Public Health Service Assurances.</p> <p>§7k. Accreditation Status Change.</p> <ul style="list-style-type: none"> ● FD report to ORO per #3. 	<p>§8a. Human Deaths.</p> <ul style="list-style-type: none"> ● Immediate oral notice to SRS. ● SRS alert to ORO, FD, and ACOS/R within 2 BD. ● Written notice to SRS per #1. <p>§8b. Human Accident, Injury, Illness, or Exposure.</p> <p>§8c. Reportable Incidents Under Federal Standards.</p> <ul style="list-style-type: none"> ● Written notice to SRS per #1. <p>§8d. Review of Incidents.</p> <ul style="list-style-type: none"> ● DTMs by convened SRS. ● Notice of SRS DTMs to FD AND ACOS/R per #2. ● Notice to FD of DTMs by other officials of a reportable event. ● FD report to ORO per #3. <p>§8e. Delayed Determinations.</p> <p>§8g. Memoranda of Understanding.</p> <ul style="list-style-type: none"> ● FD report to ORO per #3. <p>§8h. Lab Decommissions and Reassignments.</p> <ul style="list-style-type: none"> ● Written request to SRS and ACOS/R 1 month prior to implementation ● SRS DTMs. ● Notice to facility Safety Officer from ACOS/R. ● Notice to FD from ACOS/R of unauthorized decommissions or reassignments within 5 BD. ● FD report to ORO of unauthorized decommissions or reassignments per #3. 	<p>§9a. Research Laboratory Security Incidents.</p> <ol style="list-style-type: none"> (1) Intrusion, physical security breach, break-in, or other security violations in dedicated research areas. (2) Noncompliance findings by any entity other than ORO. (3) Unplanned suspensions or terminations of research due to security concerns. (4) Other deficiencies that substantively compromise the research laboratory security program. <ul style="list-style-type: none"> ● Written notice to ACOS/R within 5 BD. ● Immediate notice to VA Police Service. <p>§9b. Reporting.</p> <ul style="list-style-type: none"> ● Notice to FD and VA Police Service from ACOS/R within 5 BD. ● FD report to ORO per #3. 	<p>§10a. Research Information Security Incidents.</p> <ul style="list-style-type: none"> ● Immediate notice to ACOS/R, ISO, and PO of information security incidents related to research including inappropriate access, loss, theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; theft, loss, noncompliant destruction of equipment containing PHI. ● Immediate ACOS/R&D notice to relevant research review committee(s). ● Immediate ACOS/R&D notice to Records Management Officer if VA records destroyed. ● Written notice to ACOS/R within 5 BD. <p>§10b. Review of Incidents Reported under §10a.</p> <ul style="list-style-type: none"> ● Review and DTMs by relevant research review committee(s) within 30 BD. ● Notice of serious problem DTM to FD AND ACOS/R per #2. ● FD report to ORO of serious problem DTM per #3 <p>§10c. FD report to ORO within 5 business days of:</p> <ul style="list-style-type: none"> ● An Issue Brief on the incident for VA central office ● An NSOC requirement to notify individuals of an information breach or to provide credit monitoring ● Breach notification required under the Health Information Technology for Economic and Clinical Health (HITECH) Act ● Notification to or from the OIG regarding the incident.

¹ RCEP = Research Compliance Education Program; IRB = Institutional Review Board; AEs = Adverse Events; RCO = Research Compliance Officer

² RSAW = Research Safety and Animal Welfare Program; IACUC = Institutional Animal Care and Use Committee; SRS = Subcommittee on Research Safety

³ RISP = Research Information Security Program