

SUMMARY OF REQUIREMENTS FOR REPORTING RESEARCH EVENTS TO ORO

Human Research: Report to RO *	Animal Welfare: Report to CO RSAW *	Research Safety: Report to CO RSAW *	Laboratory Security: Report to CO RSAW *	Research Information Protection *
<p>1. Problems involving risks to subjects or others that are unanticipated <u>and</u> serious <u>and</u> related to the research, e.g., work-related injuries requiring more than minor medical intervention or extended surveillance or leading to serious complications or death; interruptions related to safety, rights, or welfare of subjects/others; Nat'l Pharm Benefits Mgt (PBM), Data Monitoring Cmte (DMC), or sponsor safety reports.</p> <p>2. Local Serious AEs (SAEs) that are unanticipated <u>and</u> serious <u>and</u> related to the research.</p> <p>3. Research Compliance Officer (RCO) audit findings of apparent serious or continuing noncompliance (also report to ORD).</p> <p>4. Institutional Review Board (IRB) findings of serious or continuing noncompliance (also report to ORD).</p> <p>5. Suspensions or terminations of study activities related to safety, rights, or welfare of subjects or others.</p> <p>6. Any proposed change in facility's Federalwide Assurance (FWA) or other ORO-approved Assurance.</p> <p>7. Notify ORO CO RCEP with copy to RO):</p> <ul style="list-style-type: none"> ◦ Assurances changes ◦ IRB designation changes ◦ IRB roster changes ◦ Substantive MOU changes ◦ RCO changes ◦ Changes in accreditation status 	<p>1. Unanticipated loss of animal life.</p> <p>2. Animal theft or potentially dangerous escape.</p> <p>3. Work-related or research-related injury to any person requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.</p> <p>4. Incidents reportable under applicable standards, including noncompliance or deficiency that substantively compromises the effectiveness of facility's animal research protection/oversight programs.</p> <p>5. Suspensions or terminations of research activities related to animal safety, health, or welfare; safety, rights, or welfare of research staff or others; or operations problems causing research interruptions.</p> <p>6. Any change in facility's Public Health Service (PHS) Animal Welfare Assurance.</p> <p>7. Any change PHS Animal Welfare Assurance of an affiliate or other entity on which the facility relies.</p> <p>8. Any new MOU or substantive change in an MOU related to laboratory animal welfare or animal care and use arrangements</p> <p>9. Facility failure to gain full accreditation or change in facility accreditation or in affiliate accreditation affecting facility research protections.</p>	<p>1. Work-related or research-related injury or exposure to hazardous, toxic, or infectious materials at greater than routine levels or any exposure or injury requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.</p> <p>2. Reportable incidents under applicable standards, including any deficiency that substantively compromises the effectiveness of facility research safety programs.</p> <p>3. Suspensions or terminations of research activities related to the safety, rights, or welfare of research staff or others.</p> <p>4. Unauthorized laboratory decommissions or reassignments requiring identification and disposal of hazardous materials, infectious agents, or equipment.</p> <p>5. Any substantive change in an MOU related to research safety arrangements.</p>	<p>1. Injury or harm to any human being or laboratory animal related to a break-in, security breach, or other security problem involving a VA research facility.</p> <p>2. Any break-in or security breach involving a VA Biosafety Level-3 (BSL-3) research laboratory.</p> <p>3. Any break-in or security breach involving a VA research facility that results in loss of any quantity of a select agent or toxin or of a highly hazardous agent, substantial damage to the facility, or substantial loss of equipment or resources.</p> <p>4. Findings of noncompliance by entities external to the facility.</p> <p>5. Any noncompliance or other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.</p> <p>6. Suspensions of terminations of research related to laboratory security concerns.</p> <p>7. Any substantive change in an MOU related to research laboratory security arrangements.</p>	<p>1. Report to ACOS for Research, Privacy Officer (PO), and Information Security Officer (ISO) Required Within 1 Hour:**</p> <p>Any unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related protected health information (PHI), individually identifiable private information, or confidential information, as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act, or 38 U.S.C. §§5701, 5705, and 7332.</p> <p>2. Report to ACOS for Research, PO, and ISO Required Within 5 Business days: **</p> <p>a. Findings of non-compliance related to research information security or privacy by entities external to the facility.</p> <p>b. Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.</p> <p>c. Suspensions or terminations of research related to information protection concerns.</p> <p>** Uses and disclosures of PHI under invalid or nonexistent HIPAA authorization or waiver or deficient ISO or PO review must be reported to the ORO RO. All other research information protection incidents must be reported to CO RIPP.</p>

*** NOTE: RO = ORO Regional Office CO = ORO Central Office RCEP = Research Compliance Education and Policy Group RSAW = Research Safety and Animal Welfare Group RIPP = Research Information Protection Group**

Except for Information Protection Item 1, the relevant research review committee(s) must be notified of these events within 5 business days. The facility Director must notify ORO within 5 business days of being informed of these events and must send a copy of the notification to the Network Director. Decision charts for reporting research events are available on the ORO Web site at <http://www.va.gov/oro/>