

EXAMPLES OF LABORATORY SAFETY AND SECURITY EVENTS IN VA RESEARCH TYPICALLY REPORTABLE TO THE VHA OFFICE OF RESEARCH OVERSIGHT (ORO) UNDER VHA DIRECTIVE 1058.01, "RESEARCH COMPLIANCE REPORTING REQUIREMENTS"

VHA Directive 1058.01: Research Laboratory Safety and Security	Additional Information	Examples
§10.a. Human Deaths Associated with VA Laboratory Research	Occupational Safety and Health Administration (OSHA) is required to be notified when an employee dies on the job. A fatality must be reported within 8 hours.	<ul style="list-style-type: none"> • A research employee collapses and dies inside a cold storage room. • A research employee becomes ill and dies several days after suffering a needlestick injury while injecting animals with a virus.
§10.b. Research Laboratory Events Reportable Under Applicable Federal Standards or Involving Serious Accident, Injury, Illness, or Exposure of a Human Involving VA Laboratory Research	<p>The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (<i>NIH Guidelines</i>) states that "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" must be reported to NIH Office of Science Policy (NIH-OSP) within 30 days. Certain types of accidents must be reported on a more expedited basis.</p> <ul style="list-style-type: none"> • Spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH. • Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. <p>NIH-OSP provides guidance regarding reportable incidents involving research subject to the <i>NIH Guidelines</i> here: https://osp.od.nih.gov/biotechnology/faqs-on-incident-reporting/</p>	<ul style="list-style-type: none"> • A serious accident, injury, illness or exposure of a human resulting from a VA research laboratory activity that: (1) requires medical attention or treatment, other than basic first aid provided at the site where the accident, injury, illness or exposure occurred; (2) requires time away from work or restricted work activities; (3) requires medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; or (4) leads to serious long term health complications or death. Specific examples of incidents that meet or could meet the aforementioned criteria include: <ul style="list-style-type: none"> ○ A research employee injures back while moving equipment in the research area. ○ A human blood sample is splashed into the eyes and nose of a research employee. ○ A laboratory employee passes out from exposure to dry ice. ○ A laboratory employee receives a severe burn on forearm from a liquid nitrogen splash. • A biosafety incident reportable under applicable federal standards/requirements such as an overt exposure to a viral vector as a result of a needle stick injury to a laboratory employee's hand while injecting the vector into a mouse. NOTE: <i>Such an event may also meet the criteria of the preceding bulleted item; however, in the event that it did not, it would still be reportable to ORO on</i>

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	<p>OSHA must be notified when an employee suffers a work-related hospitalization, amputation or loss of an eye. An in-patient hospitalization, amputation, or eye loss must be reported within 24 hours.</p> <p>OSHA provides guidance regarding reportable incidents here: https://www.osha.gov/report.html</p>	<p><i>the basis that it is reportable to another federal entity (i.e., NIH-OSP).</i></p>
<p>§10.c. Serious or Continuing Noncompliance Involving VA Laboratory Research</p>		<ul style="list-style-type: none"> • Conduct of research requiring safety review without required approval by the Subcommittees on Research Safety (SRS) or other relevant research review committees. • Continuation of research beyond the expiration date established by the SRS without appropriate renewal of the protocol, even if the research is a continuation of work that was previously approved by all relevant research review committees. • Failure to implement changes required by the SRS as a condition of approval. • Unapproved substantive deviation from an SRS-approved protocol. • Failure to comply with continuing review requirements of the SRS or other relevant research review committees. • Conduct of official SRS business by an improperly constituted committee or with less than a quorum of voting members present. • Failure to correct identified programmatic or facility deficiencies as required. • Conduct of research by unauthorized personnel or personnel who lack appropriate training.

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		<ul style="list-style-type: none"> Any noncompliance or other deficiency that substantively compromises the effectiveness of a facility's research safety programs.
§10.d. Other Events Involving VA Research Safety and Security Reportable to ORO		<ul style="list-style-type: none"> The suspension or early termination of a VA study by the SRS or institutional official due to research laboratory safety or security concerns, including concerns about the safety of individuals conducting VA laboratory research, or environmental concerns attributed to VA laboratory research. The expiration or termination of the NIH-OSP registration of any institutional biosafety committee relied upon by the VA medical facility for review and oversight of the facility's research. A security concern involving: <ul style="list-style-type: none"> An unauthorized intrusion, physical security breach, break-in or other security incident in a Biosafety Level-3 (BSL-3) research laboratory or animal research facility where VA research is conducted or animals used for VA research are housed; An unauthorized intrusion, physical security breach, break-in or other security incident in a research area where VA research involving select agents or toxins or dual use research of concern; or Any physical loss or theft of VA research materials or equipment, the loss or theft of which poses risk of harm.
§5.g.(5). VA Medical Facility Director Responsibilities		<ul style="list-style-type: none"> Issuance of a research-related citation or determination of noncompliance by a state or federal entity (OSHA, Environmental Protection Agency, NIH-OSP, etc.) or an accrediting organization.