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

VHA Directive 1058.01: Animal Research	Additional Information	Examples
§9.a. Human Deaths Associated with VA Animal Research		Any human death that may be the result of working with, caring for, or having other contact with animals used in VA research.
§9.b. VA Animal Research Events Involving Serious Accident, Injury, Illness or Exposure of a Human		• A technician is bitten by a cat during induction of anesthesia and the wound requires significant medical treatment. • A lab member accidentally inhales an infectious agent when intratracheally inoculating experimental mice.
§9.c. VA Animal Research Events Reportable to HHS National Institutes of Health Office of Laboratory Animal Welfare (NIH-OLAW)	Public Health Service (PHS) Policy, IV.F.3, requires that: "The IACUC [Institutional Animal Care and Use Committee], through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a) any serious or continuing noncompliance with this Policy; b) any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals]; or c) any suspension of an activity by the IACUC." NIH-OLAW provides extensive guidance regarding reporting expectations in NOT-OD-05-034 *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals* and on their webpage here:	• Animals were not given post-operative pain medications at the dose and/or rate specified in the approved study protocol. • Animals were given a different post-operative pain medication than the one specified in the approved study protocol. • Any finding of noncompliance with animal research requirements by other Federal or state entities that constitute serious or continuing noncompliance with *PHS Policy* or the *Guide*. • Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals. ○ To include: Unanticipated adverse events, such as increased mortality rate following experimental manipulation (e.g. surgery) or model induction.

	https://olaw.nih.gov/guidance/reporting-noncompliance.htm	• Conduct of animal-related activities without appropriate IACUC review and approval. • Failure to adhere to IACUC-approved protocols. • Implementation of any significant change to IACUC-approved protocols without prior IACUC approval. • Conduct of animal-related activities beyond the expiration date established by the IACUC. • Conduct of official IACUC business requiring a quorum in the absence of a quorum. • Conduct of official IACUC business during a period of time that the Committee is improperly constituted. • Failure to correct deficiencies identified during the semiannual evaluation in a timely manner. • Chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification. • Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained. • Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from

		anesthesia or during recuperation from invasive or debilitating procedures). • Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry). • Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO_2). • Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments). • IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the *PHS Policy*, *Animal Welfare Act*, the *Guide*, or the institution's Animal Welfare Assurance. • Failure to implement changes required by the IACUC as a condition of approval. • Significant deviation from the IACUC-approved protocol prior to receiving approval from the IACUC to implement protocol modifications. • Failure to comply with annual review requirements of the IACUC for U.S Department of Agriculture (USDA)-regulated species. • Continuation of research beyond the specified approval period, even if the research is a continuation of work that was previously approved by all relevant research review committees.

		• Failure to provide adequate veterinary care (e.g., inappropriate or ineffective pain or distress management, inadequate post-procedural care, use of improper euthanasia techniques) whether intentional or accidental. • Any noncompliance or other deficiency that substantively compromises the effectiveness of the facility's animal research protection or animal research oversight programs.
§9.d. Serious or Continuing Noncompliance Involving VA Animal Research	This includes serious or continuing noncompliance with VHA Handbook 1200.07, local policies and standard operating procedures if developed, and the requirements or determinations of the IACUC.	• Facility maintenance staff repeatedly fail to respond to alarms for excessive temperatures in animal rooms.
§9.e. Other Events Involving VA Animal Care and Use Programs Reportable to ORO		• The suspension or early termination by the IACUC or institutional official of a VA study involving animals due to the study not being conducted in accordance with applicable regulatory, policy, or IACUC requirements or due to animal or research personnel welfare concerns. • Substantial revisions to the PHS Animal Welfare Assurance that covers the VA medical facility's Animal Care and Use Program (ACUP), regardless of whether the Assurance is held by the VA medical facility or an academic affiliate. • Any change in the status (e.g., expiration, termination) of the Assurance that covers the VA medical facility's ACUP.

		• Placement of the VA medical facility (or the institution holding the accreditation for a VA medical facility's ACUP) on deferred, conditional, or probationary status by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International.
§5.g.(5). VA Medical Facility Director Responsibilities		• Issuance of a research-related citation or determination of noncompliance by a state or federal entity (USDA, NIH-OLAW, etc.) or an accrediting organization (e.g., AAALAC International) pertaining to VA animal research.