VHA Directive 1058 Timelines for Notifying the VHA Office of Research Oversight (ORO) of the Occurrence of Research-Related Events

Overview of Reporting Requirements in VHA Directive 1058, Dated November 8, 2024

This one-page overview of reporting requirements is intended for use in conjunction with the subsequent pages of this document, which provide fuller context (i.e., more detailed descriptions of the conditions for which the events below are reportable to ORO) and a listing of other events that are reportable to ORO and not included on this overview page.

NOTE: *VA medical facility Directors, or designees, are responsible for promptly notifying ORO of the events below. The timeframes specified are maximums for reporting.*

Human Deaths Reportable to ORO within 1 Business Day After Facility Personnel First Become Aware of the Death
(see page 2)

Unanticipated Problems and Events Involving Serious Accident, Injury, Illness, or Exposure of a Human Reportable to ORO within 60 Calendar Days After Facility Personnel First Become Aware of the Problem or Event
(see page 2)

Serious or Continuing Noncompliance Events Reportable to ORO within 60 Calendar Days After Facility Personnel First Become Aware of the Event
(see page 3)

Research-Related Citations or Determinations of Noncompliance by a State or Federal Entity or an Accrediting Organization Reportable to ORO within 5 Business Days After Facility Personnel First Become Aware of the Citation or Determination
(see page 3)

Study Suspensions or Early Terminations Reportable to ORO within 5 Business Days After Facility Personnel First Become Aware of the Suspension or Termination
(see page 4)

Changes in Status of Accreditation, Assurance, or Research Review Committee Registration Reportable to ORO within 5 Business Days After Facility Personnel First Become Aware of the Change
(see page 4)

Other Reportable Events to ORO
(see page 5)

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Detailed Descriptions of Reporting Requirements in VHA Directive 1058

NOTE: *VA medical facility Directors, or designees, are responsible for promptly notifying ORO of the events below. The timeframes specified are maximums for reporting.*

Human Deaths Reportable to ORO within 1 Business Day After Facility Personnel First Become Aware of the Death

- Death of a subject enrolled in a study approved by the VA medical facility that is believed to be both unexpected and related or possibly related to participation in the study.
- Death that is believed to have resulted from or possibly resulted from working with, caring for, or having other contact with animals used in VA research.
- Death that is believed to have resulted from or possibly resulted from work (or other activity) in a VA research laboratory or dedicated VA research area (e.g., research specimen storage area), or involving VA research conducted in a research laboratory or dedicated research area owned or operated by a non-VA entity.

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Unanticipated Problems and Events Involving Serious Accident, Injury, Illness, or Exposure of a Human Reportable to ORO within 60 Calendar Days After Facility Personnel First Become Aware of the Problem or Event

- Unanticipated problems involving risks to subjects or others (UPIRTSOs)* in VA human subjects research. ***NOTE:*** *Depending on the nature of the event, an information security or privacy protection lapse involving VA human subjects research may constitute a UPIRTSO.*
- Serious accidents, injuries, illnesses, or exposures* of humans in VA research that resulted from or possibly resulted from working with, caring for, or having other contact with research animals.
- Serious accidents, injuries, illnesses, or exposures* of a human that resulted from or possibly resulted from work or other activity in a VA research laboratory or dedicated VA research area (e.g., research specimen storage area), or involving VA research conducted in a research laboratory or dedicated research area owned or operated by a non-VA entity.

*See page 6 for definition.

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Serious or Continuing Noncompliance Events Reportable to ORO within 60 Calendar Days After Facility Personnel First Become Aware of the Event

- Serious or continuing noncompliance* with applicable laws, regulations, policies, and agreements pertaining to VA human subjects research. This includes, but is not limited to, serious or continuing noncompliance with the Federal Policy for the Protection of Human Subjects ("Common Rule"); VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research; VA medical facility policies, standard operating procedures (SOPs), and MOUs (or equivalent) related to human subjects research; Institutional Review Board (IRB)-approved protocols; and the requirements or determinations of an IRB.
- Serious or continuing noncompliance* with applicable laws, regulations, policies, and agreements pertaining to VA animal research. This includes, but is not limited to, serious or continuing noncompliance with the Animal Welfare Act and Regulations; U.S. Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals; VHA Directive 1200.07, VA Research with Animals; VA medical facility policies, SOPs, and MOUs (or equivalent) related to animal research, as required by VHA Directive 1200.07 and to the extent developed; Institutional Animal Care and Use Committee (IACUC)-approved protocols; and the requirements or determinations of the IACUC.
- Serious or continuing noncompliance* with applicable laws, regulations, policies, and agreements pertaining to the conduct of VA laboratory research. This includes, but is not limited to, serious or continuing noncompliance with VHA Directive 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research; VA research laboratory security requirements; VA medical facility SOPs, and MOUs (or equivalent) related to laboratory research; Subcommittee on Research Safety (SRS)-approved and Institutional Biosafety Committee (IBC)-approved protocols; and the requirements or determinations of the SRS or IBC.
- Serious or continuing noncompliance* involving research-related information security and privacy.

*See page 6 for definition.

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Research-Related Citations or Determinations of Noncompliance by a State or Federal Entity or an Accrediting Organization Reportable to ORO within 5 Business Days After Facility Personnel First Become Aware of the Citation or Determination

- Issuance of a research-related citation or determination of noncompliance by a state or Federal entity (including the VA Office of Inspector General) or an accrediting organization, pertaining to the VA medical facility's Human Research Protections Program (HRPP) and human subjects research portfolio; Animal Care and Use Program (ACUP) and animal research portfolio; Research Safety and Security Program (RSSP) and VA laboratory research portfolio; and/or research-related information security and privacy processes and practices.

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Study Suspensions or Early Terminations Reportable to ORO within 5 Business Days After Facility Personnel First Become Aware of the Suspension or Termination

- Suspension or early termination of a VA human research study by the IRB, Research & Development Committee (R&DC), or Institutional Official (IO) due to the study not being conducted in accordance with applicable regulations, policies, agreements, or IRB requirements or due to concerns about the safety, rights, or welfare of human subjects or others.
- Suspension or early termination by the IACUC, R&DC, or IO 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.
- Suspension or early termination of a VA study by the SRS (or equivalent safety committee), Institutional Biosafety Committee (IBC), R&DC, or IO 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.
- Suspension or early termination of a VA study due to information security or privacy concerns.

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Changes in Status of Accreditation, Assurance, or Research Review Committee Registration Reportable to ORO within 5 Business Days After Facility Personnel First Become Aware of the Change

- Change in the status (e.g., expiration, restriction, suspension, or termination) of the VA medical facility's human subjects research Federalwide Assurance (FWA).
- Termination or non-renewal of the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) registration status of any IRB relied upon by the VA medical facility for review and oversight of VA research.
- Failure of the VA medical facility to achieve or maintain full accreditation of its HRPP, if such accreditation is sought by the VA medical facility.
- Any change in the status (e.g., expiration, termination) of the PHS Animal Welfare Assurance that covers the VA medical facility's ACUP.
- Substantial revision of the PHS Animal Welfare Assurance that covers the VA medical facility's ACUP, regardless of whether the PHS Animal Welfare Assurance is held by the VA medical facility or an academic affiliate.
- Placement of the VA medical facility (or the institution holding the accreditation for a VA medical facility's ACUP) on deferred, conditional, probationary, or revoked status by AAALAC International.
- Expiration or termination of the National Institutes of Health (NIH) Office of Science Policy (OSP) registration of any IBC relied upon by the VA medical facility for review and oversight of the VA medical facility’s research.

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Other Reportable Events to ORO

Systemic Deficiencies

- Identification of a systemic deficiency within the VA medical facility that has a reasonable likelihood of substantially compromising the VA medical facility's research oversight programs (ACUP, HRPP, and RSSP) or research information security processes, including persistent failure by any research review committee relied upon by the VA medical facility to adhere to applicable requirements governing VA research, is reportable to ORO within 60 calendar days of identification.

Animal Research

- VA animal research events reportable to NIH Office of Laboratory Welfare (OLAW) and not otherwise addressed in this document are reportable to ORO within 60 calendar days of VA medical facility personnel becoming aware of the occurrence of the event **or** concomitantly with any notification of the event sent to NIH OLAW, whichever is sooner.
- Granting of initial IACUC approval of VA research involving sensitive animal species (i.e., canines, felines, non-human primates, and other species if designated as such by the VHA Office of Research & Development) is reportable to ORO within 5 business days of granting of approval.
- Establishment of a new internally operated IACUC by a VA medical facility that previously relied upon an external IACUC or the elimination of an internally operated IACUC and transition to reliance on an external IACUC is reportable to ORO within 5 business days of the change.

Laboratory Research

- Research safety and security events involving VA laboratory research that are reportable to the NIH OSP, Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), or other Federal entities and not otherwise addressed in this document, are reportable to ORO within 60 calendar days of VA medical facility personnel becoming aware of the occurrence of the event **or** at the same time notification of the event is sent to the other Federal entity, whichever is sooner.
- Security concerns involving the following are reportable to ORO within 5 business days of VA medical facility personnel becoming aware of the occurrence of the concerns: an unauthorized intrusion, physical security breach, break-in, or other significant security incident in an area where VA laboratory or animal research is conducted; or any physical loss or theft of VA research materials or equipment, the loss or theft of which poses risk of harm to people, animals, or the environment.
- Initiation of VA research involving Biosafety Level 3 (BSL-3) containment, select agents or toxins, or dual use research of concern is reportable to ORO within 5 business days of VA medical facility personnel becoming aware of the initiation of such research.

Research Compliance Officer (RCO)-Related

- Appointment, resignation, or substantive change in duties or effort of a VA medical facility RCO is reportable to ORO within 5 business days after the action takes effect.
- RCO auditing responsibilities not being fulfilled is reportable to ORO within 5 business days of identification that the responsibilities were not fulfilled.
- RCO annual quality assurance review determination that events covered by VHA Directive 1058 were not reported to ORO as required is reportable to ORO within 5 business days of the determination.

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DEFINITIONS

Continuing Noncompliance. For purposes of VHA Directive 1058, continuing noncompliance means repeated instances of same or similar noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

Serious Accident, Injury, Illness, or Exposure of a Human. Accidents, injuries, illnesses, or exposures of a human are considered serious if they: (1) require medical attention or treatment, other than basic first aid provided at the site where the accident, injury, illness, or exposure occurred; (2) require time away from work or restricted work activities; (3) require medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; or (4) lead (or could potentially lead) to serious long term health complications or death.

Serious Adverse Event in Human Subjects Research. A serious adverse event (SAE) in human subjects research is an untoward occurrence, whether or not considered related to a subject's participation in research, 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 that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

Serious Noncompliance. For purposes of VHA Directive 1058, serious noncompliance is any failure to adhere to requirements for conducting research that may reasonably be regarded as:

- Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects or others, including their rights to privacy and confidentiality of identifiable private information;
- Presenting a genuine risk of substantive harm to the safety of research personnel who conduct research;
- Presenting a genuine risk of substantive harm to the health or welfare of animals used in research;
- Presenting a genuine risk of substantive reputational harm to VA; or
- Substantively compromising a VA medical facility's Animal Care and Use Program (ACUP), Human Research Protection Program (HRPP), Research Safety and Security Program (RSSP), or research information security processes.

Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) in Human Subjects Research. A UPIRTSO in human subjects research is an incident, experience, or outcome that is unexpected; related or possibly related to participation in the research; **and** indicative of the research placing subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. ***NOTE:*** *For purposes of VHA Directive 1058, an unexpected serious adverse event that is related or possibly related to participation in human subjects research constitutes a UPIRTSO.*

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