

RESEARCH COMPLIANCE REPORTING REQUIREMENTS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive sets forth the requirements for reporting research noncompliance and other select research-related events to research review committees relied upon by Department of Veterans Affairs (VA) medical facilities, to VA medical facility officials, and to the VHA Office of Research Oversight (ORO).

2. SUMMARY OF MAJOR CHANGES: This VHA directive:

a. Provides added flexibility for reviewing and reporting requirements for situations where a VA medical facility relies upon a research review committee that is not operated by a VA entity. Specifically, this directive provides some flexibility for such committees to review and report events described herein in accordance with those committees' own established processes so as to alleviate the need, in many cases, for VA to negotiate changes to those committees' established processes (see paragraph 5.g.(2)).

b. Provides added flexibility with regard to the individuals in VA medical facility senior leadership to whom a VA medical facility Research Compliance Officer (RCO) may report. Specifically, this directive provides flexibility for RCOs to report to someone other than a VA medical facility Director (see paragraph 5.g.(8)(a)).

3. RELATED ISSUES: VA Directive 6500, VA Cybersecurity Program, dated January 23, 2019; VA Handbook 6500, Risk Management Framework for VA Information Systems - Tier 3: VA Information Security Program, dated March 10, 2015; VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017; VHA Directive 1200.01, Research and Development Committee, dated January 24, 2019; VHA Directive 1200.05(1), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019, amended March 3, 2020; VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011; VHA Directive 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019; VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016; VHA Directive 1605.03, Privacy Compliance Assurance Program and Privacy/Freedom of Information Act Continuous Readiness Review and Remediation, dated September 19, 2019; VHA Directive 1058.02, Research Misconduct, dated July 10, 2020; VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020.

4. RESPONSIBLE OFFICE: The Office of Research Oversight (10RO) is responsible for the contents of this directive. Questions may be referred to 202-632-7620.

5. RESCISSIONS: VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 15, 2015, is rescinded.

October 22, 2020

VHA DIRECTIVE 1058.01

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Douglas Bannerman, PhD
Executive Director, Office of Research
Oversight

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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RESEARCH COMPLIANCE REPORTING REQUIREMENTS

1. PURPOSE

This Veterans Health Administration (VHA) directive sets forth requirements for the reporting and review of research noncompliance and other select research-related events involving Department of Veterans Affairs (VA) research. **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7307; 38 Code of Federal Regulations (C.F.R) 16.108(a)(4); 9 C.F.R. § 2.37.

2. BACKGROUND

a. The VHA Office of Research Oversight (ORO) serves as the primary VHA office for advising the Under Secretary for Health and exercising oversight on matters of research compliance. **NOTE:** See *VHA Directive 1058, the Office of Research Oversight, dated March 28, 2017.*

b. VA conducts basic, translational, and clinical research that involves human research participants, protected health information (PHI), and other VA sensitive information (VASI), laboratory animals, and hazardous agents. VA research is subject to the requirements of various laws, regulations, and policies. Such requirements include the appropriate institutional review of research noncompliance; events that may pose a genuine risk of harm to the safety, rights, or welfare of human research subjects or others as a result of participation in VA research; events that may pose a genuine risk of harm to the safety, rights, or welfare of VA personnel conducting VA research; events that may compromise the care and welfare of animals used in VA research; and events that may be indicative of compromised effectiveness of a VA medical facility's research oversight program. Depending on the outcome of the institutional reviews, VA medical facility personnel will be required to report the events to ORO, as well as to other entities within and external to VA.

c. This directive describes requirements for reporting noncompliance and other select events involving VA research to research review committees, VA medical facility officials, and ORO. These requirements do not alter or replace any additional requirements for reporting such noncompliance and other events to other internal or external entities as mandated by law, regulation, policy, or agreement.

3. DEFINITIONS

a. **Adverse Event in Human Subjects Research.** An adverse event in human subjects research is any untoward physical or psychological occurrence in a human subject participating in research, whether or not considered related to the subject's participation in research. **NOTE:** See *paragraph 3.n. for the definition of a Serious Adverse Event in Human Subjects Research.*

b. **Assurance of Compliance (Human Subjects) or Federalwide Assurance.** An Assurance of Compliance (Human Subjects) or Federalwide Assurance (FWA) is a legally binding written document that commits an institution to complying with the

Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects. **NOTE:** *The term “Federalwide Assurance” refers to a specific type of assurance that is approved by the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) for Federalwide use as specified in 38 C.F.R. 16.103(a).*

c. **Continuing Noncompliance.** Continuing noncompliance means repeated instances of noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

d. **Exempt Human Subjects Research.** Exempt human subjects research is research involving human subjects determined to be exempt, as applicable, under 38 C.F.R. 16.104 of the 2018 Federal Policy for the Protection of Human Subjects (“2018 Common Rule”) or under 38 C.F.R. 16.101(b) of the pre-2018 Common Rule. **NOTE:** *Research deemed to be exempt under 38 C.F.R. 16 may not necessarily be exempt from the requirements of other regulations that may apply to the research including regulations promulgated by the U.S. Food and Drug Administration (FDA).*

e. **Exposure.** Exposure means contact with hazardous or toxic materials used in research, including unfixed fluids, tissues and cells derived from humans and other animal sources, infectious agents, hazardous chemicals, toxins, radioactive materials, and radiation sources.

f. **Local Research.** Local research is research approved by the reporting VA medical facility regardless of whether it is conducted on-site or at another institution such as the VA medical facility’s academic affiliate.

g. **Noncompliance.** Noncompliance is any failure to adhere to applicable requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreements, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee.

h. **Protected Health Information.** Protected health information (PHI), as defined by the Health Insurance Portability and Accountability Act (HIPAA), is individually identifiable health information transmitted or maintained in any form or medium by a covered entity, such as VHA. **NOTE:** *For more information, see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.*

i. **Research.** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service

programs may include research activities. Per VHA Directive 1200.05(1), clinical investigations, including clinical investigations as defined under FDA regulations in 21 C.F.R. 50.3, 312.3(b) and § 812.3(h), are considered research. **NOTE:** *Regarding activities involving animals, research means any use of animals in research, testing, or training. For more information, see VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011.* For purposes of this directive, the following activities are not considered research:

(1) Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess or investigate potential public health signals, onsets of disease outbreaks or conditions of public health importance (including trends, signals, risk factors, patterns in diseases or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each Federal agency) in support of intelligence, homeland security, defense or other national security missions.

j. **Research Misconduct.** Research misconduct is fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results. Research misconduct does not include honest error or differences of opinion. **NOTE:** *For more information, see Federal Policy on Research Misconduct 65 Federal Register (FR) 76262 (December 6, 2000) and VHA Directive 1058.02, Research Misconduct, dated July 10, 2020.*

(1) **Fabrication.** Fabrication is making up data or results and recording or reporting them.

(2) **Falsification.** Falsification is manipulating research materials, equipment or processes or changing or omitting data or results such that the research is not accurately represented in the research record.

(3) **Plagiarism.** Plagiarism is the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

k. **Research Review Committee.** A research review committee is any committee or subcommittee designated by a VA medical facility to review, approve and provide oversight of VA research. For purposes of this directive, research review committees include Institutional Animal Care and Use Committees (IACUCs), Institutional Biosafety Committees (IBCs), Institutional Review Boards (IRBs), Research & Development Committees (R&DCs), and Subcommittees on Research Safety (SRS), or the equivalents of any such committees, that are relied upon by a VA medical facility, regardless of whether the committees are operated by a VA or a non-VA entity. **NOTE:** *For more information about the aforementioned committees, see VHA Directive 1200.01, Research and Development Committee, dated January 24, 2019; VHA Directive 1200.05(1), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019, amended March 3, 2020; VHA Directive 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019; and VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011.* In addition to the aforementioned committees, other subcommittees established by the R&DC to review, approve, or provide oversight of VA research are also considered research review committees for purposes of this directive.

l. **Select Agents and Toxins.** Select agents and toxins are regulated biological agents or toxins that could pose a severe threat to public health and safety or to animal or plant health as determined by HHS and the U.S. Department of Agriculture (USDA). **NOTE:** *For more information, see VHA Directive 1200.08, as well as 7 C.F.R. 331, 9 C.F.R. 121 and 42 C.F.R. 73.*

m. **Serious Accident, Injury, Illness or Exposure of a Human.** Serious accidents, injuries, illnesses or exposures of a human are incidents that: (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 to serious long term health complications or death.

n. **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.

o. **Serious Noncompliance.** Serious noncompliance is any failure to adhere to requirements for conducting research that may reasonably be regarded as:

(1) 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;

(2) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of research personnel who conduct research;

(3) Presenting a genuine risk of substantive harm to the health or welfare of animals used in research;

(4) Presenting a genuine risk of substantive reputational harm to VA; or

(5) 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.

p. **Systemic Deficiency.** A systemic deficiency is a fundamental, underlying problem that jeopardizes the effectiveness of a VA medical facility's research protection system(s).

q. **Unanticipated Problem in Human Subjects Research Involving Risks to Subjects or Others.** An unanticipated problem involving risks to subjects or others (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 substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized. **NOTE:** *This description is adapted from guidance published by the HHS Office for Human Research Protections (OHRP). See <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html>. For purposes of this directive, an unexpected SAE that is related or possibly related to participation in human subjects research constitutes a UPIRTSO.*

(1) The term "unexpected" refers to an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

(2) The phrase "related to participation in the research" means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome. The phrase "possibly related to participation in the research" implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome.

r. **VA Personnel.** VA personnel means individuals holding compensated, without compensation (WOC), or Intergovernmental Personnel Act (IPA) appointments with VA.

s. **VA Research.** VA research is research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, other sponsors, or be unfunded. The research must be approved by the R&DC before it is considered VA research and before it can be initiated.

4. POLICY

It is VHA policy that all VA medical facilities that conduct VA research promptly review and report the following events: serious or continuing research noncompliance; events that may pose a genuine risk of harm to the safety, rights, or welfare of human research subjects or others as a result of participation in VA research, including their rights to privacy and confidentiality; events that may pose a genuine risk of harm to the safety, rights, or welfare of VA personnel conducting VA research; events that may compromise the care or welfare of animals used in VA research; and events that may be indicative of compromised effectiveness of the VA medical facility's research review and oversight programs.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health.** The Deputy Under Secretary for Health or designee serves as the Institutional Official (IO) for the VHA Central Office HRPP. The IO is the individual legally authorized as the signatory official for a research program. (See VHA Directive 1200.05(1)).

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Providing assistance to VISN Directors to resolve implementation and compliance challenges in all VA medical facilities conducting research within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive, relevant standards, and applicable regulations.

d. **Executive Director, Office of Research Oversight.** The Executive Director, ORO, is responsible for:

(1) Ensuring ORO reviews VA research-related incidents reported to ORO in accordance with the requirements of this directive.

(2) Ensuring ORO provides oversight of VA medical facility remediation efforts to resolve noncompliance reported to ORO in accordance with the requirements of this directive and noncompliance identified by ORO directly or through other means.

(3) Ensuring notification of Congress and other federal entities of ORO's oversight activities, as appropriate and in accordance with applicable law.

(4) Collaborating with other federal, VA, and VHA offices regarding the interpretation of policies and procedures related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and other matters of research impropriety.

e. **Director, Office of Research Oversight Workgroup.** ORO Workgroup Directors are responsible for ensuring their respective workgroups review and respond, as applicable, to notifications of research-related noncompliance and other events required by this directive to be reported to ORO. (See paragraphs 6-11). **NOTE:** *The appropriate ORO Workgroup contact information for a particular matter can be located on ORO's website at: https://www.va.gov/ORO/Docs/Misc/ORO_Contacts.pdf.*

f. **Veterans Integrated Service Network Director.** VISN Directors are responsible for ensuring that all VA medical facilities conducting research within their respective VISNs comply with this directive.

g. **VA Medical Facility Director.** Each VA medical facility Director whose VA medical facility has a research program is responsible for:

(1) Serving as the IO responsible for the VA medical facility's research program. References to VA medical facility Directors in this directive also apply to the IO for the VHA Central Office HRPP as appropriate. IO responsibilities include but are not limited to:

(a) Ensuring that the VA medical facility's research review and oversight programs function effectively, and that the VA medical facility provides the resources necessary to comply with all requirements applicable to the responsible conduct of research.

(b) Serving as the representative of the VA medical facility to external research regulatory and oversight entities.

(c) Ensuring prompt reporting of events covered by this directive to pertinent federal agencies, such as FDA, OHRP, Occupational Safety and Health Administration (OSHA), the National Institutes of Health Office of Laboratory Animal Welfare (NIH-OLAW), and the head of the sponsoring federal department or agency in accordance with the requirements of those agencies.

(2) Ensuring that documents (e.g., standard operating procedures (SOPs) or memoranda of understanding (MOUs)) establishing the role of a non-VA operated research review committee in the oversight of a VA medical facility's research address the non-VA operated committee's procedures for the review and reporting (including to VA medical facility personnel) of events described in this directive, including timeframes. If the procedures of the non-VA operated committee differ from, or the timeframes exceed those of, this Directive, the Director must consult with the VHA Office of Research & Development (ORD) and the appropriate ORO workgroup (as specified on ORO's website) as to the adequacy of those procedures to protect the interests of VA and those involved in VA research. **NOTE:** *In the event that a non-VA operated research review committee is unable or unwilling to review an event required to be*

reviewed under this directive, the VA medical facility's R&DC will either review the event or designate another applicable VA research review committee to review the event as would otherwise occur if the event were subject to review by a VA-operated research review committee under the requirements of this directive.

(3) Notifying the appropriate ORO workgroup(s) of the initiation of a research program or the substantial alteration of an existing research program that is related to the implementation, suspension, or termination of an ACUP, HRPP or RSSP.

(4) Notifying, or designating an individual to notify, the appropriate ORO workgroup(s) within five (5) business days after receiving written notification of any situation that is reportable to ORO under this directive. **NOTE:** *The VA medical facility Director's report is required regardless of whether the situation has been resolved at the time of the report.*

(5) Notifying, or designating an individual to notify, the appropriate ORO workgroup(s) within five (5) business days of becoming aware of the 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 an event(s) within the scope of this directive.

(6) Ensuring timely implementation of remedial actions to address research noncompliance identified by VA medical facility personnel, ORO, and other entities.

(a) Remedial actions to correct noncompliance identified by ORO or that is otherwise required to be reported to ORO must be completed within 180 calendar days after any determination of noncompliance, except where extenuating circumstances exist (e.g., remediation requires substantial renovation or fiscal expenditure, hiring, or legal negotiations).

(b) Where remedial actions cannot be completed in 180 calendar days, the VA medical facility Director must provide the appropriate ORO workgroup(s) with written justification and a reasonable timeline for completion.

(7) Ensuring accurate and timely completion of the annual VA medical facility Director's Certification of Research Oversight administered by ORO. Certification requirements are updated annually and posted on ORO's SharePoint website at <https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(8) Appointing at least one full-time Research Compliance Officer (RCO) to conduct research informed consent and regulatory audits unless ORD and ORO jointly approve a waiver to permit appointing of a part-time RCO.

(a) The RCO, or a lead RCO if one is designated in instances where a VA medical facility employs more than one RCO, must report directly to and be supervised by either the VA medical facility Director or a senior individual who reports directly to and is supervised by the VA medical facility Director and whose primary responsibilities at the

VA medical facility pertain directly to compliance. Regardless of to whom the RCO (or lead RCO if more than one RCO) directly reports, the RCO must have direct access to the VA medical facility Director for purposes of reporting research noncompliance and other research-related concerns. RCO reports of noncompliance and other research-related concerns to the VA medical facility Director must not be required to be routed “through” or be subject to approval by the Associate Chief of Staff for Research & Development (ACOS/R&D) or any other individual or research review committee in a VA medical facility’s Research Service.

(b) RCO activities must not be determined or managed by the ACOS/R&D or any other individual or research review committee in a VA medical facility’s Research Service.

(c) The VA medical facility Director must ensure that the RCO(s) has the necessary expertise, through education or experience, to fulfill the duties of the RCO position.

(d) The VA medical facility Director must ensure that the RCO(s) has ready access to research program and study documentation so that the RCO can effectively fulfill the responsibilities of the position. This includes access to documentation (e.g., research review committee meeting minutes, study approval letters, investigator study documentation) necessary to fulfill requirements related to auditing of informed consents and study protocols. **NOTE:** *In situations where the VA medical facility relies upon a research review committee operated by a non-VA entity, the VA medical facility Director must ensure that agreements to rely on such committees or other documents (e.g., the committee’s SOPs) require that the VA medical facility’s RCO has access to the committee’s records to the extent necessary for the RCO to fulfill research auditing requirements.*

(e) The VA medical facility Director must report any RCO appointment, resignation, or substantive change in duties to the appropriate ORO workgroup within five (5) business days after the action takes effect.

(9) Ensuring that all research compliance reports from any state or federal oversight entity (including ORO), as well as research accreditation reports/determinations, are provided to the ACOS/R&D, the R&DC, any other relevant research review committees, and the RCO within five (5) business days after receipt. **NOTE:** *This does not include reports from clinical trial study monitors.*

h. **Associate Chief of Staff for Research & Development.** The ACOS/R&D or equivalent is responsible for:

(1) Promptly reviewing and reporting events as specified in this directive.

(2) Alerting, or designating an individual to alert, the VA medical facility Director and ORO by email or telephone within one (1) business day after receiving the initial oral notification of a local research death of a human subject or a human death associated with VA animal or laboratory research and providing relevant information as requested. See paragraphs 7.a.(1), 9.a.(1) and 10.a.(1).

i. **Research Compliance Officer.** The RCO is appointed by the VA medical facility Director and is responsible for:

(1) Auditing VA medical facility research projects including performing annual informed consent and triennial regulatory audits of approved study protocols and other post-approval monitoring activities as specified by ORO. RCO audits must be conducted in accordance with a written audit plan or SOP that describes the RCO's auditing process, including procedures for planning and executing audits, procedures for soliciting study investigators' responses to preliminary audit findings and timelines for providing all audit results (regardless of findings) to the relevant research review committees, including the R&DC. Examples of audit plans can be found on ORO's SharePoint website located at:

<https://dvagov.sharepoint.com/sites/VACOVHAORO/RCO/default.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

(2) Informing the VA medical facility Director and applicable research review committees about research compliance concerns.

(3) Performing additional research oversight duties assigned by his or her supervisor, including assisting in compliance education to investigators, research staff and research committee staff/members; accreditation activities; the completion of the VA medical facility Director's Certification of Research Oversight; and ad hoc audits of individual studies or programs. Such duties must not conflict with or delay completion of the RCO's research audit responsibilities. RCOs must not serve as voting members of research review committees; however, RCOs may serve as consultants to research review committees and may attend meetings by invitation of a committee or as specified by local research committee SOPs.

j. **VA Medical Facility Research Integrity Officer.** The VA medical facility Research Integrity Officer (RIO) is responsible for notifying the VA medical facility Director and the ORO Research Misconduct Officer when the RIO receives a formal allegation of research misconduct. Such notification by the RIO must be made within one (1) business day of the RIO's receipt of the formal allegation. If the ACOS/R&D is not the designated RIO for a VA medical facility and is not named in the allegation as a respondent, the RIO must also notify the ACOS/R&D of the RIO's receipt of the allegation within one (1) business day. See VHA Directive 1058.02.

k. **Chair, VA Medical Facility Research Review Committee.** The Chair of a VA medical facility research review committee is responsible for:

(1) Ensuring the committee's prompt review and reporting of events as required by this directive and applicable federal regulations and policies pertaining to VA research.

(2) Within one (1) business day after receiving written notification of the local research death of a human subject or a human death associated with VA animal or laboratory research, assessing and documenting whether any actions are warranted to eliminate apparent immediate hazards to subjects or others and, if so, initiating those

actions. This may be delegated to another qualified committee voting member. See paragraphs 7.a.(2), 9.a.(2) and 10.a.(2).

(3) Within five (5) business days after receiving written notification of an apparent UPIRTSO, or of a serious accident, injury, illness, or exposure, assessing and documenting whether any actions are warranted to eliminate hazardous conditions or apparent immediate hazards to human research subjects or others and, if so, initiating those actions. This may be delegated to another qualified voting committee member. See paragraphs 7.b.(1), 9.b.(1) and 10.b.(1).

I. **VA Personnel.** VA personnel are responsible for promptly reporting research-related events, in good faith, as required by this directive and cooperating in good faith with proceedings to review the events. This includes:

(1) Reporting systemic deficiencies in writing to the VA medical facility's R&DC in accordance with paragraph 6.a.

(2) Providing oral notification to the appropriate IRB of Record and ACOS/R&D immediately upon becoming aware of any local research death of a human subject in accordance with paragraph 7.a. VA personnel must also provide follow-up written notification to the IRB within one (1) business day.

(3) Providing written notification to the appropriate IRB of Record within five (5) business days after becoming aware of an apparent UPIRTSO involving VA research in accordance with paragraph 7.b.

(4) Providing written notification to the appropriate IRB of Record within five (5) business days after becoming aware of any apparent serious and/or continuing noncompliance with applicable laws, regulations, policies, and agreements in accordance with paragraph 7.c.

(5) Providing oral notification to the appropriate IACUC of Record and ACOS/R&D immediately upon becoming aware of any human death that may be the result of working with, caring for, or having other contact with animals in accordance with paragraph 9.a. VA personnel must also provide follow-up written notification to the IACUC within one (1) business day.

(6) Providing written notification to the appropriate IACUC of Record within five (5) business days after becoming aware of a serious accident, injury, illness, or exposure of a human (not involving a death) that may be the result of working with, caring for, or having other contact with research animals in accordance with paragraph 9.b.

(7) Providing written notification to the appropriate IACUC of Record within five (5) business days after becoming aware of any event that is apparently reportable to NIH-OLAW in accordance with paragraph 9.c.

(8) Providing written notification to the appropriate IACUC of Record within five (5) business days after becoming aware of any apparent serious or continuing

noncompliance with applicable laws, regulations, policies, and agreements involving VA animal research not covered by paragraph 9.c in accordance with paragraph 9.d.

(9) Providing oral notification to the SRS and ACOS/R&D immediately upon becoming aware of any human death that may be the result of work (or other activity) in a VA research laboratory in accordance with paragraph 10.a. VA personnel must also provide follow-up written notification to the SRS within one (1) business day.

(10) Providing written notification to the SRS within five (5) business days after becoming aware of any apparent serious accident, injury, illness, or exposure (other than those that result in death) that may be the result of a research activity in a VA research laboratory in accordance with paragraph 10.b.

(11) Providing written notification to the SRS within five (5) business days after becoming aware of any apparent serious or continuing noncompliance with applicable laws, regulations, policies, and agreements pertaining to the conduct of VA laboratory research in accordance with paragraph 10.c.

(12) Providing written notification to the IRB, IACUC, SRS, or R&DC, as appropriate, within five (5) business days after becoming aware of any apparent information security or privacy incidents as indicated in paragraph 11.a.

(13) Reporting research misconduct, as defined in paragraph 3.j., in accordance with the requirements set forth in VHA Directive 1058.02.

NOTE: *VA personnel who choose to avail themselves of an anonymous reporting mechanism (regardless of whether the system is oral- or written-based) to report an event addressed in this directive that would otherwise be required to be reported in writing to a research review committee, will be considered to have fulfilled their reporting responsibilities as set forth in this directive.*

6. SYSTEMIC DEFICIENCIES

a. **Systemic Deficiencies.** VA personnel must ensure written notification is provided to the VA medical facility's R&DC within five (5) business days after becoming aware of any apparent systemic deficiency that has a reasonable likelihood of substantially compromising the VA medical facility's research protection programs (ACUP, HRPP and RSSP) or information security processes, including persistent failure by any research review committee relied upon by the VA medical facility to adhere to the requirements governing VA research. **NOTE:** *In circumstances where the apparent systemic deficiency does not pertain to the operation of a research review committee, the R&DC will delegate the review of the concern to the research review committee with primary programmatic oversight (i.e., to the IRB for HRPP-related systemic deficiencies, the IACUC for ACUP-related systemic deficiencies and the SRS for RSSP-related systemic deficiencies). Under such circumstances, the research review committee with primary programmatic oversight will fulfill the responsibilities described below, as well as fulfill any other applicable requirements set forth in this directive. The outcome of the committee's review (if not reviewed by the R&DC) must be communicated to the R&DC.*

b. In response to the written notification, the R&DC or delegated committee must:

(1) Review the written notification at its next convened meeting, not to exceed 30 calendar days after the date of written notification. **NOTE:** *Incidents covered by this subparagraph may call for immediate attention and require the committee to convene an emergency session prior to its next scheduled meeting.*

(2) Determine and document within 60 calendar days of the convened committee's initial review:

(a) whether an actual systemic deficiency exists that could substantially compromise the VA medical facility's research protection programs or information security processes, as applicable; and if so,

(b) what, if any, remedial actions are needed to ensure the effectiveness of research protection programs or information security processes, as applicable.

c. If the committee determines that an actual systemic deficiency exists per paragraph 6.b.(2)(a), it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 6.b.(2)(a) and (b) within five (5) business days after making those determinations.

d. The VA medical facility Director, or designee, must report the committee's determinations to the appropriate ORO workgroup within five (5) business days after receiving the committee's written notification under paragraph 6.c.

7. NON-EXEMPT HUMAN SUBJECTS RESEARCH

a. **Deaths of Human Subjects Participating in VA Non-Exempt Human Subjects Research.** VA personnel must ensure oral notification is provided to the appropriate IRB of Record and ACOS/R&D immediately (i.e., within one hour) upon becoming aware of any local research death of a human subject that is believed to be both unexpected and related or possibly related to participation in a VA non-exempt human subjects research study. VA personnel must also ensure that follow-up written notification is provided to the appropriate IRB of Record within one (1) business day of becoming aware of such a death.

(1) The ACOS/R&D, or designee, must alert the VA medical facility Director and appropriate ORO workgroup by email or telephone within one (1) business day after receiving the initial oral notification and provide relevant information as requested.

(2) Within one (1) business day after receiving written notification of the death, the IRB Chair or another qualified IRB voting member must assess and document whether any actions are warranted to eliminate apparent immediate hazards to subjects and, if so, initiate those actions.

(3) In response to the written notification, the IRB must (except as provided for in paragraph 7.a.(6)):

(a) Review the written notification, the immediate hazard assessment of the IRB Chair or other qualified IRB voting member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of written notification.

NOTE: *Incidents covered by this paragraph may call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting.*

(b) Determine and document within 30 calendar days of the convened IRB's initial review:

1. whether the death was both unexpected and related or possibly related to participation in the research; and

2. what, if any, protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not investigators must notify or solicit renewed/revised consent from previously enrolled subjects; and if so, when such notification or consent must take place and how it must be documented.

(4) The IRB must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 7.a(3)(b)1. and 2. within five (5) business days after making those determinations.

(5) The VA medical facility Director, or designee, must report the IRB's determinations to the appropriate ORO workgroup within five (5) business days after receiving the IRB's written notification under paragraph 7.a.(4).

(6) If the IRB is unable to make a determination on the matter within 30 calendar days of the convened IRB's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IRB must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due. The VA medical facility Director, or designee, must notify the appropriate ORO workgroup within five (5) business days after receiving the IRB's written notification that it is unable to make a determination.

b. Apparent UPIRTSO in VA Non-Exempt Human Subjects Research. VA personnel must ensure written notification is provided to the appropriate IRB of Record within five (5) business days after becoming aware of an apparent UPIRTSO involving a VA non-exempt human subjects research study. **NOTE:** *In accordance with paragraph 3.q., an apparent UPIRTSO is an apparent incident, experience or outcome that is: unexpected and related or possibly related to participation in the research and indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized. For purposes of this directive, an apparent unexpected SAE that is related or possibly related to participation in human subjects research constitutes an apparent UPIRTSO.*

(1) Within five (5) business days after receiving written notification of an apparent UPIRTSO, the IRB Chair or another qualified IRB voting member must assess and

document whether any actions are warranted to eliminate apparent immediate hazards to subjects and, if so, initiate those actions.

(2) In response to the written notification, the IRB must (except as provided for in paragraph 7.b.(5)):

(a) Review the written notification, the immediate hazard assessment of the IRB Chair or other qualified IRB voting member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of written notification.

NOTE: *Incidents covered by this paragraph may call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting.*

(b) Determine and document within 30 calendar days of the convened IRB's initial review:

1. whether the incident, experience, or outcome was unexpected and related to or possibly related to participation in the research and indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized (i.e., whether the incident, experience or outcome constituted an actual UPIRTSO); and

2. what, if any, protocol or informed consent modifications are warranted. If modifications are warranted, the convened IRB must determine and document whether or not investigators must notify or solicit renewed or revised consent from previously enrolled subjects; and if so, when such notification or consent must take place and how it must be documented.

(3) If the IRB determines that the incident, experience, or outcome constituted an actual UPIRTSO per paragraph 7.b.(2)(b)1., it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 7.b.(2)(b)1. and 2. within five (5) business days after making those determinations.

(4) The VA medical facility Director, or designee, must report the IRB's determinations to the appropriate ORO workgroup within five (5) business days after receiving the IRB's written notification under paragraph 7.b.(3).

(5) If the IRB is unable to make a determination on the matter within 30 calendar days of the convened IRB's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IRB must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due. The VA medical facility Director, or designee, must notify the appropriate ORO workgroup within five (5) business days after receiving the IRB's written notification that it is unable to make a determination.

c. **Apparent Serious or Continuing Noncompliance Involving VA Non-Exempt Human Subjects Research.** VA personnel must ensure that the appropriate IRB of Record is notified, in writing, within five (5) business days after becoming aware of any apparent serious or continuing noncompliance with applicable laws, regulations,

policies, and agreements pertaining to non-exempt human subjects research. This includes, but is not limited to, serious or continuing noncompliance with the Common Rule, local VA medical facility policies and SOPs related to human subjects research, if developed, IRB-approved protocols, and the requirements or determinations of the IRB.

NOTE: *Events addressed in paragraph 11 of this directive that involve non-exempt human subjects research may also constitute apparent serious or continuing noncompliance under this paragraph.*

(1) In response to the written notification, the IRB must:

(a) Review the written notification at its next convened meeting, not to exceed 30 calendar days after the date of written notification. **NOTE:** *Incidents covered by this paragraph may call for immediate attention and require the IRB to convene an emergency session prior to its next scheduled meeting.*

(b) Determine and document within 60 calendar days of the convened IRB's initial review:

1. whether or not serious or continuing noncompliance actually occurred; and if so,
2. what, if any, remedial actions are needed to resolve present noncompliance or prevent future noncompliance.

(2) If the IRB determines that serious or continuing noncompliance actually occurred, it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 7.c.(1)(b)1. and 2. within five (5) business days after making those determinations.

(3) The VA medical facility Director, or designee, must report the IRB's determinations to the appropriate ORO workgroup within five (5) business days after receiving the IRB's written notification under paragraph 7.c.(2).

d. Other Events Involving VA Human Research Protection Programs Reportable to ORO. The IRB must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing within five (5) business days of becoming aware of any of the following, after which the VA medical facility Director, or designee, must notify ORO within five (5) business days:

(1) The suspension or early termination of a non-exempt VA human research study by the IRB or 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, if such suspension or termination is not otherwise reportable per the requirements of paragraphs 7.a., b. or c. **NOTE:** *The notification of suspension or early termination of a non-exempt VA human research study by the IRB or IO must include a statement of the reason for the IRB's or IO's action.*

(2) Any change in the status (e.g., expiration, restriction, suspension or termination) of the facility's FWA.

(3) The termination or non-renewal of the HHS-OHRP registration of any IRB relied upon by the VA medical facility for review and oversight of VA research.

(4) Failure of a VA medical facility to achieve or maintain full accreditation of its HRPP if such accreditation is sought by the VA medical facility.

NOTE: For other ORO reporting requirements pertaining to FWAs, IRBs designated on FWAs, and MOUs for reliance on IRBs designated on FWAs, see VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020. Other events not addressed in paragraph 7 (e.g., an adverse event that is not possibly related to research, an isolated event of less than serious noncompliance) may be required to be reviewed pursuant to other applicable laws, regulations, policies or agreements. Such reviews must be conducted in accordance with all applicable requirements.

8. EXEMPT HUMAN SUBJECTS RESEARCH

For an event that would otherwise be required by paragraph 7 of this directive to be reported to and reviewed by an IRB, but that is associated with exempt human subjects research that falls under the oversight of a committee other than an IRB, the event must instead be reported to the committee with primary oversight responsibility for the research (e.g., R&DC, R&DC-designated subcommittee for the oversight of exempt human subjects research). Under the aforementioned circumstances, responsibilities ascribed by paragraph 7 to the IRB for reviewing and acting upon such events shall instead be carried out by the committee with primary oversight responsibility for the research. All other associated reporting and review requirements for such events must be carried out as specified in paragraph 7.

9. ANIMAL RESEARCH

a. **Human Deaths Associated with VA Animal Research.** VA personnel must ensure oral notification is provided to the appropriate IACUC of Record and ACOS/R&D immediately (i.e., within one hour) upon becoming aware of any human death that may be the result of working with, caring for, or having other contact with animals used in VA research. VA personnel must also ensure that follow-up written notification is provided to the appropriate IACUC of Record within one (1) business day of becoming aware of such a death.

(1) The ACOS/R&D, or designee, must alert the VA medical facility Director and the appropriate ORO workgroup by email or telephone within one (1) business day after receiving the initial oral notification and provide relevant information as requested.

(2) Within one (1) business day after receiving written notification of the death, the IACUC Chair or another qualified IACUC voting member must assess and document whether any actions are warranted to eliminate apparent immediate hazards to

individuals working, or who may have incidental contact, with animals in VA research and, if so, initiate those actions.

(3) In response to the written notification, the IACUC must (except as provided for in paragraph 9.a.(6)):

(a) Review the written notification, the immediate hazard assessment of the IACUC Chair or other qualified IACUC voting member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of written notification.

NOTE: *Incidents covered by this paragraph may call for immediate attention and require the IACUC to convene an emergency session prior to its next scheduled meeting.*

(b) Determine and document within 30 calendar days of the convened IACUC's initial review:

1. whether the death was the result of working with, caring for, or having other contact with animals used in VA research; and

2. what, if any, protocol or programmatic changes are warranted.

(4) The IACUC must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 9.a.(3)(b)1. and 2. within five (5) business days after making those determinations.

(5) The VA medical facility Director, or designee, must report the IACUC's determinations to the appropriate ORO workgroup within five (5) business days after receiving the IACUC's written notification under paragraph 9.a.(4), with copies to the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and the ORD Chief Veterinary Medical Officer (ORD CVMO).

(6) If the IACUC is unable to make a determination on the matter within 30 calendar days of the convened IACUC's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IACUC must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due. The VA medical facility Director, or designee, must notify the appropriate ORO workgroup within five (5) business days after receiving the IACUC's written notification that it is unable to make a determination.

b. VA Animal Research Events Involving Serious Accident, Injury, Illness or Exposure of a Human. VA personnel must ensure written notification is provided to the appropriate IACUC of Record within five (5) business days after becoming aware of a serious accident, injury, illness or exposure of a human (not involving a death) that may be the result of working with, caring for, or having other contact with research animals.

(1) Within five (5) business days after receiving written notification of the accident, injury, illness or exposure, the IACUC Chair or another qualified IACUC voting member must assess and document whether any immediate actions are warranted to eliminate

apparent immediate hazards to individuals working, or who may have incidental contact, with animals in VA research and, if so, initiate those actions.

(2) In response to the written notification, the IACUC must (except as provided for in paragraph 9.b.(5)):

(a) Review the written notification, the immediate hazard assessment of the IACUC Chair or other qualified IACUC voting member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of the written notification. **NOTE:** *Incidents indicative of a significant risk to the safety of research personnel, or others who may have incidental contact with VA research animals, may call for immediate attention and require the IACUC to convene an emergency session prior to the next scheduled meeting.*

(b) Determine and document within 30 calendar days of the convened IACUC's initial review:

1. whether a serious accident, injury, illness or exposure of a human (not involving a death) resulting from working with, caring for, or having other contact with research animals occurred; and

2. what, if any, protocol or programmatic changes are warranted.

(c) Ensure that the SRS has been notified in writing of those incidents involving a serious accident, injury, illness or exposure of a human that may be the result of working with, caring for, or having other contact with research animals.

(3) If the IACUC determines that a serious accident, injury, illness, or exposure of a human occurred per paragraph 9.b.(2)(b)1., it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 9.b.(2)(b)1. and 2. within five (5) business days after making those determinations.

(4) The VA medical facility Director, or designee, must report the IACUC's determinations to the appropriate ORO workgroup within five (5) business days after receiving the IACUC's written notification under paragraph 9.b.(3), with copies to AAALAC International and the ORD CVMO.

(5) If the IACUC is unable to make a determination on the matter within 30 calendar days of the convened IACUC's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the IACUC must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due. The VA medical facility Director, or designee, must notify the appropriate ORO workgroup within five (5) business days after receiving the IACUC's written notification that it is unable to make a determination.

c. **VA Animal Research Events Reportable to HHS National Institutes of Health Office of Laboratory Animal Welfare.** VA personnel must ensure that the appropriate IACUC of Record is notified in writing within five (5) business days after becoming

aware of any event that is apparently reportable to HHS NIH-OLAW per NIH Notice No. NOT-OD-05-034, *Guidance on Prompt Reporting to OLAW under the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals*. See <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>. This includes serious or continuing noncompliance with the Animal Welfare Act and Regulations, PHS Policy on Humane Care and Use of Laboratory Animals, and IACUC-approved protocols, as well as unapproved departures from the *Guide for the Care and Use of Laboratory Animals*.

(1) In response to the written notification, the IACUC must:

(a) Review the written notification at its next convened meeting, not to exceed 30 calendar days after the date of the written notification. **NOTE:** *Incidents indicative of a significant risk to the safety of research personnel or welfare of live animals used in research may call for immediate attention and require the IACUC to convene an emergency session prior to the next scheduled meeting.*

(b) Determine and document within 60 calendar days of the convened IACUC's initial review:

1. whether or not an event reportable to NIH-OLAW involving VA research has occurred; and

2. what, if any, protocol or programmatic changes are warranted.

(2) If the IACUC determines that an event reportable to NIH-OLAW has occurred, it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 9.c.(1)(b)1. and 2. within five (5) business days after making those determinations.

(3) The VA medical facility Director, or designee, must report the IACUC's determinations to the appropriate ORO workgroup within five (5) business days after receiving the IACUC's written notification under paragraph 9.c.(2), with copies to AAALAC International and the ORD CVMO.

d. Other Apparent Serious or Continuing Noncompliance Involving VA Animal Research. VA personnel must ensure that the appropriate IACUC of Record is notified in writing within five (5) business days after becoming aware of any apparent serious or continuing noncompliance involving VA animal research not covered by paragraph 9.c. This may include serious or continuing noncompliance with VHA Handbook 1200.07, local policies and SOPs if developed, and the requirements or determinations of the IACUC, insofar as such apparent noncompliance is not reportable to NIH-OLAW (and, correspondingly, is not covered by paragraph 9.c. above).

(1) In response to the written notification, the IACUC must:

(a) Review the written notification at its next convened meeting, not to exceed 30 calendar days after the date of the written notification. **NOTE:** *Incidents indicative of a*

significant risk to the safety of research personnel or welfare of live animals used in research may call for immediate attention and require the IACUC to convene an emergency session prior to the next scheduled meeting.

(b) Determine and document within 60 calendar days of the convened IACUC's initial review:

1. whether or not serious or continuing noncompliance actually occurred; and if so,
2. what, if any, actions are needed to remediate present noncompliance or prevent future noncompliance.

(2) If the IACUC determines that serious or continuing noncompliance actually occurred, it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 9.d.(1)(b)1. and 2. within five (5) business days after making those determinations.

(3) The VA medical facility Director, or designee, must report the IACUC's determinations to the appropriate ORO workgroup within five (5) business days after receiving the IACUC's written notification under paragraph 9.d.(2), with copies to AAALAC International and the ORD CVMO.

e. Other Events Involving VA Animal Care and Use Programs Reportable to ORO. The IACUC must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing within five (5) business days of becoming aware of any of the following, after which the VA medical facility Director, or designee, must notify ORO and the ORD CVMO within five (5) business days:

(1) The suspension or early termination by the IACUC 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, if such suspension or termination is not otherwise reportable per the requirements of paragraphs 9.a., b., c., or d. **NOTE:** *The notification of suspension or early termination of a VA study by the IACUC or IO must include a statement of the reason for the IACUC's or IO's action.*

(2) Substantial revisions to the PHS Animal Welfare Assurance that covers the VA medical facility's ACUP, regardless of whether the Assurance is held by the VA medical facility or an academic affiliate.

(3) Any change in the status (e.g., expiration, termination) of the Assurance that covers the VA medical facility's ACUP.

(4) 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 AAALAC International.

10. RESEARCH LABORATORY SAFETY AND SECURITY

a. **Human Deaths Associated with VA Laboratory Research.** VA personnel must ensure oral notification is provided to the SRS and ACOS/R&D immediately (i.e., within one hour) upon becoming aware of any human death that may be the result of work (or other activity) in a VA research laboratory or dedicated VA research area (e.g., research specimen storage area), or involving VA-approved research conducted in a research laboratory or dedicated research area owned or operated by a non-VA entity. VA personnel must also ensure that follow-up written notification is provided to the SRS within one (1) business day of becoming aware of such a death. **NOTE:** *This paragraph does not cover deaths of human subjects participating in VA human subjects research. Such events are addressed in paragraphs 7.a. and 8 of this directive.*

(1) The ACOS/R&D, or designee, must alert the VA medical facility Director and ORO by email or telephone within one (1) business day after receiving the initial oral notification and provide relevant information as requested.

(2) Within one (1) business day after receiving written notification of the death, the SRS Chair or another qualified SRS voting member must assess and document whether any actions are warranted to eliminate apparent immediate hazards or hazardous conditions and, if so, initiate those actions.

(3) In response to the written notification, the SRS must (except as provided for in paragraph 10.a.(6)):

(a) Review the written notification, the immediate hazard assessment of the SRS Chair or other qualified SRS voting member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of written notification. **NOTE:** *Incidents covered by this paragraph may call for immediate attention and require the SRS to convene an emergency session prior to its next scheduled meeting.*

(b) Determine and document within 30 calendar days of the convened SRS' initial review:

1. whether the death was the result of hazards used in, or hazardous conditions related to, the conduct of VA research; and

2. what, if any, protocol or programmatic changes are warranted.

(4) The SRS must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 10.a.(3)(b)1. and 2. within five (5) business days after making those determinations.

(5) The VA medical facility Director, or designee, must report the SRS' determinations to the appropriate ORO workgroup within five (5) business days after receiving the SRS' written notification under paragraph 10.a.(4).

(6) If the SRS is unable to make a determination on the matter within 30 calendar days of the convened SRS' initial review due to insufficient information or due to a lack of sufficient time to complete its review, the SRS must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due. The VA medical facility Director, or designee, must notify the appropriate ORO workgroup within five (5) business days after receiving the SRS' written notification that it is unable to make a determination.

b. Research Laboratory Events Reportable Under Applicable Federal Standards or Involving Serious Accident, Injury, Illness, or Exposure of a Human Involving VA Laboratory Research. VA personnel must ensure written notification is provided to the SRS within five (5) business days after becoming aware of any apparent serious accident, injury, illness, or exposure of a human (other than those that result in death) that may be the result of a research activity (1) in a VA research laboratory or dedicated VA research area (e.g., research specimen storage area), (2) in a research laboratory or dedicated research area owned or operated by a non-VA entity, or (3) that requires research laboratory safety events to be reportable under applicable federal requirements, including OSHA and relevant VHA policy requirements.

(1) Within five (5) business days after receiving written notification of the accident, injury, illness, or exposure, the SRS Chair or another qualified SRS voting member must assess and document whether any actions are warranted to eliminate apparent immediate hazards or hazardous conditions and, if so, initiate those actions.

(2) In response to the written notification, the SRS must (except as provided for in paragraph 10.b.(5)):

(a) Review the written notification, the immediate hazard assessment of the SRS Chair or other qualified SRS voting member, and the actions taken to date at its next convened meeting, not to exceed 30 calendar days after the date of notification. **NOTE:** *Incidents indicative of a significant risk to the safety of research personnel or the environment may call for immediate attention and require the SRS to convene an emergency session prior to the next scheduled meeting.*

(b) Determine and document within 30 calendar days of the convened SRS' initial review:

1. whether a serious accident, injury, illness, or exposure of a human (not involving a death) resulted from work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area);

2. whether a research safety event reportable under applicable federal requirements has occurred; and

3. what, if any, protocol or programmatic changes are warranted.

(3) If the SRS determines that a serious accident, injury, illness, or exposure of a human resulted per paragraph 10.b.(2)(b)1. or a reportable research safety event

occurred per paragraph 10.b.(2)(b)2., it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 10.b.(2)(b)1., 2. and 3. within five (5) business days after making those determinations.

(4) The VA medical facility Director, or designee, must report the SRS' determinations to the appropriate ORO workgroup within five (5) business days after receiving the SRS' written notification under paragraph 10.b.(3).

(5) If the SRS is unable to make a determination on the matter within 30 calendar days of the convened SRS' initial review due to insufficient information or due to a lack of sufficient time to complete its review, the SRS must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing no later than five (5) business days after the determination was due. The VA medical facility Director, or designee, must notify the appropriate ORO workgroup within five (5) business days after receiving the SRS' written notification that it is unable to make a determination.

c. Apparent Serious or Continuing Noncompliance Involving VA Laboratory Research. VA personnel must ensure that the SRS is notified in writing within five (5) business days after becoming aware of any apparent 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, VA research security requirements, local policies and SOPs if developed, SRS-approved protocols, and the requirements or determinations of the SRS.

(1) In response to the written notification, the SRS must:

(a) Review the written notification at its next convened meeting, not to exceed 30 calendar days after the date of the written notification. ***NOTE: Incidents indicative of a significant risk to the safety of research personnel or the environment may call for immediate attention and require the SRS to convene an emergency session prior to the next scheduled meeting.***

(b) Determine and document within 60 calendar days of the convened SRS' initial review:

1. whether or not serious or continuing noncompliance actually occurred; and if so,
2. what, if any, actions are needed to remediate present noncompliance or prevent future noncompliance.

(2) If the SRS determines that serious or continuing noncompliance actually occurred, it must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations under paragraphs 10.c.(1)(b)1. and 2. within five (5) business days after making those determinations.

(3) The VA medical facility Director, or designee, must report the SRS' determinations to the appropriate ORO workgroup within five (5) business days after receiving the SRS' written notification under paragraph 10.c.(2).

d. Other Events Involving VA Research Safety and Security Reportable to ORO. The SRS must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing within five (5) business days of becoming aware of any of the following, after which the VA medical facility Director, or designee, must notify ORO within five (5) business days:

(1) The suspension or early termination of a VA study by the SRS 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, if such a suspension or termination is not otherwise reportable per the requirements of paragraphs 10 a., b., or c. **NOTE:** *The notification of suspension or early termination of a VA study by the SRS or IO must include a statement of the reason for the SRS' or IO's action.*

(2) The expiration or termination of the NIH Office of Science Policy registration of any IBC relied upon by the VA medical facility for review and oversight of the facility's research.

(3) A security concern, if such a concern is not otherwise reportable per the requirements of paragraphs 10 a., b., or c., involving:

(a) 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;

(b) 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 (see <https://www.phe.gov/s3/dualuse/Pages/default.aspx>) is conducted; or

(c) Any physical loss or theft of VA research materials or equipment, the loss or theft of which poses risk of harm.

NOTE: *For events described in paragraph 10 that pertain to VA research subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (<https://osp.od.nih.gov/biotechnology/nih-guidelines/>), reporting to and review by the IBC with oversight of the research must occur contemporaneously with the reporting to and review by the SRS. The results of the IBC's review must be reported to the SRS.*

NOTE: *Per VHA Directive 1200.08, the SRS must carefully review all incidents involving research laboratory security and determine if any changes in the Research Security Plan or other local policies are necessary to prevent future occurrences.*

11. RESEARCH INFORMATION SECURITY AND PRIVACY

a. **Information Security and Privacy Incidents Involving VA Research.** VA personnel must ensure written notification is provided to the IRB, IACUC and/or SRS, as appropriate, within five (5) business days after becoming aware of any apparent information security or privacy incidents related to VA research, including any inappropriate access, loss, theft, noncompliant storage, transmission, removal or destruction of PHI or other VA research information deemed to be sensitive; theft, loss or noncompliant destruction of equipment containing PHI or other VA research information deemed to be sensitive; or uses and disclosures of PHI for research without legal authority (e.g., without a valid authorization or waiver of authorization). If the incident is not relevant to at least one of these committees, VA personnel must notify the R&DC instead, which must either review the incident or assign review of the incident to another responsible research review committee, if and as appropriate. ***NOTE: The reporting requirements set forth in paragraph 11 do not supersede applicable reporting requirements set forth in other VA and VHA policies (including the VA National Rules of Behavior and VA Handbook 6500, Risk Management Framework for VA Information Systems—Tier 3: VA Information Security Program, dated March 10, 2015) with regard to reporting such incidents to an individual's supervisor and the applicable Information System Security Officer (ISSO), Privacy Officer (PO) or Records Management official. VA policy requires an individual's immediate reporting of any suspected or actual information security or privacy incidents to their applicable local ISSO, PO, Records Management official and supervisor upon discovery.***

(1) In response to the written notification, the relevant review committee(s) must:

(a) Review the incident in accordance with requirements set forth in paragraphs 7.b., 7.c., 8, 9.c., 9.d., or 10.c. of this directive, as applicable.

(b) Consult with the ISSO, PO or Records Management official, as applicable, when determining whether and what remedial actions are warranted.

(2) Committee determinations must be reported, if required by and in accordance with paragraphs 7.b., 7.c., 8, 9.c., 9.d. or 10.c. of this directive, as applicable.

b. **Other Information Security and Privacy Incidents Involving VA Research Reportable to ORO.** The VA medical facility Director, or designee, must report to ORO the suspension or early termination of a VA study due to research information security or privacy concerns, if such a suspension or termination is not otherwise reportable per other requirements set forth in this directive. The VA medical facility Director must report the suspension or termination to the appropriate ORO workgroup within five (5) business days after taking or becoming aware of such action(s).

12. TRAINING

There are no formal training requirements associated with this directive.

13. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created pursuant to this directive must be managed per the National Archives and Records Administration (NARA) approved records schedules found in VHA RCS 10-1. The disposition schedule for research records are found in chapter 8 of RCS 10-1. Any questions regarding any aspect of records management should be directed to the VA medical facility Records Manager or Records Liaison.

14. REFERENCES

- a. 7 U.S.C. 2131 et seq.
- b. 9 C.F.R. Part 2.
- c. 38 C.F.R. Part 16.
- d. 45 C.F.R. Part 164.
- e. VA Directive 6500, VA Cybersecurity Program, dated January 23, 2019.
- f. VA Directive 6609, Mailing of Sensitive Personal Information, dated May 20, 2011.
- g. VA Handbook 6500, Risk Management Framework for VA Information Systems—Tier 3: VA Information Security Program, dated March 10, 2015.
- h. VHA Directive 1058, The Office of Research Oversight, dated March 28, 2017.
- i. VHA Directive 1058.02, Research Misconduct, dated July 10, 2020.
- j. VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020.
- k. VHA Directive 1058.04, Debarments and Suspensions Based on Research Impropriety in VA Research, dated November 14, 2019.
- l. VHA Directive 1200, Research and Development Program, dated May 13, 2016.
- m. VHA Directive 1200.01, Research and Development Committee, dated January 24, 2019.
- n. VHA Directive 1200.05(1), Requirement for the Protection of Human Subjects in Research, dated January 7, 2019, amended March 3, 2020.
- o. VHA Directive 1200.08, Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019.
- p. VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

q. VHA Directive 1605.02, Minimum Necessary Standard for Access, Use, Disclosure, and Requests for Protected Health Information, dated April 4, 2019.

r. VHA Directive 1605.03, Privacy Compliance Assurance Program and Privacy/Freedom of Information Act (FOIA) Continuous Readiness Review and Remediation, dated September 19, 2019.

s. VHA Handbook 1200.07, Use of Animals in Research, dated November 23, 2011.

t. VHA Office of Research Oversight Contacts, last updated February 11, 2019, available online at https://www.va.gov/ORO/Docs/Misc/ORO_Contacts.pdf.

u. U.S. Public Health Service, Policy on Humane Care and Use of Laboratory Animals, last updated 2015, available online at <http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>.