

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

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REPORTABLE EVENTS RELATED TO ANIMAL RESEARCH, RESEARCH LABORATORY
SAFETY & SECURITY, AND RESEARCH INFORMATION PROTECTION

OBJECTIVE:

- To establish a documented process for reporting and responding to serious unanticipated problems, unanticipated serious adverse events, and apparent serious or continuing noncompliance.
- To assure a safe and compliant environment with respect to animal research, research laboratory safety and security, and research information protection.
- To educate research staff to assure they understand applicable regulations, guidelines, policies and procedures

SCOPE & POLICY:

Noncompliance and/or unanticipated events concerning human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security are to be reported to VA research facility's relevant research review committees, ACOS for Research and facility Director. Relevant committees will determine if the event will be reported to higher levels in the organization and will direct such reporting.

In May 2010, the VHA Office of Research Oversight (ORO) issued VHA Handbook 1058.01, "Research Compliance Reporting Requirements" that set forth the requirements for reporting certain research events to facility officials, relevant research review committees, and the ORO. The handbook identifies research events that must be reported to facility entities, ORO Regional Offices, and ORO Central Office and the methods, timelines and specifics for the reports. The Handbook also delineates the reporting requirements for apparent serious or continuing noncompliance found through Research Compliance Officer (RCO) audits vs. reporting requirements for other types of events or possible noncompliance. This SOP covers the animal

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research, research laboratory safety and security, and research information protection portions of Handbook 1058.01 with emphasis on the role of the VAMHCS R&D Service and its investigators. Reporting requirements related to the human research program are described in Research Service Sop 01.08, "Reportable Events".

In October 2008, the VHA Office of Research Oversight (ORO) formally established the role of Research Compliance Officer (RCO) and a mandatory research compliance audit program of signed informed consent forms and triennial regulatory audits of research studies.

The VAMHCS takes seriously any issue of noncompliance of research staff with regard to protections of research personnel, animals, and research information. Because the Research Service is responsible for the conduct of research by VA investigators, it has a role in ensuring that corrective actions are resolved and may need to engage actively with investigators to achieve this goal.

RESPONSIBILITIES:

Compliance with institutional and regulatory policies and procedures is an ongoing responsibility of everyone involved in the VAMHCS research program.

The ACOS/R&D is responsible for:

- Notifying required individuals and entities within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of laboratory security incidents, any decommissioning implemented without the required authorization, research information incidents, incidents of noncompliance not found through RCO audits;
- Working collaboratively with the RCO, HARPO and others to promote research compliance among researchers;
- Ensuring that corrective action plans are implemented and resolved;
- As needed, suspending or terminating studies for reasons related to concerns about the safety, health, or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research.

The Human & Animal Research Protections Officer (HARPO) is responsible for:

- Generating, tracking and updating reports of incidents and corrective action plans;
- Reporting to research review committees on applicable incidents and noncompliance not found through RCO audits.
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The Research Compliance Officer (RCO) is responsible for:

- Conducting the ORO mandatory audit program of human, animal and laboratory research as described in VHA Handbook 1058.01;
- Informing principal investigators of audit results promptly and accurately;

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- Informing relevant research review committees of the results of all RCO regulatory audits, regardless of outcome (including “apparent serious or continuing noncompliance”), in a timely fashion.
- Reporting apparent serious or continuing noncompliance to the MCD, the COS, the ACOS/R&D, R&D Committee Chair, IRB/IACUC/SRS Chair, other VAMHCS entities, regulatory agencies, and sponsors as delineated in this SOP;
- Serving as a consultant, as needed, to the facility’s R&D Committee, IRB, and other committees as requested (the RCO may not be a voting or nonvoting member of these committees).

The R&D Committee is responsible for:

- Reviewing the results of audits conducted by the RCO;
- Reviewing HARPO incident reports;
- Reviewing IRB/IACUC/SRS determinations of serious or continuing noncompliance or other reportable events;
- Reviewing corrective action plans as presented or requiring additional steps to remedy the noncompliance;
- Deliberating research compliance issues or other reportable events that are not under the purview of RDC research review subcommittees;
- Other assistance as requested by the HARPO or RCO.

The Principal Investigator is responsible for:

- Being compliant with institutional and regulatory policies and procedures that protect the rights and safety of research participants, animals, research personnel, laboratory safety & security, research information and the scientific integrity of their research projects;
- Ensuring that research team members are compliant with all local and VA requirements;
- Reporting incidents of noncompliance or unanticipated problems to the IRB/IACUC/SRS according to this SOP and subcommittee policies and procedures;
- Notifying the ACOS/R&D, HARPO, and relevant research review subcommittee (IRB, IACUC, SRS) when a complaint has occurred or potential noncompliance is discovered;
- Cooperating with audits and investigations of complaints or allegations of noncompliance,
- Responding to queries and corrective action plans (CAPs) in a timely manner.

DEFINITIONS:

Active study. An “active” study is a study approved by and under continuing oversight from the Research and Development Committee (R&DC), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), or other VA or VA-designated research oversight committee, regardless of whether the study is “open” or “closed” to accrual.

Allegation of noncompliance: an assertion without proof or before proving that an act or practice of noncompliance has occurred or is occurring.

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Completed study. A “completed” study is a study for which oversight by all relevant research oversight committees has been concluded.

Laboratory Animal. A laboratory animal is generally defined as a live (non-human) vertebrate used or intended for use in research, training, experimentation, biological testing, or a related purpose. **NOTE:** *Animal research is discussed in VHA Handbook 1200.7, which provides a detailed regulatory definition*

Institutional Animal Care and Use Committee (IACUC). An IACUC is a committee formally designated by an institution to review and conduct continuing oversight of animal research to ensure ethical treatment of animals and compliance with animal research regulations and guidelines. The IACUC is responsible for monitoring the animal care and use program (ACUP) and the facilities utilized to house and work with animals, and for working with the IO to correct any problems that have been identified. At the VAMHCS, the UMB IACUC is a subcommittee of the VAMHCS R&D Committee. **NOTE:** *IACUCs are discussed in VHA Handbook 1200.7.*

Noncompliance is the failure to comply with applicable Federal Regulations (including VA regulations, local VAMHCS policies & procedures, and UMB IRB, IACUC or IBC policies and procedures.

RCO audit. RCO audits are audits conducted, supervised, or verified by the facility’s lead RCO. The RCO audits human research studies, animal research studies, and laboratory safety and security.

Related AE or a Related Problem. A “related” AE or a “related” problem in VA research is an AE or problem that may reasonably be regarded as caused by, or probably caused by, the research (see 21 CFR 312.64).

Research Compliance Officer (RCO). An RCO is an individual whose primary responsibility is auditing and reviewing research projects relative to requirements for the protection of human subjects, laboratory animal welfare, research safety, and other areas under the jurisdiction of and specified by the ORO. In addition to conducting required audits, the RCO may serve as a nonvoting consultant, as needed, to the facility’s R&D Committee, IRB, IACUC, Subcommittee on Research Safety (SRS), and other research review committees. The RCO may not serve as a voting or nonvoting member of these committees. The RCO may attend meetings of these committees when requested by the committee or as specified by local SOP’s.

Research Misconduct. Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or reporting research results. **NOTE:** *Research misconduct is discussed in VHA Handbook 1058.2*

Suspension or Termination of Research. Relative to VA research:

- (1) Suspension refers to a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.
- (2) Termination refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

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The terms “suspension” and “termination” apply to interruptions related to concerns regarding: (a) The safety, rights, or welfare of human subjects, research investigators, research staff, or others; or (b) The safety, health, or welfare of laboratory animals. Suspension and termination **do not include**: Interruptions in research resulting solely from the expiration of a project approval period, or “Administrative holds” or other actions initiated voluntarily by an appropriate facility official, research investigator, or sponsor for reasons other than those described in VHA HB 1058.01 or this SOP.

Unanticipated (Unexpected). The terms “unanticipated” and “unexpected” refer to an event or problem in VA research 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

SEE ALSO

Attachment 1	Information Required for ORO Reports
VHA Handbook 1058.01	Research Compliance Reporting Requirements
VHA Directive 2008-079	
VAMHCS Policy 512-00-010	Research Compliance

PROCEDURES:

1. Requirements Related to Animal Research

- 1.1. Investigators and research staff must comply with local SRS, R&D Committee and Research Service policies and procedures for reporting of events.
- 1.2. In addition, VHA Handbook 1058.01 requires that the following situations must be reported in writing to relevant authorities according to Item 7 below within 5 business days of becoming aware of the incident.
 - 1.2.1. Any **unanticipated loss of animal life** (including loss due to physical plant deficiencies, engineering failures, worker errors, or other mishaps). Losses associated with experimental manipulations that are within the range of expected outcomes described in the IACUC-approved protocol need not be reported. *NOTE: In large colonies, occasional loss of individual animals, or even the occasional loss of a litter of animals, can be anticipated due to natural or otherwise anticipated mortality rates.* Expected attrition due to anticipated disease, old age, etc. is reported to the UMB IACUC if/as required by the IACUC.
 - 1.2.1.1. Investigators and staff must report according to UMB IACUC policies and procedures and any applicable additional reports in item 7 below.
 - 1.2.2. Any suspected or confirmed **animal theft or potentially dangerous escape of animals.** *NOTE: The occasional escape of an animal within the primary holding room that is resolved without incident is not usually considered significant or reportable, whereas the escape of an infected or potentially dangerous animal or the unexplained disappearance of animals that cannot be reconciled must be reported to the local IACUC for review and appropriate action.*

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- 1.2.2.1. If animal terrorists are involved or suspected, notify VAMHCS Police service immediately.
- 1.2.2.2. Investigators/staff must report the escape of any infected or potentially dangerous animal according to UMB IACUC policies and procedures and any applicable additional reports in Item 7 below.
- 1.2.3. Any **work-related or research-related injury to animal research personnel** (or any apparent injury to any other person related to animal research) that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death.
 - 1.2.3.1. Investigators and research staff must report the injury in writing to the IACUC, the SRS, and other entities according to Item 7 below.
 - 1.2.3.2. Immediate medical care must be obtained for the research individual as necessary, and reporting of the incident must be made to Employee Health and Infection Control according to VAMHCS policies and procedures
- 1.2.4. The following are examples of (but not limited to) reportable incidents under applicable federal standards. Investigators, staff, VAMHCS RCO and Research Service must report according to UMB IACUC policies and procedures and any applicable additional reports in item 7 below.
 - 1.2.4.1. Any finding of noncompliance with animal research requirements;
 - 1.2.4.2. Initiation of VA animal research without written notification from the ACOS/R&D that the project may begin;
 - 1.2.4.3. Conduct of VA animal procedures without approval by the IACUC;
 - 1.2.4.4. Continuation of research beyond the specified approval period, even if the research is a continuation of work that was previously approved by all relevant research review committees;
 - 1.2.4.5. Failure to implement changes required by the IACUC as a condition of approval;
 - 1.2.4.6. Significant deviation from the IACUC-approved protocol prior to receiving approval from the IACUC to amend the protocol formally;
 - 1.2.4.7. Failure to comply with annual review requirements of the IACUC or other relevant research review committees;
 - 1.2.4.8. Conduct of official IACUC business by an improperly constituted committee or with less than a quorum of voting members present;
 - 1.2.4.9. Failure to provide adequate veterinary care (e.g., inappropriate or ineffective pain or distress management, inadequate post-procedural care, use of improper euthanasia techniques) whether intentional or accidental;
 - 1.2.4.10. Failure to implement remedial actions within the periods specified;
 - 1.2.4.11. Conduct of animal procedures by untrained or unauthorized personnel;
 - 1.2.4.12. Noncompliance or other deficiency that substantively compromises the effectiveness of the facility's animal research protection or animal research oversight programs;
 - 1.2.4.13. Suspensions or terminations of animal research projects;
 - 1.2.4.14. Changes in assurances, accreditations, or MOUs.

2. Requirements Related to Research Laboratory Safety

- 2.1. Investigators and research staff must comply with local SRS, R&D Committee and Research Service policies and procedures for reporting of events.

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2.2. In addition, VHA Handbook 1058.01 requires that the following situations *must be reported in writing to relevant authorities according to Item 7 below within 5 business days of becoming aware of the incident.*

- 2.2.1. **Work-Related or Research-Related Injuries.** Members of the VA research community are required to ensure that any apparent work-related injury to VA research personnel (or any apparent research-related injury to any other person) that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death, members of the VA research community are required to ensure that the injury has been reported in writing to the SRS.
- 2.2.1.1. Immediate medical care must be obtained for the research individual as necessary, and reporting of the incident must be made to Employee Health and Infection Control according to VAMHCS policies and procedures.
- 2.2.2. **Work-Related Exposures** Members of the VA research community are required to ensure that any apparent work-related exposure of VA research personnel (or apparent research-related exposure of any other person) to hazardous, toxic, or infectious materials at greater than routine levels (i.e., Permissible Exposure Limits or Infection Threshold) or any exposure or injury that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death, has been reported in writing to the SRS.
- 2.2.2.1. Immediate medical care must be obtained for the research individual as necessary, and reporting of the incident must be to Employee Health and Infection Control according to VAMHCS policies and procedures.
- 2.2.3. **Reportable Incidents Under Applicable Federal Standards.** Members of the VA research community are required to ensure that any incident reportable under applicable Federal standards, including but not limited to VHA Handbooks on research safety, NIH OBA guidelines, Occupational Safety and Health Administration requirements, CDC requirements, Department of Transportation requirements, and Nuclear Regulatory Commission (NRC) requirements, members of the VA research community are required to ensure that the incident has been reported in writing to the SRS. Examples include, but are not limited to:
- 2.2.3.1. Any finding of noncompliance with research safety requirements by any VA office (other than ORO) or any other Federal or state entity. Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings;
- 2.2.3.2. Initiation of VA research requiring safety review without written notification from the ACOS for Research that the project may begin;
- 2.2.3.3. Conduct of research requiring safety review without required approval by the SRS or other relevant research review committees;
- 2.2.3.4. Continuation of research beyond the expiration date established by the SRS without appropriate renewal of the protocol, even if the research is a continuation of work that was previously approved by all relevant research review committees;
- 2.2.3.5. Failure to implement changes required by the SRS as a condition of approval;

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- 2.2.3.6. Unauthorized deviation from an SRS-approved protocol. *NOTE: The SRS must be consulted in advance of implementing changes to determine if a protocol modification requires prior SRS approval;*
 - 2.2.3.7. Failure to comply with continuing review requirements of the SRS or other relevant research review committees;
 - 2.2.3.8. Conduct of official SRS business by an improperly constituted committee or with less than a quorum of voting members present;
 - 2.2.3.9. Failure to correct identified programmatic or facility deficiencies within the periods specified at subparagraphs 5d(1) or 5d(2) in the absence of the justification described at subparagraph 5d(3);
 - 2.2.3.10. Conduct of research by unauthorized personnel or personnel who lack appropriate training;
 - 2.2.3.11. Any noncompliance or other deficiency that substantively compromises the effectiveness of a facility's research safety programs.
 - 2.2.4. **Laboratory Decommissions.** The PI or Laboratory Director must obtain authorization (i.e., permission) from the SRS and the ACOS for Research prior to reassigning, vacating, converting to non-laboratory use, or otherwise decommissioning existing laboratory space that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses.
 - 2.2.4.1. The request for authorization to decommission laboratory space must be made in writing at least 1 month prior to implementation. Upon receiving such a request, the ACOS for Research must notify the VISN Safety Office to coordinate inventory and removal of hazardous materials, infectious agents, or equipment. See Research Service SOP "Procedure for Reassigning, Vacating, Converting To Non-Laboratory Use, Or Otherwise Decommissioning Existing Laboratory Space".
3. Requirements Related to Research Laboratory Security
- 3.1. Members of the VAMHCS research community are required to ensure that a situation involving research laboratory security has been reported in writing to the ACOS for Research.
 - 3.2. Investigators and research staff must comply with local SRS, R&D Committee and Research Service policies and procedures for reporting of events.
 - 3.3. In addition, VHA Handbook 1058.01 requires that the following situations *must be reported in writing to relevant authorities according to Item 7 below within 5 business days of becoming aware of the incident:*
 - 3.3.1. **Physical Security Problems.** Any break-in, physical security breach, or other physical security problem affecting VA research that involves any of following:
 - 3.3.1.1. Injury or harm to a human individual or laboratory animal;
 - 3.3.1.2. A Biosafety Level 3 (BSL-3) research laboratory;
 - 3.3.1.3. Loss of any quantity of a select agent or toxin;
 - 3.3.1.4. Loss of any quantity of a highly hazardous agent. **NOTE:** *For VA research, highly hazardous agents include select agents or toxins; agents, toxins, or other biological materials requiring handling at BSL-3 or higher containment; highly toxic chemicals and gases that have the potential for readily causing widespread harm if misused; and high risk radioactive materials and/or radiation sources;*

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- 3.3.1.5. Substantial damage to the facility;
 - 3.3.1.6. Substantial loss of equipment, physical resources, or research animals.
NOTE: Loss of any equipment that holds electronic data or documents must be reported in accordance with Item 7 below.
 - 3.3.2. **Findings of Noncompliance.** Any findings of noncompliance related to research laboratory security by any VA office (other than ORO) or any Federal or state entity (e.g., Department of Homeland Security). Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.
 - 3.3.3. **Other Deficiencies.** Any other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.
 - 3.3.4. **Suspensions or Terminations.** Any suspension or termination of research (e.g., by the ACOS for Research or other facility official) related to concerns about research laboratory security.
4. Requirements Related to Research Information Protection
- 4.1. **Research Information Protection Incidents requiring *Immediate Reporting*.** Within 1 hour of becoming aware of any situation described in 4.1.1 and 4.1.2 below, members of the VA research community are required to ensure that the situation has been reported to the ACOS for Research, the facility ISO, and the facility PO.
 - 4.1.1. **Unauthorized Access.** Unauthorized access to VA sensitive information, (including unauthorized use, disclosure, transmission, removal, theft, or loss) related to research, including but not limited to protected health information, individually-identifiable private information (as defined in 38 CFR 16.102(f)(2)), and confidential information protected by HIPAA, or by Federal records requirements at 38 U.S.C. §§5701, 5705, and 7332.
 - 4.1.2. **Reportable Network Security Operations Center (NSOC) Incidents.** Any research-related incident reportable to the Office of Information and Technology (OI&T) NSOC that impacts, inhibits, or compromises network security.
 - 4.1.3. The ACOS for Research must immediately notify the facility Director, the R&D Committee, and any relevant research review committee upon discovering, receiving, or otherwise becoming aware of a credible report of a research information protection incident described in preceding subparagraph 4.1.1 and 4.1.2 and must ensure that the facility ISO and facility PO have also been notified.
 - 4.1.3.1. Any oral report or notification of an incident must be followed as quickly as possible by a written report.
 - 4.2. **Research Information Protection Incidents requiring *Regular Reporting*.** Members of the VA research community are required to ensure that any situation described in 4.2.1, 4.2.2, 4.2.3 has been reported in writing to the ACOS/R&D, the VAMHCS ISO, and the VAMHCS PO within 5 business days of becoming aware of the situation.
 - 4.2.1. **Findings of Noncompliance.** Any findings of noncompliance related to research information security or privacy by any VA office (other than ORO) or any other Federal or state entity. Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.
 - 4.2.2. **Other Deficiencies.** Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.

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- 4.2.3. **Suspensions or Terminations.** Any suspension or termination of research (e.g., by the ACOS for Research or other facility official) related to concerns about research information protection.
5. Reportable Incidents under Applicable Federal Standards
- 5.1. Report any incident reportable under applicable Federal standards, including but not limited to VHA Handbooks on laboratory animal welfare and research safety, NIH OLAW requirements, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Lab Animals.
6. Requirements Related to Research Misconduct
- 6.1. The full procedures for handling research misconduct allegations are found in VHA Handbook 1058.2.
- 6.2. **Notification Requirements.** ORO Central Office must be notified as soon as possible (preferably by telephone or email) of any allegation of research misconduct. Subsequent written notification must be provided as specified by ORO Central Office.
7. General Requirements for Notifications and Reports
- 7.1. Initial notifications:
- 7.1.1. Investigators, research staff, Research Service staff, and the RCO (as applicable) must report any applicable incidents (as listed above or in VHA Handbook 1058.01) in writing as soon as possible but within 5 business days of becoming aware of the incident (with the exception of incidents involving research information immediate reporting; see Item 4.1 above).
- 7.1.2. Internal notifications must be made to the ACOS/R&D and the HARPO. An email notification, including description of the incident and relevant details is acceptable.
- 7.1.3. Notifications must be made to the IACUC, SRS, and RDC according to those policies and procedures.
- 7.1.4. The ACOS/R&D and the HARPO notifies the RDC Chair, VAMHCS COS and VAMHCS director as required.
- 7.1.5. In the case of injury or exposures of staff or others, notification must be made to Employee Health, Infection Control, and other VAMHCS entities according to VAMHCS policies and procedures.
- 7.2. Incidents Requiring IACUC Review
- 7.2.1. The IACUC must review any report involving an apparent incident or event as described in 1.2 at its next convened meeting. Incidents that present a significant risk to the safety of research personnel, animals, or the environment may require immediate attention and result in the need to convene an emergency session of the IACUC prior to the next scheduled meeting.
- 7.2.2. Should the IACUC determine that a reportable incident or event as listed in 1.2 occurred, the IACUC Chair, or designee must report the determination directly (without intermediaries) to the Director, VAMHCS within 5 business days after the IACUC's determination.
- 7.2.3. An initial report of an IACUC determination is required regardless of whether the determination is preliminary and still under investigation or final disposition of the matter has been resolved at the time of the report.

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7.2.4. **NOTE:** *The IACUC must reach a determination that a reportable event did (or did not) occur within 30-45 days after receiving a relevant report. According to subparagraph 5d, remedial actions involving a specific study or research team must be completed within 90-120 days after the IACUC's determination. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the IACUC's determination, unless remediation requires substantial renovation, fiscal expenditure, legal negotiation, etc. Where it is known at the outset that completion of remedial actions will extend beyond these periods, for example where significant infrastructure improvements or major equipment purchases are needed, the ORO RO must be consulted regarding development of an acceptable plan to minimize negative impact on animal welfare or critical research activities.*

7.2.5. Any suspension or termination of research related to concerns about the safety, health, or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research, must be reported directly (without intermediaries) to the facility Director within 5 business days after the suspension or termination occurs.

7.2.6. Reports must be made in writing, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research review committee.

7.3. Incidents Requiring SRS Review

7.3.1. The SRS must review at its next convened meeting any report involving an incident or event listed in 2.2 above. Incidents that present a significant risk to the safety of research personnel or the environment may require immediate attention and result in the need to convene an emergency session of the SRS prior to the next scheduled meeting.

7.3.1.1. Should the SRS determine that a reportable incident or event as listed in 2.1 occurred, the SRS Chair must report the determination directly (without intermediaries) to the Director, VAMHCS within 5 business days after the SRS's determination.

7.3.1.2. The SRS must reach a determination that a reportable event did (or did not) occur within 30-45 days after receiving a relevant report. According to subparagraph 5d, remedial actions involving a specific study or research team must be completed within 90-120 days of the SRS's determination. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the SRS's determination, unless remediation requires substantial renovation, fiscal expenditure, legal negotiation, etc.

7.3.1.3. Any suspension or termination of research related to concerns about the safety, health, or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research, must be reported directly (without intermediaries) to the facility Director within 5 business days after the suspension or termination occurs.

7.3.1.4. Reports must be made in writing, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research review committee.

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7.4. Suspensions or terminations of research

7.4.1. Any suspension or termination of research (e.g., by the IACUC or other research review committee, or by the ACOS for Research or other facility official) related to concerns about the safety, health, or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research, must be reported directly (without intermediaries) to the facility Director within 5 business days after the suspension or termination occurs.

7.5. Reports from the ACOS/R&D

7.5.1. The ACOS for Research must report the following (without intermediaries) to the VAMHCS Director with copies to the COS, RDC Chair(s), and subcommittee Chairs (as applicable):

7.5.1.1. Any decommissioning implemented without the required authorization.

NOTE: the VISN Safety Office must also be notified.

7.5.1.2. Applicable incidents involving research laboratory security (see Item 3 above). *NOTE: the VAMHCS Police Service must also be notified.*

7.5.1.3. Any suspension or termination of a research study activated by the ACOS/R&D related to concerns about the safety, health, or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research.

7.5.1.4. Research Information incidents requiring immediate reporting: A credible report of a research information protection incident described in preceding item 4.1.1 and 4.1.2. *NOTE: the VISN ISO and PO must also be notified **and** the notification must occur immediately upon discovering, receiving, or otherwise becoming aware of the incident. An initial oral notification is permissible if followed by a written notice.*

7.5.1.5. Research Information incidents requiring regular reporting: Within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any situation described at Item 4.2.1, 4.2.2, 4.2.3 above. *NOTE: the VISN ISO and PO must also be notified*

7.5.2. Notifications must be made in writing and within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of applicable situations. *NOTE: Notifications related to item 7.5.1.4 must occur **immediately** upon discovering, receiving, or otherwise becoming aware of a credible report of a research information protection incident described in preceding subparagraph 4.1.1 and 4.1.2, and an oral initial notification is permissible (must be followed by a written report).*

7.6. Reports from the Medical Center Director¹

7.6.1. The Director, VAMHCS must report the IACUC's or SRS's determination (i.e., that a reportable incident or event occurred) to ORO Southern Regional Office (SRO), with a simultaneous copy to the VISN Director and VA ORD, within 5 business days after receiving such notification.

¹ See Attachment 1: Information Required for ORO Reports

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- 7.6.1.1. An initial report of an IACUC or SRS determination is required regardless of whether the determination is preliminary and still under investigation or final disposition of the matter has been resolved at the time of the report.
- 7.6.2. The Director must report any suspension or termination of research by the IACUC or other research review committee, or by the ACOS for Research or other facility official related to concerns about the safety, health, or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research, must be reported directly (without intermediaries) to SRO within 5 business days after receiving notification
- 7.6.2.1. Suspensions or terminations of animal research are to be reported whether they impact a specific study or the entire program.
- 7.6.3. The Director must report the following additional research events to SRO within 5 business days after being notified:
- 7.6.3.1. Any unauthorized decommissioning;
- 7.6.3.2. Reports of research laboratory security incidents (see Item 3)
- 7.6.4. The Director must report the following research events to ORO Central Office, with a simultaneous copy to SRO, within 5 business days after being informed of them:
- 7.6.4.1. **Assurance Changes.** Any change in the facility's Animal Welfare Assurance status as filed with OLAW, or in the Animal Welfare Assurance status of an affiliate institution or other entity upon which the facility relies. Simple Assurance renewals, without changes in status, need not be reported.
- 7.6.4.2. **New MOU or Substantive MOU Changes.** The implementation of any new MOU, or any substantive change in an existing MOU, with an affiliate institution (or other entity) related to laboratory animal welfare or animal care and use arrangements.
- 7.6.4.3. **Accreditation Problems.** Failure of the VA facility to achieve the accreditation status required by ORD for animal care and use programs, any change in the facility's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's animal care and use program.
- 7.6.5. The Research Service HARPO or designee ensures that corrective action plans are resolved and that ORO SRO and the VISN office are updated as required.
- 7.7. Updates to ORO Southern Regional Office (SRO)
- 7.7.1. Updates to ORO regional office (Southern Regional Office; SRO) are sent as requested or as additional information is available.
- 7.7.2. Updates must incorporate the full scope of relevant determinations and remedial actions, including programmatic actions as warranted. If a letter to external entities has been sent by the UMB or the VAMHCS, updates may refer to those letter(s).
- 7.7.3. Updates are sent from the ACOS/R&D, HARPO and/or RCO (as applicable) through VAMHCS leadership (the MCD, COS) to VISN 05 (Network Director, network medical officer, relevant administrative staff). The RDC Chair, relevant subcommittee Chair(s), and relevant administrative staff are cc'd.
- 7.7.4. Formal letter(s) or cover letter(s) to ORO SRO are reviewed and approved by the MCD and the COS before being signed by the MCD. Scanned copies of the signed documents are sent to SRO and the VISN via encrypted email

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7.7.5. If the applicable deadlines for the CAP cannot be accomplished, ACOS/R&D, HARPO and/or RCO (as applicable) must report the reasons and progress to the MCD, R&D Committee and SRO. The facility must provide ORO with a written justification for the delay and an acceptable timeline for completion

7.8. Reports to Other Entities

7.8.1. Following IACUC review and determinations of applicable incidents, additional entities must be notified as applicable and according to NIH OLAW requirements, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and United States Department of Agriculture (USDA) Animal Welfare Act Regulations (UAWAR).

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE**ATTACHMENT 1: Information Required for ORO Reports**
[VHA Handbook 1058.01 Par 5.b-c]

b. **Contents of Initial Reports to ORO.** Initial reports to ORO of reportable research events must (as applicable) include:

- (1) The name and any relevant Assurance number of the reporting VA facility.
- (2) The title of the research project(s).
- (3) The number(s) used by the facility's Research Service or relevant research review committee(s) to identify the project(s).
- (4) The name of any external sponsor(s) of the project(s).
- (5) The funding source(s) for the project(s).
- (6) The name of any agencies or organizations external to VA that were notified, or need to be notified, of the event.
- (7) A description of the event being reported.
- (8) A description of any immediate actions taken to address or investigate the reported event.

c. **Contents of Follow-Up Reports to ORO.** After the initial report, additional investigation and review are frequently needed to obtain a complete understanding of the facts associated with the case. Interim and final reports must be provided as directed by ORO to incorporate the full scope of relevant determinations and remedial actions, including programmatic actions as warranted.