**SUBJECT: Reporting Research Events**

## 1. PURPOSE:

To set forth the requirements for reporting research compliance events to research review committees, facility officials, and the Office of Research Oversight (ORO).

## 2. DEFINITIONS:

a) **Noncompliance**: any failure to adhere to the requirements for conducting VA research

   1) **Continuing Noncompliance**: the persistent failure to adhere to the legal and policy requirements governing human research.

   2) **Serious Noncompliance**: a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

      a. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; including their rights to privacy and confidentiality of identifiable private information, or

      b. Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

b) **Reportable**: any situation that requires an official report to ORO or any other regulatory entity beyond the local level.

c) **Research Misconduct**: fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or reporting research results.

d) **Research Review Committee**: any committee or subcommittee designated to ensure compliance with the requirements for research. These committees include the Research and Development Committee (RDC) and its subcommittees:

   1) the Human Research Protection Program (HRPP) (which includes the Institutional Review Boards (IRB);

   2) Institutional Animal Care and Use Committee (IACUC);

   3) Subcommittee on Research Safety (SRS) and the Institutional Biosafety Committee (IBC, a subcommittee of SRS).

e) **Serious Accident/Injury**: Serious accidents/injuries include those that require medical attention or treatment, other than basic first aid provided at the site where the accident/injury occurred; those that require extended medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; and those that lead to a serious long term health complication or death.

f) **Serious Adverse Event (SAE)**: an untoward occurrence in human 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.

g) **Serious Problem**: A serious problem is a problem in human research information security that may reasonably be regarded as:

1) Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or including their rights to privacy and confidentiality of identifiable private information; or

2) Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs or research information security program.

h) **Suspension (Animal Research)**: the withdrawal of Institutional Animal Care and Use Committee (IACUC) approval for use of animals in research (relative to a procedure, protocol, or program), as determined by a majority vote at a convened meeting. Suspension of an animal activity requires the IO, in consultation with the IACUC, review the reasons for the suspension, implement appropriate corrective actions, and report the actions and the circumstances surrounding the suspension to relevant regulatory authorities in accordance with USDA regulations at 9 CFR 2.31(d)(6-7) and paragraph IV.C.7 of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

i) **Suspension (All Other Research)**: a temporary interruption in selected research activities (e.g., new enrollments or specific interventions) due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action to suspend was taken by an investigator, facility official, research review committee, or external entity. Suspension does not refer to interruptions for other reasons, including the expiration of project approval periods.

j) **Systemic Deficiency**: a fundamental, underlying problem that jeopardizes the effectiveness of the facility's research protection system(s).

k) **Termination**: a permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, or about the welfare of laboratory animals, regardless of whether the action to terminate was taken by an investigator, facility official, research review committee, or external entity.

## 3. OVERVIEW:

All MVAHCS research personnel (including WOCs), the Research Compliance Officers, members (both voting and ex officio) of the RDC and all its subcommittees are required to comply with the requirements for reporting research events related to human research, animal research, research safety, research laboratory safety, and research information security, as outlined in the attached Appendix A.

## 4. RESPONSIBILITIES:

a) **Institutional Official (IO)**: As the IO, the Facility Director is the legally authorized Signatory Official for the research program and is responsible for all official communications to external agencies and the VA Office of Research Oversight (ORO). The Facility Director must:

1) Report to ORO within 5 business days after receiving notification from a research review committee of a determination of a reportable event;

2) Assure all research compliance reports from any State or Federal oversight entity (including ORO), regardless of findings are provided to the ACOS/R&D, the R&D Committee, any other relevant research review committees, and the RCO within 5 business days after receipt;

3) Report to ORO within 60 days any information security and privacy incidents involving VA research, such as data loss or destruction, unauthorized access, etc. as described in VHA Directive 1058;

4) Foster a culture of accountability and transparency relative to research compliance; and

5) Complete the annual VA Facility Director Certification of Research Oversight.

b) **Associate Chief of Staff/Research & Development (ACOS/R&D)**: The ACOS/R&D administers the R&D program through delegated authority of the IO, reporting to the Chief of Staff. The ACOS/R&D:

1) Receives and reviews all reports of local research review subcommittee determinations necessitating reporting to the IO and works with the facility, research staff and R&DC to identify appropriate remedial actions are completed and systemic deficiencies are addressed;

2) Reviews research compliance reports from any State or Federal oversight entity (including ORO), regardless of findings and assures appropriate remedial actions are completed; and

3) Acts as Facility Research Integrity Officer, assuring reporting requirements regarding research misconduct are consistent with VHA Directives 1058 and 1058.02.

c) **R&D Committee (RDC)**: The RDC:

1) Reviews any apparent systemic issues reported to identify if the report involves an actual systemic deficiency that could substantially compromise the VA facility's research protection program; and

2) Determines what remedial actions, if any, are warranted to ensure effective research protections and will notify the IO of the determination.

d) **Research Review Committee**: Each research review committee is responsible for:

1) Receiving and reviewing reports related to their respective areas of research. The reports of apparent serious noncompliance, apparent serious adverse events, apparent reportable events, or apparent serious problems must be reviewed within timeframes as outlined in Appendix A;

2) Making required determinations and identification of remedial actions. These actions must occur within timeframes addressed in Appendix A; and

3) Reporting to identified facility personnel and oversight entities as specified.

e) **Research Compliance Officer (RCO)**: The RCO is responsible for:

1) Auditing documentation related to research projects and informing the Facility Director and research review committees about compliance concerns. The RCO audits are conducted in accordance with a written audit plan.

2) Performing additional research oversight duties assigned by the Facility Director, including assisting in compliance education, accreditation activities, Facility Director Certifications, and monitoring or auditing individual studies or programs for the research review committees.

f) **Investigator**: The Principal Investigator is responsible for:

1) Reporting serious events and serious problems related to their research in writing to the relevant research oversight committee within time frames identified in Appendix A.
2) Reporting serious events and serious problems to external funding source as outlined in the contract agreement with the funder.

**5. REFERENCES:**

VHA Directive 1058 "Office of Research Oversight" (08 November 2024)

VHA Directive 1058.02 "Research Misconduct" (10 July 2020)

VHA Directive 1200.01 "Research and Development Committee" (24 January 2019)

VHA Directive 1200.05 "Requirements for the Protection of Human Subjects in Research" (07 January 2019)

VHA Directive 1200.07 "VA Research with Animals" (23 May 2023)

VHA Directive 1200.08 "Safety of Personnel and Security of Laboratories Involved in VA Research" (24 April 2019)

VHA Directive 1605.01 "Privacy and Release of Information" (24 July 2023)

VA Handbook 6500 "Risk Management Framework for VA Information Systems VA Information Security Program" (24 February 2021)

HRPP Standard Operating Procedure 10-004 (March 2023)

**6. R&D COMMITTEE APPROVAL:** 07 January 2025

**7. RECISSIONS:** Minneapolis Research Service SOP R&D-005 "Reporting Research Events" (06 June 2023)

**8. EXPIRATION DATE:** N/A

**9. FOLLOW-UP RESPONSIBILITY:** Research and Development (R&D) Committee

## Appendix A: Timelines for Notifying ORO of Research-Related Events

For full guidance, refer to VHA Directive 1058.

For a summary of guidance, refer to materials on VA Office of Research Oversight web page at https://www.va.gov/ORO/Docs/Guidance/VHA_Directive_1058_Timelines_for_Notifying_ORO_of_Research_Events.pdf