

## RESEARCH SERVICE POLICIES AND PROCEDURES FOR ALLEGATIONS OF NON-COMPLIANCE

**1. PURPOSE:** To establish policies and procedures for managing research-related allegations of noncompliance. This policy ensures that all research-related allegations of noncompliance related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, and debarment for research impropriety policies will be addressed to uphold compliance and ethical standards of the Ralph H. Johnson VA Medical Center (RHJVAMC). The VA ensures the safety, rights and welfare of investigators, staff and research participants through evaluation, management and reporting of certain research events.

### **2. GENERAL REPORTING GUIDELINES:**

A. It is the responsibility of each member of the Research Service to assure appropriate compliance with all policies and procedures. Information regarding these policies and procedures is available in the appropriate Procedures and Guidelines manuals, laboratory-specific SOPs, annual required training material, and ongoing information provided by the administration of the Research Service. Any obvious or suspected deviations from established policies and procedures should be reported immediately for the general welfare of all personnel as well as the research activities of the Research Service itself.

B. If a member of the Research Service has concerns or allegations, they can be addressed directly to the ACOS/Research, Administrative Officer (AO) for Research, Research Compliance Officer (RCO), Biosafety Officer (BSO), any member of the Research and Development (R&D) Committee, or any member of the appropriate subcommittees (Institutional Animal Care and Use Committee and Subcommittee on Research Safety). These inquiries and/or allegations may be submitted personally or anonymously as appropriate.

C. As a means to report concerns or allegations, Research subjects are provided with a telephone contact under *Whom to Contact* on the research consent form. The consent form states any patient concerns or allegations involving rights as a research subject may be directed to the administrative offices of the Research Service and/or forwarded to the Institution's Patient Advocate. Concerns and allegations are monitored by the RCO and administration of the Research Service.

D. All Research personnel and committee members are assured that asking questions, voicing concerns, detailing complaints, or reporting apparent policy/procedure violations will be protected and that they can report such matters without any fear of reprisal or discrimination.

E. Committee members who feel they are experiencing coercion or undue influence should report this complaint to the ACOS/Research, Subcommittee Chair, R&D Committee Chair or RCO.

F. Individuals within the hospital or community can direct concerns or questions regarding research noncompliance issues to ACOS/Research, AO for Research, RCO, any member of the R&D Committee, and any member of the appropriate subcommittees and/or Research Service.

G. The ACOS/Research, AO for Research, BSO, and the RCO, with the assistance of others when needed, will investigate any concern or allegation of noncompliance to determine its merit. If there appears to be any validity to the allegation, it will be reported by the RCO and handled as outlined within this memorandum. This investigation may include interviewing persons presenting the allegation or associated with the allegation including and/or reviewing documents or materials associated with the allegation. If the allegation is deemed unjustified or unsubstantiated, a written response will be sent to the person making the accusation, if known, and no further action will be taken. The letter will give the individual information about the next line of authority if they want to pursue this further

H. For concerns or allegations of noncompliance involving a specific subcommittee and/or its members, the ACOS/Research, AO for Research, and the RCO will investigate the allegation to determine its merit. If there appears to be any validity to the allegation, it will be reported by the RCO and handled as outlined in this memorandum.

I. For concerns or allegations of noncompliance involving the R&D Committee and/or member(s), the ACOS/Research, AO for Research, and the RCO will investigate the allegation to determine its merit. If there appears to be any validity to the allegation, it will be reported by the RCO and handled as outlined in this memorandum.

J. For concerns or allegations of noncompliance involving the members of the administrative offices of the Research Service, the RCO will investigate the allegation to determine its merit. If there appears to be any validity to the allegation, it will be reported by the RCO and handled as outlined in this memorandum.

K. All persons obtaining information about a concern or allegation of noncompliance must respect and maintain confidentiality regarding the identity of the person submitting the allegation and the situation of the allegation, to the extent possible.

### 3. DEFINITIONS:

A. **Noncompliance** is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to research. Noncompliance may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more serious violations, which pose risk to subjects and/or violations of their rights and welfare.

B. **Continuing noncompliance** is defined as a pattern of recurring or ongoing instances of actions or omissions, which indicates an underlying deficiency in knowledge of the regulations and requirements.

C. **Serious noncompliance** is defined as knowingly disregarding or violating federal regulations or institutional policies and procedures applicable to research which could place subjects or staff at risk of significant harm. Serious noncompliance may result from:

- i. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human or animal research subjects, research staff, or others; or
- ii. Substantively compromising the effectiveness of a facility's human or animal research protection or human or animal research oversight programs.

D. **Research Misconduct** is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Allegations of research misconduct

are not covered by this policy, and will be referred to the R&D Committee. Procedures for handling research misconduct allegations will be in accordance with VHA Handbook 1058.2.

**4. RESPONSIBILITIES AND PROCEDURES RELATED TO REPORTING:** The following procedures for reporting findings of noncompliance should be followed:

- A. Reports of Apparent Serious or Continuing Noncompliance by any VA personnel including WOC and IPA appointees
  - a. Reports must be made within five business days after becoming aware of any incident that is reportable under relevant VHA Handbooks or applicable Federal requirements related to research safety or animal welfare.
    - i. The report must be made in writing, and directed to the Associate Chief of Staff for Research, the Research and Development Committee, Subcommittee chairperson (IACUC, SRS, or IRB), BSO, or RCO.
    - ii. The Medical Center Director must report the apparent serious or continuing non-compliance to the appropriate ORO research officer, with a simultaneous copy to the Veterans Integrated Service Network (VISN) Director, ORD, and any other applicable agency/organization, within five business days after receiving such notification.
- B. Research Compliance Officer Reports of Apparent Serious or Continuing Noncompliance
  - a. Within five business days of identifying apparent serious or continuing noncompliance based on a consent document audit, regulatory audit, other systematic audit of VA research or based on information provided to the RCO, the RCO must report the apparent noncompliance directly (without intermediaries) to the Medical Center Director.
    - i. The report must be made in writing, with a simultaneous copy to the Associate Chief of Staff for Research, the Research and Development Committee, the IRB, and any other relevant research review committee.
    - ii. The Medical Center Director must report the apparent serious or continuing non-compliance to the appropriate ORO research officer, with a simultaneous copy to the Veterans Integrated Service Network (VISN) Director, ORD, and any other applicable agency/organization, within five business days after receiving such notification.
    - iii. An initial report of apparent serious or continuing noncompliance based on a RCO consent document audit, RCO regulatory audit, other systematic RCO audit or based on information provided to the RCO, is required regardless of whether disposition of the matter has been resolved at the time of the report.
- C. Subcommittee Review of Apparent Serious or Continuing Noncompliance as applicable to IRB, IACUC and SRS.
  - a. The Subcommittee must review any report of apparent serious or continuing noncompliance at its next convened meeting which occurs monthly. If the incident in question involves a human death or presents a significant risk to the safety of research personnel, live animals used in research, the environment, or require immediate attention, the Subcommittee will convene an emergency session prior to the next scheduled meeting.
    - i. Should the Subcommittee determine that the reported incident constitutes serious noncompliance or continuing noncompliance, the Subcommittee chair, or designee must report the determination directly (without intermediaries) to the Medical Center Director within five business days after the determination, ideally with the recommended plan of action. An initial report of a Subcommittee determination that serious noncompliance or continuing noncompliance occurred is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report.

- ii. The Subcommittee chair's report must be made in writing, with a simultaneous copy to the ACOS/R, AO for Research, RCO, the R&D Committee and any other relevant research review committee.
  - iii. The Medical Center Director must report the determination to the appropriate ORO research officer, with a simultaneous copy to the Veterans Integrated Service Network (VISN) Director, ORD, and any other applicable agency/organization, within five business days after receiving such notification, unless the non-compliance has already been reported.
- b. The Subcommittee must reach a determination that serious or continuing noncompliance did (or did not) occur within 60 days after receiving a report of apparent noncompliance, however, the expectation at this facility is that a determination be identified immediately upon review of the situation whenever possible. If an issue involves human or animal subject protection and/or safety, immediate action will be taken to minimize potential harm to subjects or staff pending the outcome of a formal review. In the event of a human death that may be the result of either working with, caring for, or other contact with research animals or work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area), VHA Handbook 1058.01 Section 7.c(1) and 8.a(1) also requires that: The IACUC/SRS must alert ORO by e-mail or telephone within 2 business days after receiving such notification. The VA facility Director and the ACOS/R&D must receive concurrent notification.
  - i. Remedial action involving a specific study or research team must be completed within 120 days after the Subcommittee's determination and the Subcommittee must report their findings to include the following elements:
    - 1. Determination of the nature, extent, and significance of any policy/procedure violation.
    - 2. Recommendations for remedial action to be taken
    - 3. Recommendations for the consequences of any past or continued noncompliance.
    - 4. Recommendations for a timeline controlling any educational, disciplinary, or dismissal action
  - ii. All determinations will be reported to the R&D Committee.
  - iii. Monitoring of and compliance with remedial action will be the responsibility of the Subcommittee.
  - iv. The Subcommittee will document all discussion and outcomes of the incident in their minutes which are shared with the R&D Committee. The Subcommittee will provide additional information and/or documentation to the R&D Committee upon request.
- c. Requirements related to Research Information Protection incidents require immediate reporting. Within 1 hour of becoming aware of any situation described in c (i), members of the VA research community are required to ensure that the situation has been reported to the ACOS/Research, with a simultaneous copy to the appropriate ORO Regional Office.
  - i. 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.
  - ii. Notification of Facility Director. The ACOS/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 and must ensure that the facility Information Security Officer has been notified.

- d. Remedial actions involving programmatic noncompliance must be completed within 120 days after the Subcommittee's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, legal negotiating, etc.
  - i. If an issue involves human or animal subject protection and/or safety, immediate action will be taken to minimize potential harm to subjects or staff pending the outcome of a formal review.
  - ii. Dependent upon the nature of the event or circumstances, any of the following actions may occur:
    - 1. Further inquiry may be initiated;
    - 2. Administrative action may be taken;
    - 3. Details and recommendations forwarded to the appropriate committee Chairs for consideration in their committees and action;
    - 4. Details and recommendations forwarded to the Chief of Staff and/or the Medical Center Director for action;
    - 5. Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up;

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

- a. The name and any relevant assurance number of the facility.
- b. The title of the research project(s).
- c. The number(s) used by the facility's Research Service or relevant research review committee(s) to identify the project(s).
- d. The name of any external sponsor(s) of the project(s).
- e. The funding source(s) for the project(s).
- f. The name of any agencies (i.e. OHRP, FDA) or organizations external to VA that were notified, or need to be notified, of the event.
- g. A description of the event being reported.
- h. A description of any immediate actions taken to address or investigate the reported event.

**5. DESCRIPTIONS OF REPORTABLE EVENTS:** The following events constitute reportable findings of research noncompliance. This list provides examples, and does not account for every situation which may constitute research noncompliance.

A. Reportable events under regulation of the Animal Care and Use Committee (IACUC)

- a. Accidental human deaths
- b. Accidental theft/escape of animals
- c. Human Accident, Injury, Illness, or Exposures
- d. Reportable Incidents Under other Applicable Federal Standards
- e. New or substantially revised MOUs related to the use of animals in research
- f. Any substantial revision to the PHS Animal Welfare Assurance that covers the facility's animal care and use program
- g. Failure of the facility to achieve or maintain the accreditation status that is required by VA, or after any change in the status of an affiliate institution upon which the facility relies.

B. Reportable events under regulation of the Subcommittee for Research Safety (SRS)

- a. Accidental human deaths
- b. Human Accident, Injury, Illness, or Exposures

c. Reportable Incidents Under other Applicable Federal Standards (such as OSHA, NIH Office of Science Policy for rDNA exposures, as applicable)

C. Reportable events relevant to Research Security

- a. Any intrusion, physical security breach, break-in, or other security violation that occurs in dedicated research areas. 3
- b. Any finding by any entity other than ORO of noncompliance with research laboratory security requirements.
- c. Any unplanned suspension or termination of research by the ACOS/R&D or another facility official due to concerns about research laboratory security.
- d. Any other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.

**REFERENCES:** VHA Handbook 1058.01, VHA Handbook 1200.05, VHA Handbook 1200.07, VHA Handbook 1058.02, VHA Handbook 1059.03

**RESPONSIBLE OFFICE:** The RHJVAMC Research Service is responsible for the contents of this standard operating procedure.

**RESCISSION:** None

**RECERTIFICATION:**



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