

RESEARCH SERVICE POLICIES AND PROCEDURES FOR ALLEGATIONS OF NON-COMPLIANCE

1. PURPOSE:

To establish policies and procedures for managing research-related allegations of non-compliance. This policy ensures that all research-related allegations of non-compliance related to human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, debarment for research impropriety policies will be addressed to uphold compliance and ethical standards of research at the VA Nebraska-Western Iowa Health Care System (NWIHCS).

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, research investigators packets, annual required training material, and ongoing information provided by the Research Administrative Office (RAO). 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, Research Compliance Office (RCO), any member of the Research and Development (R&D) Committee, or any member of the appropriate subcommittees (Subcommittee of Human Studies, Subcommittee of Animal Studies and Research Safety/Biosafety Subcommittee) and/or any member of the Research Service. 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 Research Administrative Office and/or forwarded to the Institution's Patient Advocate. Concerns and allegations are monitored by the Patient Advocate in the Patient Advocate Tracking Program.

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 non-compliance issues to ACOS/Research, RCO, any member of the R&D Committee, and member of the appropriate subcommittees (Subcommittee of Human Studies, Subcommittee of Animal Studies and Subcommittee for Research Safety) and/or any member of the Research Service.

G. The ACOS/Research, Deputy ACOS/Research 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 non-compliance involving a specific subcommittee and/or its members, the ACOS/Research, Deputy ACOS/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 non-compliance involving the R&D Committee and/or member(s), the ACOS/Research, Deputy ACOS/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 non-compliance involving the Research Administrative Office and/or member(s), 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 non-compliance 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.

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 Research Integrity Officer (RIO).

4. RESPONSIBILITIES AND PROCEDURES RELATED TO REPORTING

The following procedures for reporting findings of non-compliance should be followed:

- A. Research Compliance Officer Reports of Apparent Serious or Continuing Non-compliance

- a. Within five business days of identifying apparent serious or continuing non-compliance based on a consent document audit, regulatory audit, other systematic audit of VA research or based on information provided to the RCO, a research compliance officer must report the apparent non-compliance 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 non-compliance based on a Research Compliance Officer consent document audit, Research Compliance Officer regulatory audit, other systematic Research Compliance Officer 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.
- B. Subcommittee Review of Apparent Serious or Continuing Non-Compliance – applicable to IRB, IACUC and SRS.
 - a. The Subcommittee must review any report of apparent serious or continuing non-compliance at its next convened meeting which occurs monthly.
 - i. Should the Subcommittee determine that the reported incident constitutes serious non-compliance or continuing non-compliance, 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 non-compliance or continuing non-compliance 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, 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 non-compliance did (or did not) occur within 30-45 days after receiving a report of apparent non-compliance, 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
 - i. Remedial action involving a specific study or research team must be completed within 90-120 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) or c(ii), 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. 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.
 - iii. 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 c(i) or c(ii) and must ensure that the facility ISO and facility PO have also been notified.
- d. Remedial actions involving programmatic non-compliance must be completed within 120-180 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;

6. Other actions as deemed appropriate.
- iii. If an active research project is found in non-compliance with institutional policies, the appropriate subcommittee, either in a regularly scheduled or specially convened meeting, will determine whether or not a research project.
 1. May continue;
 2. May continue with modifications;
 3. May be suspended; or
 4. May be terminated.
- iv. If an active research project is found in non-compliance with institutional policies, a recommendation will be made as to whether or not a Principal Investigator or anyone involved with the research project:
 1. May continue conducting research;
 2. May continue conducting research with modifications; or
 3. May be suspended from conducting research.



DEBRA ROMBERGER, M.D.
ACOS/Research Service