

**COMPLAINTS AND ALLEGATIONS OF NON-COMPLIANCE
PERTAINING TO HUMAN RESEARCH**

1. **PURPOSE:** To establish a service level policy for any person, including patients, research participants, investigators, research staff, Research and Development (R&D) Committee members, Institutional Review Board (IRB) members, medical staff, nursing staff and others to voice research-related complaints and allegations of non-compliance with institutional policies, including undue influence, pertaining to all research at the Portland VA Medical Center (PVAMC)
 - a. Non-compliance is defined as failure to follow any applicable federal or state regulations, the requirements and determinations of the R&D Committee, any of its subcommittees, or VA requirements.
 - b. Serious non-compliance is defined as willful and neglectful failure to adhere to IRB or Human Research Protection Program (HRPP) regulations, requirements, or determinations or violations of procedures, policies, regulations, or laws that results in increased risks to participants or in adverse effects on the rights and welfare of research participants.
 - c. Continuing non-compliance refers to a pattern of non-compliance that suggests an inability or unwillingness to maintain compliance with R&D, IRB/HRPP, regulations, requirements, or determinations.
 - d. Additionally, this policy
 - (1) requires investigation of all complaints and allegations;
 - (2) establishes remedial actions and consequences for findings of non-compliance with the HRPP and IRB policies;
 - (3) identifies individuals who have responsibility for ensuring corrective action has been taken; and
 - (4) includes a process for reporting to institutional officials and other appropriate parties and authorities.

This policy ensures that all research-related complaints and allegations of non-compliance with HRPP and IRB policies, including undue influence, will be addressed as necessary to ensure compliance and uphold ethical standards of human research at the Portland VA Medical Center. (PVAMC)

2. **POLICY:** Investigators and research staff are required to report all allegations and findings of non-compliance to the IRBs as soon as possible after recognition. Serious and/or continuing non-compliance must be reported to the IRB no later than 10 working days after recognition of the non-compliance. Patients, research participants, investigators, research staff, IRB members, medical staff, nursing staff and others are able to voice to the Research Service research-related complaints and allegations of non-compliance with institutional policies related to the HRPP. All complaints and allegations of non-compliance pertaining to the HRPP and IRB policies will be investigated and addressed promptly, initially at the administrative level. The ACOS/R&D and Research Assurance & Compliance Coordinator (RACC) will evaluate the facts and take appropriate action, dependent upon the nature of the events and circumstances. The responsible individuals identified below will ensure a response and appropriate actions as necessary to address all complaints and allegations of non-

compliance pertaining to human research. Remedial action and consequences will be determined for findings of non-compliance with the HRPP and IRB policies and when necessary, institutional officials and other appropriate parties and authorities will be notified.

3. RESPONSIBILITIES

- a. The **Associate Chief of Staff for Research & Development (ACOS/R&D)** is responsible for
 - (1) Developing and managing policies and procedures for individuals to voice research-related complaints and allegations of non-compliance with institutional policies related to the HRPP for research conducted at the PVAMC;
 - (2) Evaluating the facts surrounding all research-related complaints and allegations of non-compliance regarding the HRPP institutional policies as brought forward by, and in consultation with the RACC; and
 - (3) Ensuring all research-related complaints and allegations of non-compliance regarding the HRPP institutional policies brought forward by the RACC have been thoroughly investigated and, if appropriate, remedial action taken.

- b. The **Research and Development Committee (R&D)** is responsible for:
 - (1) Reviewing research-related complaints and allegations of non-compliance with the HRPP and IRB policies brought to its attention by the RACC or IRB;
 - (2) Determining and voting on recommendations for corrective action, including those forwarded by the IRB;
 - (3) Documenting in the R&D Committee meeting minutes the discussion, deliberation and final determinations for remedial action voted on by the R&D Committee;

- c. The **Institutional Review Board Chairperson** is responsible for
 - (1) Notifying the RACC of any research-related complaints and allegations of non-compliance with the HRPP institutional policies that have been raised by any individual;
 - (2) Reviewing research-related complaints and allegations of non-compliance with the HRPP and IRB policies that have been brought forward from the RACC; and
 - (3) Determining whether a special meeting of the IRB must be convened if an immediate patient safety issue is raised or whether the issue may be held until the next scheduled meeting.

- d. The **Institutional Review Board** is responsible for
 - (1) Notifying the RACC of any research-related complaints and allegations of non-compliance with the HRPP institutional policies that have been raised by any individual;
 - (2) Notifying the RACC of any undue influence exerted by any individual involved in research on either an IRB member or a research participant;
 - (3) Addressing any research-related complaints and allegations of non-compliance with HRPP and IRB policies raised against a principal investigator or research staff. Such allegations will be brought to the IRB by the IRB Chairperson or RACC;

- (4) Determining the validity of complaints and allegations brought to its attention by the RACC or IRB Chairperson, determining whether each incident represents serious or continuing non-compliance, and making a recommendation for remedial action;
 - (5) In the case of serious or unexpected harm to participants, suspending or terminating the research;
 - (6) Determining whether a valid complaint concerns an unanticipated problem involving risks to participants or others;
 - (7) Determining and requiring optional actions as appropriate, with consideration as to whether or not non-compliance is determined to be serious and/or continuing:
 - modification of protocol and/or informed consent,
 - providing additional information to past participants,
 - re-consent of current participants,
 - modification of the continuing review schedule,
 - monitoring of the research and/or the consent process and/or
 - referral to other organizational entities.
 - (8) Documenting in the IRB meeting minutes the discussion, deliberation and final recommendation to the R&D Committee.
- e. The **Research Assurance and Compliance Coordinator** is responsible for
- (1) Documenting all research-related complaints and allegations of non-compliance with the HRPP and IRB policies;
 - (2) Maintaining a log and associated documentation of all research-related complaints and allegations of non-compliance with the HRPP and IRB policies;
 - (3) Conducting an initial review, as appropriate to the nature of the complaint or allegation, of all research-related complaints and allegations of non-compliance with the HRPP and IRB policies;
 - (4) Notifying the ACOS/R&D of any incident that arises and that an inquiry has begun;
 - (5) Evaluating the facts gathered in consultation with the ACOS/R&D and taking appropriate action;
 - (6) Forwarding non-frivolous research-related complaints and allegations of non-compliance with the HRPP and IRB policies, including allegations of attempts to unduly influence IRB members to the appropriate individuals and committees; and
 - (7) Ensuring that all complaints and allegations of non-compliance with the HRPP and IRB policies, including undue influence, have been addressed.
- f. **Principal Investigators** are responsible for:
- (1) Notifying the RACC of any research-related complaints and allegations of non-compliance with the HRPP institutional policies raised by any individual;
 - (2) Immediately providing all information requested by the RACC to address any complaints and allegations of non-compliance with the HRPP and IRB policies; and
 - (3) Complying with decisions made by the IRB and R&D Committee regarding findings of non-compliance.
- g. **Medical Center and Research Staff** are responsible for
- (1) Notifying the RACC of any research-related complaints and allegations of non-compliance and/or undue influence raised by any individual;

- (2) Immediately providing all information requested by the RACC to address any complaints and allegations of non-compliance with the HRPP and IRB policies; and
- (3) Complying with decisions made by the IRB and R&D Committee regarding findings of non-compliance.

4. DEFINITION:

- a. **Frivolous complaint or allegation:** A complaint or allegation may be considered frivolous if the following two elements are met:

- (1) The case is not an immediate threat to patient safety and/or privacy; and
- (2) Upon initial review, none of the presented information is nor appears to be verifiable or accurate.

For example, in some cases, a misunderstanding about the study can be resolved immediately. If so, the complaint and the information provided to resolve the complaint should be documented with the RACC.

5. PROCEDURES:

- a. **Patients, research participants, investigators, research staff, medical staff, nursing staff, IRB members and others are informed of their ability and responsibility to report and/or voice any research-related complaints and allegations of non-compliance with the HRPP and IRB policies according to the following procedures:**

- (1) All Research Study Participants for whom informed consent is required, as determined by the Portland VAMC IRB, shall receive a copy of the corresponding study's consent form containing
 - (a) encouragement to contact the IRB Chair to discuss any concerns about their research study participation; and
 - (b) other contacts for other specific situations as follows:
 - i. For answers to pertinent questions about the research, the principal investigator, co-investigator or other responsible research team member;
 - ii. For answers to questions about subjects' rights, the chair of the IRB through the Research Service; and
 - iii. In the event of a research-related injury, a study investigator or other responsible research team member.
 - iv. In the event of a breach of privacy/confidentiality, the Portland VA Privacy Officer.
- (2) Medical Center and Research staff as well as IRB members shall receive notification every six months via e-mail through VISTA and MS Outlook regarding who to contact and how to report any research-related complaints and allegations of non-compliance with the HRPP and IRB policies and attempts to unduly influence.

b. Notifying the Research Assurance & Compliance Coordinator (RACC)

- (1) All research-related complaints and allegations of non-compliance with the HRPP and IRB policies and undue influence should be reported directly to the RACC as soon as possible and no later than 5 working days after recognition of the alleged non-compliance.
- (2) The RACC may be contacted as follows:
 - (a) Mail:
Research Assurance & Compliance Coordinator
Portland VA Medical Center
Mailcode: R&D - Research & Development Service
3710 S.W. U.S. Veterans Hospital Road
Portland, OR 97239
 - (b) Phone: 503-220-82262, ext. 54989 or 503-273-5125
 - (c) Fax: 503-273-5152
 - (d) e-mail: Vista: **G.RESEARCH FEEDBACK**
Outlook: **research.feedback@va.gov**
- (3) To protect their rights when voicing research-related complaints and allegations of non-compliance and/or undue influence pertaining to human research an individual's identity shall be kept confidential, unless pertinent to the investigation.
- (4) Anonymous research-related complaint(s) and allegation(s) may also be left by voice mail at: 503-220-8262 ext. 54989.
- (5) The RACC shall reassure the individual that all possible efforts will be made to inquire into the facts and circumstances and appropriate measures will be taken to address the issue.

c. Research Assurance & Compliance Coordinator

The RACC must act promptly upon becoming aware of a complaint or allegation of non-compliance, taking immediate action if patient safety, privacy or information security are at issue, and adhere to the following procedures:

- (1) Review all research-related complaints and allegations of non-compliance with the HRPP and IRB policies and undue influence.
- (2) Document all research-related complaints and allegations of non-compliance with the HRPP and IRB policies and undue influence in the R&D Service "Complaints and Allegations of Non-Compliance in Human Research Institutional Policies Log." Minimum information to be documented shall include the individual's name, address and phone number, unless the complaint or allegation is anonymous; the study protocol title; the principal investigator's name; relevant dates; and a summary of the complaint or allegation.
- (3) Conduct an initial review, as appropriate to the nature of the complaint or allegation, of all research-related complaints and allegations of non-compliance with the HRPP and IRB policies.
- (4) Notify the ACOS/R&D of any incident that has arisen and that an inquiry has begun. In consultation with the ACOS/R&D, evaluate the facts and take appropriate action.
 - (a) If an immediate patient safety issue is raised, the IRB Chair shall be immediately notified; the IRB Chair shall determine whether a special meeting of the IRB

must be convened or if the issue may safely wait until the next scheduled meeting.

- (5) Notify the appropriate principal investigator(s) and any other involved individuals regarding a complaint and/or allegations of non-compliance or undue influence involving the respective party(ies), regardless of whether or not the complaint or allegation is determined to be frivolous.
- (6) Notify the IRB of any non-frivolous complaints and allegations of non-compliance or undue influence pertaining to the HRPP and IRB policies.
- (7) Notify the R&D Committee Chair of any non-frivolous complaints and allegations of non-compliance with the HRPP and IRB policies, including undue influence, by the IRB or IRB member(s).
- (8) Notify the PVAMC Information Security Officer if report involves an information security issue.
- (9) Notify PVAMC Privacy Officer if report involves violation of privacy and confidentiality regulations.
- (10) Document and file all actions and correspondence regarding research-related complaints and allegations undue influence and/or other non-compliance with the HRPP and IRB policies.
- (11) Assist in the collection of all necessary background data to allow for a full investigation by the IRB and/or R&D Committee, as necessary.
- (12) Ensure all research-related complaints and allegations of non-compliance, including undue influence are addressed appropriately.

d. Investigation of Complaints and Allegations of Non-compliance

- (1) The RACC in consultation with the ACOS/R&D and IRB Chair and if applicable, the Privacy Officer and Information Security Officer, will first review complaints and allegations of non-compliance at the administrative level in order to maintain the confidentiality of involved individuals in the event the complaint or allegation may be frivolous.
- (2) Non-frivolous complaints regarding a specific study, investigator, and/or study staff shall be addressed by the IRB. Any recommendation for corrective action shall be forwarded to the R&D Committee.
- (3) Non-frivolous complaints involving the IRB and/or member(s) shall be addressed by the R&D Committee.
- (4) Non-frivolous complaints involving the R&D Committee and/or member(s) shall be addressed by the ACOS/R&D and/or the Privacy Officer as appropriate.

e. Determination for Remedial Action

- (1) If an issue involves human subject protection and safety, immediate action will be taken to minimize potential harm to subjects or staff pending the outcome of a formal review. The IRB must review all non-compliance in human research, determine whether serious and/or continuing, and decide on remedial action.
- (2) Dependent upon the nature of the event or circumstances, any of the following actions may occur:
 - (a) Further inquiry may be initiated;
 - (b) Administrative action may be taken;

- (c) Details and recommendations may be forwarded to the appropriate committee Chairpersons (IRB and R&D Committee) for consideration and action by those committees;
 - (d) Details and recommendations may be forwarded to the Chief of Staff and/or the Medical Center Director for action;
 - (e) Details and recommendations may be forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up; and/or
 - (f) Other actions as deemed appropriate.
- (3) If an active research project is found to be in non-compliance with the HRPP and IRB policies, the IRB, at either the next regularly scheduled or specially convened meeting, will determine whether or not a research project
- (a) May continue;
 - (b) May continue with modifications;
 - (c) shall be suspended; or
 - (d) shall be terminated.
- (4) If an active research project is found to be non-compliant with the HRPP and IRB policies, or an investigator or research staff member has been found to have exerted undue influence on an IRB member, a recommendation will be made as to whether or not a Principal Investigator or anyone involved with the research project
- (a) May continue conducting research;
 - (b) May continue conducting research with modifications; or
 - (c) Shall be suspended from conducting research.
- (5) Complaints and allegations of non-compliance with the HRPP and IRB policies against the IRB and/or member(s) will be reviewed by the IRB and recommendations to prevent this issue from arising in the future shall be forwarded to the R&D Committee.
- (6) Complaints and allegations of non-compliance with the HRPP and IRB policies against the R&D Committee and/or member(s) will be reviewed by the ACOS/R&D and action taken to prevent this issue from arising in the future.

f. Notification

- (1) The RACC, through the ACOS/R&D, will notify all previously contacted individuals in writing of the decision(s) made and action(s) taken regarding the research-related complaints and allegations of non-compliance related to the HRPP and IRB policies.
- (2) Any individual voicing an anonymous research-related complaint or allegation will not be notified of the decision(s) made and action(s) taken regarding the complaint(s) or allegation(s) by virtue of being anonymous.
- (3) If an allegation or complaint is determined to be frivolous, the IRB and R&D Committees will be notified of the frivolous allegation or complaint, but the information presented will be stripped of all identifiers.

g. Reports to Institutional Officials and other Appropriate Parties and Authorities

The final course of action regarding the complaint or allegation is entirely dependent upon the nature, severity, and degree of seriousness of the findings. As described in this policy, all actions taken shall be at the institutional level most appropriate for the circumstances. The IRB Chair or ACOS/R&D, at the request of the Medical Center

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Director as the Institutional Official for the Human Research Protection Program will report all actions requiring reporting to regulatory bodies outside the medical center, such as the Regional Office of Research Oversight (ORO), VHA Information Security Officer (ISO) if information security is at issue, institutional Privacy Officer (PO) if privacy is at issue, Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA) if investigational devices or drugs are involved, and/or any other federal agencies overseeing research who require separate reports from OHRP. Instances that may require such notification, include

- (1) findings of serious or continuing noncompliance with the regulations for the protection of human subjects or with the requirements of the IRB;
- (2) any unanticipated problems involving risks to subjects or others (e.g., death of healthy volunteers participating in research); and
- (3) suspension or termination of IRB approval (e.g., associated with unexpected harm, research not being conducted in accordance with the IRB's requirements).

Reports to regulatory bodies shall be made as soon as possible after recognition of a reportable event and no later than five days after such recognition or within the maximum allowable time required by the applicable regulatory body as indicated below:

- ORO - Reports should be provided to ORO as soon as possible, but no later than 10 working days after the issue has come before the responsible facility official or oversight committee.
- FDA – promptly. PVAMC will follow the same timeline for reporting as for ORO, i.e. no later than 10 working days.
- OHRP - promptly. PVAMC will follow the same timeline for reporting as for ORO. i.e. no later than 10 working days

5. REFERENCES: 38CFR16.103(b)(5)

38CFR16.116(a)(7)

45CFR46.103(b)(5)

45CFR46.116(a)(7)

21CFR50.25(a)(7)

21CFR56.108(b)(2) and (5)

OHRP Guidance on Reporting Incidents to OHRP

VHA Handbook 1200.5 7

6. CONCURRENCES: Endorsed by the Research & Development Committee 03/03/2008.

7. RESCISSION: HRPP: Complaints and Allegations of Non-Compliance Pertaining to Human Research 08/27/2007.

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

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