

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

1. **PURPOSE:** To establish a service level policy for any person, including patients, research participants, investigators, research staff, Research and Development Committee (R&DC) members, Institutional Review Board (IRB) members, medical staff, nursing staff and others to voice research-related complaints and/or allegations of non-compliance with federal or state regulations and institutional policies, including exercise of undue influence, pertaining to all research activities at the Portland VA Medical Center (PVAMC). This policy will help to ensure that all research activities are conducted in accordance with the ethical standards of the Portland VA Medical Center (PVAMC) and compliance with all federal and state regulations governing human, animal and basic research. This policy does not replace the responsibilities of all research personnel as detailed in the Human Research Protection Program (HRPP) policy entitled [Required Reports in Human Research](#) or the R&D policy entitled [Required Reporting](#). However, this policy offers another avenue to participants and others for reporting perceived or suspected non-compliance.

2. **DEFINITIONS:**
 - a. Non-compliance is defined as failure to follow any applicable federal or state regulations, the requirements and determinations of the R&DC, any of its subcommittees, or VA requirements.

 - a. Serious non-compliance is defined as the failure to adhere to the laws, regulations, or policies governing VA research that
 - 1) results in substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of human subjects, research staff, or others, or to the safety or welfare of research animals; or
 - 2) substantively compromises the integrity or effectiveness of research protections, either systemically or relative to a particular project.

 - b. Continuing non-compliance is defined as persistent or repeated failure, either in the past or extending into the present, to satisfy VA or other Federal research requirements.

 - b. Frivolous complaint or allegation: A complaint or allegation may be considered frivolous if the following two elements are met:
 - 1) The complaint does not involve a possible risk to safety and/or privacy of patients or personnel or safety of research animals; 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 by the Research Assurance Officer (RAO).

3. **POLICY:** This policy establishes remedial actions and consequences for findings of non-compliance with the policies of the HRPP and IRB, Subcommittee on Research Safety (SRS), Institutional Animal Care and Use Committee (IACUC), and R&DC, identifies individuals who have responsibility for ensuring corrective action has been taken, and establishes a process for reporting to institutional officials and other appropriate parties and authorities.

VA MEDICAL CENTER, PORTLAND, OREGON
Human Research Protection Program Policy & Procedure
Complaints of Non-Compliance

Effective: 12/06/2010

- a. Patients, research participants, investigators, research staff, IRB members, medical staff, nursing staff and others may report research-related complaints and allegations of non-compliance with all institutional research policies. Such complaints and allegations may be made anonymously, if desired.
- b. All complaints and allegations will be investigated and addressed promptly by the Associate Chief of Staff/Research & Development (ACOS/R&D) and RAO.
- c. When appropriate, a report will be made to the IRB, and when necessary, institutional officials and other appropriate parties and authorities will be notified.
- d. Per the HRPP policy entitled [Required Reports in Human Research](#), and Research policy entitled Required Reporting in Animal and Lab Studies investigators and research staff are required to report all allegations and findings of non-compliance to the appropriate authority as soon as possible after recognition. Non-compliance must be reported by investigators to the appropriate committee or sub-committee (IRB, SRS, IACUC, or R&DC) through the ACOS/R&D no later than five (5) working days after awareness. This policy does not replace that requirement.

4. RESPONSIBILITIES:

- a. The **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) Thoroughly investigating and attempting to determine the facts surrounding all research-related complaints and allegations of non-compliance regarding the institutional research policies as brought forward by, and in consultation with, the RAO; and
 - 3) Ensuring appropriate action and reporting in compliance with local and national VA policies.
- b. The **RAO** is responsible for
 - 1) Reporting all complaints and allegations of non-compliance to the ACOS/R&D and the appropriate subcommittee or R&DC when appropriate;
 - 2) Documenting all research-related complaints and allegations of non-compliance with institutional policies;
 - 3) Maintaining a log and associated documentation of all research-related complaints and allegations of non-compliance with institutional policies;
 - 4) 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 institutional policies;
 - 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 institutional policies, including allegations of attempts to unduly influence IRB members, to the appropriate individuals and entities; and
 - 7) Ensuring that all complaints and allegations of non-compliance institutional policies, including undue influence, have been addressed.
- c. The **chairperson** of the **IRB/SRS/IACUC/R&DC** is responsible for
 - 1) Reviewing research-related complaints and allegations of non-compliance with institutional policies that have been brought forward by the RAO, and

VA MEDICAL CENTER, PORTLAND, OREGON
Human Research Protection Program Policy & Procedure
Complaints of Non-Compliance

Effective: 12/06/2010

2) Determining whether a special meeting of the IRB must be convened if an immediate patient safety risk is raised or whether the issue may be held until the next scheduled meeting.

d. The **IRB/SRS/IACUC/R&DC** is responsible for

1) Notifying the RAO of any research-related complaints and allegations of non-compliance with institutional policies that have been raised by any individual;
2) Notifying the RAO of any undue influence exerted by any individual involved in research on either a subcommittee/R&DC member or a research participant;
3) Addressing any research-related complaints and allegations of non-compliance institutional policies raised against a principal investigator or research staff. Such allegations will be brought to the appropriate sub-committee(s) or R&DC Chairperson or RAO. Each subcommittee/R&DC shall review based on related applicable committee/subcommittee Standard Operating Procedures (SOP).

4) Determining the validity of complaints and allegations brought to its attention, determining whether each incident represents serious or continuing non-compliance, and making a recommendation for remedial action, if necessary;

5) In the case of serious or unexpected harm to participants or others, suspending or terminating the research;

6) Determining whether a valid complaint indicates an unanticipated problem involving risks to participants or others;

7) Determining and requiring optional actions, such as those in the following list, 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 subcommittee meeting minutes the discussion, deliberation and final recommendation to the R&DC.

e. The **R&DC** is responsible for

1) Reviewing research-related complaints and allegations of non-compliance with institutional policies brought to its attention by the ACOS/R&D, RAO or a subcommittee;

2) Determining and voting on recommendations for corrective action, including those forwarded by any subcommittee;

3) Documenting in the R&DC meeting minutes the discussion, deliberation and final determinations for remedial action voted on by the R&DC;

f. **Principal Investigators (PIs)** are responsible for:

1) Notifying the RAO 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 RAO 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&DC regarding findings of non-compliance.

g. **Medical Center and Research Staff** are responsible for

1) Notifying the RAO of any research-related complaints and allegations of non-compliance and/or undue influence raised by any individual;

VA MEDICAL CENTER, PORTLAND, OREGON
Human Research Protection Program Policy & Procedure
Complaints of Non-Compliance

Effective: 12/06/2010

- 2) Immediately providing all information requested by the RAO to address any complaints and allegations of non-compliance with PVAMC policies; and
- 3) Complying with decisions made by the IRB/SRS/IACUC and R&DC regarding findings of non-compliance.

5. PROCEDURES: For a summary of procedures, see attached flow chart, "Actions Following Complaint or Allegation of Non-Compliance in Research."

a. Notification: Patients, research participants, investigators, research staff, clinical staff, IRB/SRS/IACUC/R&DC members and others are informed of the opportunity and responsibility to report and/or voice any research-related complaints and allegations of non-compliance with PVAMC policies according to the following procedures:

- All research study participants receive a brochure from the PI containing general information about their rights and the contact information for the RAO if they have questions or concerns about research in general, a specific research study, or research personnel.
- Anyone with a complaint should contact the RAO as follows:

Research Assurance Officer
Portland VA Medical Center
Mailcode: R&D - Research & Development Service
3710 S.W. U.S. Veterans Hospital Road
Portland, OR 97239

Phone: 503-220-82262, ext. 54989 or 503-273-5125

Fax: 503-273-5152

E-mail: Vista: **G.RESEARCH FEEDBACK**

Outlook: **research.feedback@va.gov**

- 1) To protect their rights when voicing research-related complaints and allegations of non-compliance and/or undue influence pertaining to research, an individual's identity shall be kept confidential, unless pertinent to the investigation.
- 2) Anonymous research-related complaint(s) and allegation(s) may also be left by voice mail at 503-220-8262 ext. 54989, or faxing to 503-273-5152.
- 3) The RAO shall reassure the individual that all possible efforts will be made to determine the facts and circumstances, and appropriate measures will be taken to address the issue.

b. Investigation: The RAO shall act promptly upon becoming aware of a complaint or allegation of noncompliance, taking immediate action if the safety, rights, or welfare (including privacy or information security) of participants, research personnel or others are at issue, and adhere to the following procedures:

- 1) Document all research-related complaints and allegations of noncompliance in the official, related log kept by the Research Administration Office. Minimum information to be documented shall include the individual's name and contact information (unless the complaint or allegation is anonymous); the study title and PI's name, if applicable; the name of any particular person against whom the complaint or allegation is lodged; relevant dates; and a summary of the complaint or allegation.
- 2) Conduct an initial review, as appropriate to the nature of the complaint or allegation, to investigate any research-related complaint and allegations of noncompliance.
- 3) In consultation with the ACOS/R&D, evaluate the facts and take appropriate action .
- 4) If an immediate patient safety issue is raised, immediately notify the IRB Chairperson; the IRB Chairperson shall determine whether a special meeting of the IRB must be convened or if the issue may be held until the next scheduled IRB meeting.

- 5) Notify the appropriate PI(s) and any other involved individuals, regardless of whether or not the complaint or allegation is determined to be frivolous.
- 6) Notify the applicable research committee(s) of complaints and allegations of noncompliance that are determined to have a basis in fact.
- 7) Notify the R&DC Chair of any valid complaints and allegations of non-compliance with PVAMC policies, including undue influence, by the IRB/SRS/IACUC or member(s) of committee.
- 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 of undue influence and/or other non-compliance with PVAMC policies.
- 11) Assist in the collection of all necessary background data to allow for a full investigation by the IRB/SRS/IACUC and/or R&DC, as necessary.
- 12) Ensure all research-related complaints and allegations of non-compliance, including undue influence are addressed appropriately.

c. Determination for Remedial Action

- 1) An IRB Chair or designee will initially review all local serious adverse events and problems that may involve risk to patients or others. If an issue involves human subject protection and safety, the IRB chair or a designated IRB member will determine if immediate action is needed to minimize potential harm to subjects or staff pending the outcome of convened IRB review. If the IRB reviewer determines the problem is not related, or is related but is anticipated and does not involve possible serious or continuing non-compliance, no further review is required. The convened IRB will review in the following instances:
 - When a complaint relates to a serious adverse event or problem involving risk (includes non-compliance), and the initial reviewer determines it is related to the research and unanticipated, the IRB must then determine any appropriate remedial action(s) and if the event was serious.
 - In the case of non-compliance, regardless of whether the non-compliance caused harm to any participants or a problem involving risk, the convened IRB must review to determine if serious and/or continuing.
- 2) Complaints and allegations of non-compliance with PVAMC policies against the IRB/SRS/IACUC and/or member(s) will be reviewed and appropriate action taken by the R&DC.
- 3) Complaints and allegations of non-compliance with PVAMC policies against the R&DC and/or member(s) will be reviewed by the ACOS/R&D and action taken to prevent this issue from arising in the future.

- d. Reports to Individuals, Institutional Officials and Agencies:** 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 RAO will facilitate reports as required based on the PVAMC policies, [Required Reports in Human Research](#) and Required Reports in Animal and Laboratory Research ([Required Reporting](#)).
- 1) Any investigator about whom a complaint or allegation of non-compliance has been made will be notified, given an opportunity to respond and explain, and notified of the final determination and any outside required reports.
 - 2) The person who made the complaint or allegation will be notified of the determination unless they choose to remain anonymous.

VA MEDICAL CENTER, PORTLAND, OREGON
Human Research Protection Program Policy & Procedure
Complaints of Non-Compliance

Effective: 12/06/2010

6. **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 1200.05
VHA Handbook 1058.01
7. **CONCURRENCES:** Endorsed by the Research & Development Committee 12/06/2010.
8. **RESCISSION:** HRPP: Complaints and Allegations of Non-Compliance Pertaining to Human Research 03/03/2008 and 04/05/2010.
9. **FOLLOW-UP RESPONSIBILITY:** ACOS, Research & Development Service (R&D)

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service

**ACTIONS FOLLOWING COMPLAINT OR ALLEGATION OF
 NON-COMPLIANCE IN RESEARCH**

RAO receives complaint or allegation of non-compliance.

RAO immediately notifies ACOS/R&D.

RAO and/or ACOS investigate:

- contact PI or others as appropriate;
- if applicable, review medical or research records;
- verify any documentation.

Does the complaint/allegation have some likely basis in fact?

YES

NO

Within 5 business days of determination, RAO reports in writing to IRB/SRS/IACUC Chair with copy to PI.

1. ACOS/R&D reports to -
 - involved investigator
 - complainant unless anonymous
 2. RAO documents outcome in log.

Does the complaint involve human research?

YES

NO

Follow policy: [Required Reports in Animal & Lab Research](#)

1. Per IRB SOP, IRB chair reviews using Initial Reviewer Checklist for Research Event, determines if urgent action required.
 2. Convened IRB reviews, makes determination and recommendation.
 3. Follow policy: [Required Reports in Human Research](#).

ACOS/R&D reports to -
 -involved investigator
 -complainant unless anonymous
 RAO documents outcome in log.