

## Continuous Quality Improvement in the Human Research Protection Program

1. **PURPOSE:** Establish a Continuous Quality Improvement (CQI) program to evaluate Human Research Protection Program (HRPP) effectiveness and develop quality improvement activities to continuously measure, assess and improve investigator compliance with federal regulations, applicable state regulations, and institutional HRPP policies and practices to protect human research participants. The program should also assure that research files for both investigators and R&D Service are properly maintained and that investigators follow the rules of good clinical practice in conducting human research.
2. **POLICY:** Research projects involving human research participants active at the Portland VA Medical Center (PVAMC) must be conducted in accordance with institutional HRPP policies and procedures as well as state and federal regulations. All active research projects at the PVAMC involving human research participants will be audited by the Research Compliance Officer at least once every three years or once during the life of the study if the study is completed in less than three years in compliance with [VHA Directive 2008-064](#) - Research Compliance Officers and The Auditing Of VHA Human Subjects Research To Determine Compliance With Applicable Laws, Regulations, And Policies. For-cause audits may also be conducted if ordered by the IRB, the R&D Committee, and/or the ACOS/R&D. Investigators found by the IRB to be in serious and/or continuing non-compliance will be closely monitored, remedial actions will be determined, and their performance will be reviewed by the R&D Committee and the ACOS/R&D. Actions may include suspension or termination of particular studies and/or temporary or permanent barring of the investigator from all human research.
3. **RESPONSIBILITIES:**
  - a) The **Associate Chief of Staff for Research & Development (ACOS/R&D)** is responsible for developing and managing policies and procedures to evaluate HRPP effectiveness at the PVAMC, as well as assess and improve compliance with HRPP policies and practices.
  - b) The **Deputy ACOS/R&D** may act for the ACOS/R&D as directed by the ACOS/R&D.
  - c) The **Administrative Officer/R&D (AO/R&D)** is responsible for reviewing HRPP policies, overseeing human research personnel hiring and credentialing, and other duties as delegated by the ACOS or Deputy ACOS/R&D.
  - d) The **Research and Development Committee (R&D)** is responsible for the following:
    - (1) Reviewing performance evaluations of IRB membership and human research investigators, including investigator compliance with HRPP and IRB requirements based on audits and reports of investigator non-compliance.
    - (2) Reviewing the Human Research Protection Program (HRPP) on an annual basis.

- (3) Making recommendations, as needed, regarding appropriate proposed corrective actions included in the reports and results of compliance assessment and quality assurance/improvement activities (QA/QI) related to research.
  - (4) Reviewing any recommendations for action proposed by the IRB based on audit or other reports; proposing, discussing, and voting on other possible actions.
- e) The **Institutional Review Board (IRB)** is responsible for the following:
- (1) Reviewing audit reports and reports of non-compliance.
  - (2) Making recommendations regarding proposed quality improvement efforts and/or measures to improve performance based on audit reports and reports of non-compliance.
  - (3) Voting on all recommendations for action to be forwarded to the R&D Committee.
- f) **Research Assurance Officer (RAO)** is responsible for the following:
- (1) Conducting for-cause audits when directed by the IRB or the ACOS/R&D.
  - (2) Forwarding for-cause audit reports to the IRB and ACOS/R&D for review and evaluation as completed and to the R&D Committee after review by the IRB.
  - (3) Developing and maintaining an evaluation instrument and participating in annual evaluation of IRB membership performance with input from IRB members (self-evaluations), IRB staff, the ACOS/R&D, and the chair of the R&D Committee.
  - (4) Annually reviewing the HRPP including IRB composition, credentialing and training status report, budget, space, support, quality improvement activities, compliance issues, and goals for the next year.
  - (5) Reporting annually the results of review of the HRPP and evaluation of IRB membership. The report shall include the following:
    - Measures of compliance with regulations and policies, indicating levels of quality, efficiency and effectiveness of the HRPP. Examples include # of investigators with studies suspended for cause, lapsed approvals, and terminations (either for cause or administrative) of studies compared with previous years; # investigators who failed to complete training and were suspended or terminated from research; any measures requested by the R&D Committee or based on audit reports by the RCO; # of complaints of non-compliance.
    - Goals for the coming year, e.g., fewer lapsed approvals and suspensions, as well as progress toward goals from the previous year.
- g) **Research Compliance Officer (RCO)** is responsible for the following:
- (1) Auditing all research studies once every three years or once during the life of the study if less than three years
  - (2) Reporting results of audits to the R&D Committee, IRB and any other relevant subcommittee
  - (3) Meeting with the ACOS and Deputy ACOS/R&D and AO regarding audit findings and issues of concern.
- h) **IRB Staff** are responsible for the following:
- (1) Meeting regularly with the RAO to discuss IRB process and HRPP issues.

- (2) Making recommendations to the RAO concerning perceived investigator non-compliance and knowledge gaps with regard to the HRPP.
- (3) Developing or changing processes within the office to increase or improve human research protection.
- (4) Assisting annually in evaluation of IRB membership.

i) **Principal Investigators (PI)** are responsible for the following:

- (1) Coordinating the research project audit date and place with the RCO
- (2) Ensuring that all study-related documents are available for review.
- (3) Assembling and preparing study-related documents.
- (4) Cooperating with audit procedures.
- (5) Complying with decisions made by the RCO, RAO, IRB and/or R&D Committee regarding audit findings and recommendations.

4. **PROCEDURES:**

a) **Regulatory Audits**

- (1) The RCO and RCO staff will conduct the regulatory audits per [VHA Directive 2008-064](#), Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations, and Policies.
- (2) The ACOS and Deputy ACOS/R&D and the Administrative Officer/R&D (AO/R&D) shall meet with the RCO twice monthly to discuss audit findings and determine areas of weakness in investigator knowledge that require further education and monitoring.
- (3) The RCO will submit audit reports to the IRB as audits are completed for review at the next convened meeting.
- (4) The IRB will review all reports and investigator responses. They will determine if any findings constituted serious and/or continuing non-compliance or problems involving previously unknown risk and determine actions that should be taken to address their findings.

b) **For-cause Audits**

- (1) The RCO or the RAO may conduct for-cause audits as directed by the IRB and/or the ACOS/R&D. Such audits will be based on good clinical practice and will include review of all source documents, regulatory files, informed consents, and if directed, informed consent process.
- (2) The auditor will submit a formal report of the audit results to the principal investigator and to the IRB. The investigator will also be asked to respond to the report and the response will be sent to the IRB.
- (3) The IRB will review all reports and investigator responses. They will determine if any findings constituted serious and/or continuing non-compliance or problems involving previously unknown risk and determine actions that should be taken to address their findings.

**VA MEDICAL CENTER, PORTLAND, OREGON**  
**Human Research Protection Program Policy & Procedure**  
**Continuous Quality Improvement in the HRPP**

Effective: 12/06/2010

**c) Recommendations and Actions for Improvement**

- (1) The ACOS/R&D, Deputy ACOS/R&D, AO, RAO, and Senior IRB coordinator will meet twice monthly to discuss ways to address weaknesses among investigators and determine what educational programs are needed.
- (2) The ACOS/R&D and others as directed by the ACOS will periodically conduct Investigator Workshops to address weaknesses identified by audits and reports of non-compliance.
- (3) The RAO will maintain a list of educational topics to be addressed.
- (4) The RAO will participate in quarterly clinical coordinator workshops conducted by the PVAMC affiliate, Oregon Health & Science University, presenting VA regulations and the PVAMC HRPP.

**d) Review and Recommendations by the R&D Committee**

- (1) The R&D Committee shall review all audit reports and determinations by the IRB, including determinations of serious and/or continuing non-compliance.
- (2) The R&D Committee may make further recommendations for remediation including individual investigator education or education for all investigators.
- (3) The RAO shall report yearly to the R&D Committee an evaluation of the HRPP and of the IRB membership.
- (4) The R&D Committee will review the reports and may recommend changes and actions to improve investigator performance and compliance and/or programmatic or systemic process changes to improve the protection of human research participants.

5. **REFERENCES:** [VHA Handbook 1058.01](#), [VHA Directive 2008-064](#), and Association for the Accreditation of Human Research Protection Programs (AAHRPP) Accreditation Standards (<http://www.aahrpp.org/www.aspx?PageID=318>).

6. **CONCURRENCES:** Endorsed by the Research & Development Committee 12/06/2010.

7. **RESCISSION:** Human Research Protection Program Policy & Procedure No. 9 endorsed 12/15/2003 and Continuous Quality Improvement in the Human Research Protection Program 08/30/2010.

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

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