

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 Research and Development (R&D) Service are properly maintained and that investigators follow the rules of good clinical practices (GCP) in conducting human research.
2. **POLICY:** Active research projects involving human research participants 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 (RCO) in compliance with relevant guidance from the Office of Research Oversight (ORO). For-cause audits may also be conducted if ordered by the IRB, the R&D Committee (R&DC), and/or the Associate Chief of Staff (ACOS)/R&D. Investigators found by the IRB to be in serious and/or continuing non-compliance will be closely monitored, with remedial actions determined as appropriate and their performance reviewed by the R&DC 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 **ACOS/R&D** is responsible for developing and managing policies and procedures to evaluate HRPP effectiveness at the PVAMC, as well as to 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/R&D or Deputy ACOS/R&D.
 - d) The **R&DC** 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 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, and 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&DC.
- f) The **Research Assurance Officer (RAO)** is responsible for the following:
 - (1) Performing educational reviews of studies in order to provide individualized guidance regarding GCP, as needed, to investigators.
 - (2) Conducting for-cause audits, when directed by the IRB, R&DC or ACOS/R&D.
 - (3) Forwarding the results of for-cause audit reports to the IRB and ACOS/R&D for review and evaluation and then to the R&DC after review by the IRB and ACOS/R&D.
 - (4) Developing and maintaining an IRB member evaluation instrument(s) and participating in annual evaluation of IRB member performance with input from IRB members (self-evaluations), the ACOS/R&D, and the chair of the R&DC.
 - (5) 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.
 - (6) Reporting annually the results of the HRPP review and evaluation of IRB membership to the R&DC.
- g) The **RCO** is responsible for the following:
 - (1) Auditing all research studies in compliance with relevant guidance from the Office of Research Oversight (ORO).
 - (2) Reporting results of audits to the R&D Committee, IRB and any other relevant subcommittee(s).
- 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) i) **Principal Investigators (PIs)** are responsible for the following:
 - (1) Coordinating the research project audit or educational review date and place with the RCO and/or RAO respectively.
 - (2) .
 - (3) Assembling and preparing all study-related documents and ensuring that they are available for review during an audit or educational review.
 - (4) Cooperating with audit procedures.

- (5) Complying with decisions made by the RCO, RAO, IRB and/or R&DC regarding audit findings and recommendations.

4. PROCEDURES:

a) Regulatory Audits

- (1) The RCO and RCO staff will conduct the regulatory audits in compliance with relevant guidance from the Office of Research Oversight (ORO).
- (2) The RCO will submit regulatory audit reports to the IRB at regular intervals (e.g. quarterly) for review at a convened IRB meeting. Based on the information in the reports, the IRB 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, R&DC and/or the ACOS/R&D. Such audits will be based on GCP and will include review of all study documents, files, informed consents, and if directed, informed consent process.
- (2) The auditor will submit a formal report of the audit results to the PI, ACOS/R&D and to the IRB. The PI 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.
- (4) After review by the IRB and ACOS/R&D, the report and any associated materials will be forwarded to the R&DC for their review.

c) Educational Reviews

- (1) The RAO will perform educational reviews to assess for general adherence to GCP. The reviews will include an assessment of organization and tracking methods for particular study-related documents and information and a review of the study records for a single participant, record or specimen.
- (2) During the review and/or in a subsequent written summary, the RAO will provide any suggestions for improving adherence to GCP.
- (3) Any reportable events identified during the review will be reported as per the IRB Policies & Procedures.

d) Recommendations and Actions for Improvement

- (1) The ACOS/R&D, Deputy ACOS/R&D, AO, RAO, and Lead IRB Analyst will be scheduled to meet twice monthly, with discussions to include ways of addressing any areas for improvement in the HRPP and determining what related educational programs may be needed.

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- (2) The ACOS/R&D, Deputy ACOS/R&D and/or AO will be scheduled to meet with the RCO twice monthly regarding audit findings and issues of concern.
- (3) The ACOS/R&D and others, as directed by the ACOS/R&D, will periodically conduct investigator seminars to address areas for improvement in the HRPP, as identified by audits, educational reviews and reports of non-compliance.

e) Review and Recommendations by the R&DC

- (1) The R&DC will review all audit reports and determinations by the IRB, including determinations of serious and/or continuing non-compliance.
- (2) The R&DC may make further recommendations for remediation, including individual investigator education or education for all investigators.
- (3) The RAO shall report yearly to the R&DC an evaluation of the HRPP and of the IRB membership.
- (4) The R&DC 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:

ORO Research Compliance Education Program: <http://www.va.gov/ORO/rcep.asp>
[VHA Handbook 1058.01](#)

6. CONCURRENCES: Endorsed by the Research & Development Committee on 06/02/2014.

7. RESCISSION: Continuous Quality Improvement in the Human Research Protection Program 12/06/2010.

8. FOLLOW-UP RESPONSIBILITY: ACOS/R&D

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