

POLICY:

- I. In accordance with the federal regulations, the IRB has the responsibility and authority to observe or authorize a third party to observe ongoing research projects and the consent process, including the auditing of research records. As part of the UIC HSPP, the OVCR Associate Director for Research Compliance through the Quality Improvement Program (QIP) directs, compiles, and analyzes audits of investigator and departmental activities to monitor and promote protections of human subjects and compliance with institutional policies, federal regulations, accreditation requirements, and applicable policies and directives governing human subjects research. The OVCR QIP will conduct periodic spot audits, as well as for-cause assessments as directed by the IRB, HPA or IO.
- II. The OVCR QIP also conducts periodic compliance audits of OPRS to assess IRB compliance with federal regulations, state and local laws and UIC policies and procedures.

PROCEDURE:

- I. The OVCR Associate Director for Research Compliance oversees the auditing and monitoring of continuous quality improvement and quality assurance activities of the OVCR QIP. In doing so, the activities assure investigator compliance with human subject protections regulations and policies as well as to verify that research is conducted in accordance with the terms of the IRB-approved protocols.
- II. Any findings of non-compliance are handled in accordance with the UIC HSPP policy *Handling Complaints and Allegations of Potential Non-compliance with Human Subject Protection Regulations*.
- III. The OVCR QIP works with the Research Compliance Officer of the JBVAMC for monitoring and conducting audits at the JBVAMC.
- IV. Full cooperation by the Principal Investigator and other members of the research team and OPRS is expected.
- V. Investigator Auditing Activities.
 - A. Periodic Spot Audit.
 1. The OVCR QIP may conduct spot audits with designated research staff to determine whether and to what extent the PI is complying with

- applicable federal regulations and Human Research Protection requirements in accordance with the IRB-approved research protocol.
2. Research studies will be selected and prioritized for review in accordance with the perceived risk or complexity of the research protocol. The following is a list of factors which may be considered in the selection process:
 - a) Investigator-initiated studies;
 - b) Significant risk device studies, Phase I and/or first in human use studies (rare in protocol mix at UIC);
 - c) Protocols in which the UIC or VA investigator is the IND or IDE holder;
 - d) Protocols involving both vulnerable populations and various waivers;
 - e) Protocols involving tissue banking or genetic testing;
 - f) High risk studies reporting few or no adverse events or UPIRSOs;
 - g) Protocols of an Investigator with frequent lapses in IRB approval;
 - h) Protocols that received initial approval more than five years ago.
 3. The Spot Reviews normally will involve the review of only a specific aspect of a study, but if serious deficiencies are found the scope of the original Spot Audit may be expanded and may become a For-Cause Audit.
 4. Examples of Spot Reviews include, but are not limited to:
 - a) Review of the executed informed consent documents and HIPAA authorizations;
 - b) Review of eligibility criteria (inclusion/exclusion criteria);
 - c) Monitor informed consent process, including in-person observation;
 - d) Review of required VA documentation; and
 - e) Review of required committee approval documentation before research commences.
 5. Following the completion of the evaluation, the findings of the audit will be discussed with the PI (or designee). The PI will also receive a written audit report, including recommendations to align the research to bring it into compliance with institutional policies and regulatory requirements.
 - a) If the audit findings note the occurrence of an UPIRSO or non-compliance, the PI is responsible for promptly reporting the occurrence to the IRB in accordance with the UIC HSPP policies *Unanticipated Problems Involving Risks to Subjects and Others* and *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations* policies.

- b) If the audit findings identify a need for revision of the research protocol or informed consent process, the PI is responsible for submitting an Amendment to the IRB in accordance with the UIC HSPP *Amendment* policy.
 6. The OVCR Associate Director for Research Compliance provides a written report of the audit findings and a suggested action plan to the Director of OPRS, corresponding IRB, HPA, IO, other institutional committees (CRC, CC-PRC, IBC) and, if VA Research related, the ACOS for R&D and the Executive Committee.
- B. For-Cause Audits.
 1. If the IRB or other components of the HSPP (HPA, IO, HSEIC, HSIC) is presented with an allegation or concern that raises issues as to research subject's safety and well-being, or investigator non-compliance (concerning IRB requirements, institutional policies and procedures, federal regulations, VA policies and directives, and/or other guidelines) or the integrity of the study data, a For-Cause audit may be requested by the IRB, HPA or IO to investigate the allegations.
 2. For-Cause Audits may be conducted by the OVCR QIP on site or remotely without prior notice to the principal investigator. To protect the safety and well-being of subjects, the research may be suspended by the IRB until the audit is completed and the findings reviewed.
 3. The scope of the evaluation will be initially limited to the investigation of the matter, but the scope may be expanded based on the initial results of the audit.
 4. Issues that can trigger For-Cause Audits include, but are not limited to:
 - a) Directed by the IRB, HPA, including by the HSEIC or HSIC, or IO;
 - b) Unexpected research participant death;
 - c) Research subject, family, or research staff complaint;
 - d) Numerous and/or significant serious adverse events and/or protocol violations;
 - e) Reports or allegations of non-compliance by investigators, research personnel, subjects or others;
 - f) Results of audits or monitoring by other entities (internal or external to UIC);
 - g) Concerns expressed by the Department Chair, VA R&D staff, or other committees.
 5. Following the completion of the audit, the findings will be discussed with the PI (or designee). The PI will also receive a written audit report, including recommendations to align the research to bring it into compliance with institutional policies and regulatory requirements. If the audit findings note the occurrence of an UPIRSO or non-compliance, the PI is responsible for promptly reporting the occurrence to the IRB in accordance with the UIC HSPP policies *Unanticipated Problems Involving Risks to Subjects and Others and Handling*

Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations policies.

- a) If the audit findings identify a need for revision of the research protocol or informed consent process, the PI is responsible for submitting an Amendment to the IRB in accordance with the UIC HSPP *Amendments* policy.
6. The OVCR Associate Director for Research Compliance provides a written report of the audit findings and a suggested action plan to the entity authorizing the audit and including the HSEIC, HSIC, Director of OPRS, IRB, the HPA, IO, other institutional committees (CRC, CC-PRC, IBC) and, if VA Research related, the ACOS for Research and Development and Executive Committee.
- C. Investigator Requested Education and/or Needs Assessment.
 1. An investigator may request that the OVCR QIP provide guidance and/or conduct an audit of their research regarding compliance with applicable federal regulations, good clinical practice, and Human Research Protection requirements in accordance with the IRB-approved research protocol.
 2. If an audit is requested and following its completion, the audit's findings will be discussed with the PI (or designee). Following the discussion, the PI will also receive a written audit report. The report may include recommendations for additional training/education or resources, and/or corrective actions to align the research and bring it into compliance with institutional policies and regulatory requirements. The corrective actions may include submission of prompt reports to the IRB regarding the identification of unanticipated problems or non-compliance, or the submission of an amendment revising the research.
 3. When deficiencies are observed in the research, the PI will be informed that a follow-up audit will be performed to ensure that adequate corrective actions have been taken.

VI. IRB/OPRS Periodic Spot Audits.

A. Periodic Spot Audit.

1. The OVCR QIP may conduct spot audits to determine whether and to what extent the IRB is complying with applicable federal regulations and Human Research Protection requirements. The evaluation may include the review of meeting minutes or the detailed examination of protocol files.
2. The OVCR Associate Director for Research Compliance provides a written report of the audit findings and a suggested action plan, if necessary to the Director of OPRS, the HPA, IO and, if VA Research related, the ACOS for Research and Development and Executive Committee.

REFERENCES:

- [21 CFR 56.109](#)
- [38 CFR 16.109](#)
- [45 CFR 46.109](#)
- [VHA Handbook 1200.5](#)
- [OHRP Guidance on Written Institutional Review Board \(IRB\) Procedures](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 10/06/09	1.0, 07/28/08	Addition of section V.C. Investigator Requested Education and/or Needs Assessment; Removal of section VI.B. statement that OPRS QI/QA activities are shared