

**OPRS Quality Improvement/ Quality  
Assurance Program**

310 AOB (MC 672)  
1737 West Polk Street  
Chicago, IL 60612-7227  
Phone: 312 996-4995 Fax: 312 413-0238  
[www.research.uic.edu/protocolreview/irb](http://www.research.uic.edu/protocolreview/irb)

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**POLICY:**

- I. The Assistant Director of Quality Assurance/Quality Improvement (QA/QI) designs and implements the OPRS internal compliance plan; leads the research accreditation process; drafts policies and procedures and compliance tools; creates and implements auditing and monitoring plans; provides regulatory support to OPRS staff and IRB members as needed; reviews and updates JBVAMC-related policies and procedures as needed, and evaluates the UIC HSPP.
- II. Detailed for-cause and not-for-cause audit findings and quality improvement activities, as applicable, are reported to the Director of OPRS on a monthly basis. The report will include proposed corrective actions and possible solutions from which the Director of OPRS may choose, when applicable. The Director of OPRS will respond in writing to the findings or quality improvement activities and provide the affected personnel and/or their supervisor with the information needed to apply corrective actions.
- III. A general summary report of identified risk areas, compliance program structure and progress, general audit findings and their resolution, quality improvement initiatives, corrective action plan updates, and any other related compliance information will be provided to the Institutional Official on an annual or, as necessary, more frequent basis.
- IV. If the audit involves a protocol where the JBVAMC is a performance site, the written report will also be sent to the JBVAMC ACOS for R&D and the EC.
- V. The Assistant Director of QA/QI will work with the Assistant Director responsible for education to communicate auditing and monitoring findings when appropriate and collaborate on educational programs for OPRS staff based on these findings.
- VI. If the Assistant Director of QA/QI reasonably believes that the OPRS Director is not taking appropriate action with respect to noncompliance with policies and procedures and/or federal, state, or accreditation requirements, then the Assistant Director of QA/QI consults the Office of University Counsel to determine the significance of the matter. If after consult with the Office of University Counsel the Assistant Director of OPRS reasonably believes that greater attention is needed as to noncompliance with policies and procedures and/or federal, state, or accreditation

requirements, then the Assistant Director of QA/QI may at his or her discretion bring the matter to the attention of the Institutional Official.

- VII. Noncompliance findings are handled in accordance with the UIC HSPP policy, *Handling Complaints and Allegations of Potential Non-compliance with Human Subject Protection Regulations*.

#### PROCEDURE:

##### I. Peer Evaluation of IRB Chair / IRB Members.

- A. The Assistant Director of QA/QI annually asks the IRB Chair to evaluate the IRB members through the completion of a survey instrument entitled *Evaluation of Board Member*. The Assistant Director of QA/QI collects these survey instruments and provides a summary report to the Director of OPRS based on the results.
- B. The Director of OPRS provides the results to IRB Chairs and members. The IRB Chairs provide both positive and negative feedback to the IRB members through a formal, documented process at least on an annual basis and as needed.
- C. The Assistant Director of QA/QI annually asks the IRB members to evaluate the IRB Chair through the completion of a survey instrument entitled *Evaluation of Board Chair*. The Assistant Director of QA/QI collects these survey instruments and provides a summary report to the Director of OPRS.

##### II. Auditing OPRS files and IRB determinations and documentation.

###### A. Not for Cause Review.

1. The Assistant Director of QA/QI annually selects criteria to focus QA/QI efforts and compiles a QA/QI audit plan. Typically, the audits will involve items from the following list; however, the Director of OPRS, the OPRS Associate Director and IRB may request audits based upon other criteria at their discretion.
  - a. Studies that relate to the topic of corrective action plans entered with an oversight entity, such as a regulatory department or agency or an accreditation entity;
  - b. Investigator-initiated studies;
  - c. Significant risk device studies, Phase I and/or first in human use studies;
  - d. Protocols in which the UIC or VA investigator is the IND or IDE holder;
  - e. Protocols involving both vulnerable populations and waivers;
  - f. Protocols involving tissue banking or genetic testing ;
  - g. High risk studies reporting few or no adverse events or unanticipated events;
  - h. Protocols with frequent lapses in IRB approval;
  - i. Investigators with a significant number of concurrent trials;
  - j. Protocols that received initial approval more than five years ago;
  - k. Protocols actively recruiting among the VA population;

- I. Protocols that involve a SEAM; and/or
    - m. Protocols funded by a clinical trial agreement with an industry sponsor.
  2. The Assistant Director of QA/QI creates a database of protocols that identifies protocols that fall within the above risk areas, as well as other risk areas, and tracks previously audited protocols and noncompliance resolution.
  3. The Assistant Director of QA/QI selects an appropriate sample of protocols to be audited, or may choose to audit all affected protocols, and creates audit tool/s to isolate a compliance variable.
  4. The Assistant Director of QA/QI reviews, analyzes, and summarizes the audit results in a written report. The report will include, if necessary, a suggested corrective action plan in response to the findings, including suggesting revising policies and procedures and/or implementing education. Reports will be generated as described in Section I above.
- B. Spot Auditing and Feedback to IRB Members, IRB Chairs, and IRB Staff.
  1. On a monthly basis, the Assistant Director of QA/QI randomly performs a Spot Audit of a single review action for each UIC IRB. The Assistant Director of QA/QI will analyze the results and provide written feedback to the Director of OPRS. These Spot Audits may become Routine or For Cause Audits if deficiencies are found. The audits will include:
    - a. One expedited review;
    - b. One initial review;
    - c. One continuing review;
    - d. One amendment; and
    - e. One exemption determination.
  2. On a monthly basis, the Assistant Director of QA/QI will obtain and review meeting minutes for each UIC IRB to determine whether the meeting minutes and discussion follow applicable regulations, accreditation requirements, and internal UIC policies and procedures.
    - a. The Assistant Director of QA/QI provides feedback on the minutes review to the IRB Chair, IRB staff, and IRB Members as necessary and provides improvement suggestions, such as education programs.
    - b. The Assistant Director of QA/QI reports the findings of the minutes review in writing to the OPRS Director and in accordance with Section I of this policy and procedure.
  3. On a monthly basis, the Assistant Director of QA/QI will complete random reviews of protocols. The review will include confirmation of information noted in the letters, as well as the presence of a grant, if federally funded, research protocol, and investigator's brochure, if applicable.

### III. Additional Responsibilities.

- A. The Assistant Director of QA/QI is responsible for working with the Assistant Director responsible for education to plan and develop internal and external educational programs highlighting policy changes or compliance issues. The Assistant Director of QA/ QI evaluates the educational program in March, June, September, and December and submits a written report to the OPRS Director in a timely manner.
- B. The Assistant Director of QA/QI is responsible for staying informed of changes to federal, state, institutional, internal, and accreditation requirements and to submit recommended changes to policies and procedures, review guides, and forms in a reasonable time to the Director of OPRS for approval. This responsibility includes familiarity with industry interpretation of the above requirements.
- C. The Assistant Director of QA/QI is responsible for staying informed of OPRS operational practice through OPRS staff interviews, auditing, and monitoring to ensure that the operational practice reflects the procedures outlined in the policies and procedures, review guides, and forms and to submit recommended educational programs and/or changes to policies and procedures, review guides, and forms in a reasonable time to the Director of OPRS for approval.
- D. The Assistant Director of QA/QI is responsible for working with the Executive Director of the Office of Research Services to audit a random sample of five clinical trial agreements per month to ensure that the clinical trial agreements sampled address how results will be communicated to study subjects when subject safety or medical care could be directly affected by study results. The Assistant Director will work with the Executive Director of the Office of Research Services to ensure that any errors found are remedied through a review of the template checklist used by negotiators and the development of educational materials and in person training.
- E. On a semi-annual basis, or as needed, the Assistant Director of QA/QI will review all OPRS policies and procedures, review guides, and forms to ensure that these materials reflect current OPRS practice and current federal, state, university, and accreditation requirements.
- F. On a regular basis, or as needed, the Assistant Director of QA/QI assesses and suggests improvements to UIC OPRS outreach activities.

### IV. Regulatory questions.

- A. The Assistant Director of QA/QI supports all OPRS staff and IRB members with respect to regulatory issues, policies and procedures, and questions about the HSPP.
- B. OPRS staff and IRB members may email, call, and/or speak in person about their question. Operational questions will be directed to the appropriate OPRS staff.

### V. Suggestions, Complaints, and/or Concerns. Please refer to UIC HSPP policy and procedure *Complaints or Concerns Received from Subjects or Others*.

VI. VI. OPRS Quality Improvement Program.

- A. On an annual basis, the Assistant Director of QA/QI is required to review the entire UIC HSPP to assess whether it is effective in achieving its intended outcomes. Intended outcomes are the protection of human research subjects and the furthering of knowledge gained by conducting research.
- B. Quality improvement metrics include but are not limited to: (1) transparency of OPRS activities to the campus; (2) the human research subject experience; (3) transparency of regulatory and institutional requirements to potential subjects, investigators, and OPRS staff; (4) reducing unnecessary barriers or burdens on investigators; (5) finding greater flexibility in the regulations; (6) ease of use of policies and procedures and review guides; (7) process improvements that help maximize limited resources allotted to the HSPP; and (8) process improvements that enable compliance.
- C. The Assistant Director of QA/QI is required to identify and create quality improvement projects based on the evaluation of the HSPP. Examples of past projects include: (1) rewriting policies and procedures to be user-friendly and to include clear procedures so people could understand how to implement the policies; (2) restructuring the web site into a virtual library to be more user friendly; (3) establishing weekly OPRS staff training following the updating of the policies and procedures; (4) a review guide pilot project to create more user friendly and efficient IRB review guides for more meaningful reviews; and (5) and OPRS staff pre-review sections.

**REFERENCES:**

- [21 CFR 56.107](#)
- [38 CFR 16.107](#)
- [45 CFR 46.107](#), [45 CFR 46.304](#)
- [VHA Handbook 1200.05](#), [VHA Handbook 1200.01](#)
- [OHRP Guidance on Written Institutional Review Board \(IRB\) Procedures](#)
- [FDA Information Sheets: Non-Local IRB Review, IRB Membership](#)

**REVISION LOG:**

Version (#, date)	Replaces (#, date)	Summary of changes
2.0, 06/18/09	1.0, 10/15/08	Revised entire document, previously named <i>IRB Chair, IRB Staff, and IRB Coordinator Compliance Monitoring and Auditing.</i>
2.1, 09/17/09	2.0, 06/06/09	Updated references to the HPA
2.2, 02/17/10	2.1, 09/17/09	Clarified Procedure Section I(B); Drafted new sections III(A) and III(D).