



OPRS Quality Assurance Program

Version: 3.0; Date: 02/07/2017

Approved by: Human Protections Administrator, Director
of OPRS, and Executive IRB Chair

AAHRPP REF #: 126

AAHRPP Elements: I.4.B., I.5.A., I.5.B.

**Office for the Protection of Research
Subjects (OPRS)
Institutional Review Board
FWA# 00000083**

201 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-1711
Fax: 312 413-2929

<http://research.uic.edu/human-subjects-irbs/>

POLICY:

- I. The Associate Director of Compliance (Investigator Outreach) designs and implements the OPRS internal compliance plan; drafts compliance tools; creates and implements auditing and monitoring plans; provides regulatory support to OPRS staff and IRB members 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 OPRS Director and Chair(s) of the relevant IRBs on a semi-annual, or as needed, basis. The report will include proposed corrective actions and possible solutions from which the Director may choose, when applicable. The Director 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 an audit involves a protocol where the research is reviewed by CHAIRb, the written report will also be sent to the chair of CHAIRb, CAPriCORN Steering Committee and the relevant CHAIRb performance sites.
- V. The Associate Director of Compliance will work with the Assistant Director, Education, to communicate auditing and monitoring findings when appropriate and collaborate on educational programs for OPRS staff and IRB members based on these findings.
- VI. If the Associate Director of Compliance 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 Associate Director notifies the Vice Chancellor of Research (i.e., Institutional Official) of their concerns.



- 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. Auditing OPRS files and IRB determinations and documentation.

A. Not for Cause Review.

1. The Associate Director of Compliance annually selects criteria to focus efforts and compiles an audit plan. Typically, the audits will involve items from the following list; however, the 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 is the IND or IDE holder;
 - e. Protocols involving vulnerable populations;
 - 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 involve a SFI-DMP; and/or
 - k. Protocols funded by a clinical trial agreement with an industry sponsor.
2. The Associate Director of Compliance 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 Associate Director of Compliance 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 Associate Director of Compliance 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 item II of the "Policy" section above.

B. Spot Auditing and Feedback to IRB Members, IRB Chairs, and IRB Staff.

1. The Associate Director of Compliance randomly performs a Spot Audit of a single review action for each UIC IRB. The Associate Director will analyze the results and provide written feedback to the Director. 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; and
 - d. One amendment.
2. The Associate Director will randomly perform a Spot Audit of exemption determinations. As the exemption determinations are not linked to an IRB, the Spot Audits are not included with the description above.
3. The Associate Director 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 Associate Director 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 Associate Director reports the findings of the minutes review in writing to the Director in accordance with item II of the "Policy" section.
4. The Associate Director 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.

II. Additional Responsibilities.

- A. The Associate Director of Compliance is responsible for working with the Assistant Director, Education, to plan and develop internal and external educational programs highlighting policy changes or compliance issues.
- B. The Associate Director of Compliance 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 for approval. This responsibility includes familiarity with industry interpretation of the above requirements.
- C. The Associate Director of Compliance 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 for approval.
- D. On an annual basis, or as needed, the Associate Director, External Relations, will review 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.



- E. On a regular basis, or as needed, the Associate Directors of External Relations and of Compliance assess and suggest improvements to UIC OPRS outreach activities.

III. Regulatory questions.

- A. The Associate Directors of External Relations and of Compliance support 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.

IV. Suggestions, Complaints, and/or Concerns. Please refer to UIC HSPP policy and procedure [Complaints or Concerns Received from Subjects or Others](#).

V. Annual Review of UIC HSPP.

- A. On an annual basis, the Director and Associate Director, External Relations, review the 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. 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.

REFERENCES:

21 CFR 56.107

38 CFR 16.107

45 CFR 46.107, 45 CFR 46.304

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).
2.3, 04/29/12	2.2, 02/17/10	Updated the title of responsible party. Removed IRB Member Evaluations as these are not the purview of the QA/QI Program.
3.0, 02/07/17	2.3, 04/29/12	Rewrite of policy to describe the role of the Associate Director of Compliance rather than the Associate Director, External Relations and Quality Assurance. Removal of JBVAMC. Editorial corrections.