

**University of Illinois at Chicago
Human Subjects Protection Program
Plan**

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POLICY:

- I. The IO is ultimately responsible for the development and implementation of the HSPP Plan and the coordination of all its components.

PROCEDURE:

- I. UIC HSPP Mission. The mission of the OPRS is to ensure that there are mechanisms developed and maintained to ensure an effective HSPP, which in turn should ensure the protection of the rights and welfare of all human subjects involved in research. The OPRS works with the institution, investigators, research staff, students, institutional units (ORS, COI, OUC, IDS, CRC), and the institutional review committees (IRBs, IBC, ACC, ESCRO, Radiation Safety, RDRC) as stakeholders in the HSPP, working together toward accomplishing this goal. The OPRS recognizes its clientele is first and foremost the subjects, and also includes the public, research sponsors and agencies, the UIC investigators and research staff, and the UIC IRBs.
- II. Underlying Principles.
 - A. UIC investigators, research staff, IRB members, IRB staff, and UIC in working with sponsors, follow the ethical principles of the *Belmont Report* for all human subjects research. Additionally, UIC applies DHHS regulations (45 CFR 46, including Subparts A, B, C, & D) to federally sponsored research involving human participants. UIC applies the principles of the Belmont Report and the Common Rule (45 CFR 46 SubPart A) to all research. However, UIC has elected not to extend OHRP's authority to all research through its Federalwide Assurance.

The ethical principles provided in the *Belmont Report* are:

1. Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
2. Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and
3. Justice: Fairness in the distribution of research benefits and burdens.

- B. UIC HSPP further agrees to apply the additional regulations to the extent required when applicable to research involving human participants under review such as:
 - 1. The U.S. Food and Drug Administration Human Subject Regulations (including but not limited to 21 CFR 50, 56, 312, 600 and 812);
 - 2. The Health Insurance Portability and Accountability Act of 1996 45 CFR 160 and 164 SubParts A and E;
 - 3. The VA regulations at 38 CFR 16, VHA Handbook provisions, as well as any VA directives when applicable;
 - 4. The registration of clinical trials through the ClinicalTrials.gov Protocol Registration System a service of the U.S. NIH, in accordance with FDA requirements [The Food and Drug Administration Amendments Act of 2007 (US Public Law 110-85)] and the International Committee of Medical Journal Editors policy;
 - 5. The application of additional regulations/policies on a case-by-case basis for projects funded or covered by Federal agencies such as Department of Defense, Department of Education, Department of Housing and Urban Development, National Science Foundation, and Department of Justice when applicable and only to the extent required; and
 - 6. Federal, state and local law.
- C. UIC PIs conducting research in Illinois must follow Illinois state law. When the research is conducted outside of Illinois, those local laws take precedence.
- D. UIC HSPP must apply the most stringent law, regulation or policy in a situation where more than one is applicable.
- E. Research conducted at UIC also follows all ethical, scientific, and financial principles under Good Clinical Practice Guidelines as adopted by the U.S. Food and Drug Administration, when applicable.
- F. The UIC HSPP also strives to comply with AAHRPP accreditation standards, which in many cases are greater than the regulatory requirements.

III. Research Conducted/Overseen by UIC's HSPP.

- A. Research conducted/overseen at UIC includes research involving human subjects according to DHHS, FDA, and VA regulations (see glossary for applicable definitions).
- B. UIC IRBs review biomedical and social behavioral research and research involving all phases of clinical trials for both drugs and devices.
- C. Participants in research include patients, healthy volunteers, federally defined vulnerable populations, the decisionally impaired, students, employees, and/or members of the community.

IV. Organizational Structure of the HSPP.

- A. The UIC HSPP is an integrated system that has organization-wide and agency support and encompasses all aspects of human subjects research enterprise, spanning the continuum of research design to study closure.
- B. Roles and Responsibilities of the Components of the UIC HSPP:
 - 1. Institutional Official: UIC's institutional authority for the HSPP rests with the Chancellor of UIC who by example and mandate sets the tone that supports the primacy of human subjects protections through the

principles embodied in *The Belmont Report*. The Chancellor has delegated this authority to the VCR, who serves as the IO. The IO is responsible for assuring compliance with the terms of the FWA and all federal, state, and institutional requirements for conducting research involving human participants. (See also UIC HSPP policy [*Institutional Oversight and Authority*](#)).

2. Human Protections Administrator: The UIC faculty member or academic staff identified by the IO as the point of contact with OHRP for human subjects protection issues, including the investigation and reporting of non-compliance matters, and plays a key role in ensuring that the institution fulfills its responsibilities under its FWA.
3. Office for the Protection of Human Research Subjects: The OPRS is the primary coordinating office for the HSPP.
4. Institutional Review Boards: All research involving human participants that is not determined to be exempt from IRB oversight is reviewed by one of four UIC IRBs that are responsible for considering the Criteria for Approval (including but not limited to DHHS, FDA, and VA) when reviewing all submissions (initial review, continuing review, amendments, modifications, unanticipated events). One board is dedicated to social and behavioral research, another is dedicated to VA Research, one is dedicated to biomedical research and the fourth is dedicated to health sciences and social behavioral research
5. Education. The Assistant Director responsible for education prepares and provides campus, department, investigator, OPRS staff, and IRB member training on a wide range of human subjects protection matters, including but not limited to HIPAA, Investigator 101, and accreditation. This individual also develops and presents OPRS staff training based on auditing and monitoring findings.
6. Assistant Director of Quality Improvement/ Quality Assurance: This individual designs and implements the OPRS internal compliance plan, leads the research accreditation process, drafts policies and procedures, audits and monitors, provides regulatory support, collaborates on educational materials and presentations, assists the JBVAMC R&D Office with policies and procedures on an as needed basis, and evaluates the UIC HSPP. This individual provides monthly reports of findings to the Director of OPRS and semi-annual reports to the IO or as needed.
7. HSEIC/HSIC: Committees convened by the HPA or IO to evaluate complaints or allegations of research non-compliance received through the HSPP involving human subjects research. The HSEIC/HSIC membership may include but is not limited to IRB members, OVCR staff, UIC Faculty, and University Counsel. The Committee's findings and recommendations for corrective actions, if appropriate, are issued to the VCR, IRB, respondent, and other institutional officials/units.
8. Collaborative IRB Executive Committee: The EC has been organized to coordinate communication regarding human subjects protection among the IRB #4 Chair and Vice-Chair and the JBVAMC, UIC and NU staff and administration in accordance with the executed MOUs. The EC also may make recommendations regarding IRB #4 resources and

review, draft, or recommend revision of UIC OVCR policies and procedures related to IRB #4. The EC may assist the IRB in the review of allegations of non-compliance and the appropriate members of the EC coordinate compliance investigations with their respective institutions as necessary and as directed by the IRB #4 Chair and/or IRB #4.

9. Departmental Review: The UIC HSPP requires Departmental Review for all protocols that are submitted for convened review, unless the protocol qualifies for review by the Cancer Center Protocol Review Committee (CC-PRC). If the protocol involves cancer or cancer patients, then the CC-PRC review is required and may be substituted for Departmental Review. Likewise if the research protocol involves the utilization of the Clinical Research Center (CRC), then review is required in addition to Departmental Review. Protocols that are submitted for exempt or expedited review do not require Departmental Review, but individual departments may continue to use the Departmental review system for protocols in these categories. The primary purpose of the Departmental Review process is to have persons with similar areas of expertise and knowledge review the research for scientific merit and research design. If any issues are noted in the Departmental Review, they are to be addressed before the research is submitted to the IRB. The IRB receives copies of the Departmental Review forms and a summary of any revisions made as a result of the Departmental Review in the initial review submission packet.
10. Cancer Center Protocol Review Committee: The CC-PRC reviews each cancer-related protocol at the time of initial review and continuing review, and reviews amendments that involve revisions to the protocol or Investigator's brochure. The goals of the CC-PRC are 1) to conduct a scientific review of all proposed cancer research, 2) to monitor all clinical cancer research protocols for sufficient progress, 3) to monitor all clinical protocols as to their observance of all the requirements established by the regulatory bodies, and 4) to terminate cancer protocols not achieving goals in a reasonable time frame. The CC-PRC review replaces Departmental Review for cancer-related protocols. The CC-PRC review provides scientific review of the research protocol by peers with the medical training and expertise to understand protocols involving cancer subject matter. This review process is distinct from the IRB review process; however, the IRB reviews the determinations of the CC-PRC, and as the IRB membership includes members of the CC-PRC, the IRB is adequately informed of any issues or concerns related to a particular protocol. The two review processes complement each other and together work to improve the human subjects protection program.
11. Radiation Safety Committee: This committee authorizes the use radiation-producing devices and radioactive material in operations, education, research, and development activities. The RSC establishes radiation policies and procedures for the University in accordance with state and federal regulatory requirements governing the procurement,

- use, storage, and disposal of radiation-producing devices and radioactive material. The RSC authorizes individual investigators and study personnel to use these devices in the conduct of their research; however, prospective users must submit proposals to the RSC for review and approval. The RSC review is completed prior to initial review conducted by the IRB, which may not approve research requiring RSC review without prior approval from the RSC.
12. Radioactive Drug Research Committee: Basic research designed to study the metabolism of a radioactive drug or to gain information about human physiology, pathophysiology, or biochemistry in response to radioactive drug use is subject to review by the UIC Radioactive Drug Research Committee, as well as the IRB. Formed under the authorization of the FDA and the University, the RDRC is responsible for reviewing and approving all radioactive drug research projects that fall under the purview of FDA regulations as specified in 21 CFR 361.1. Investigators submit research protocols which meet the criteria for review, as outlined in the regulations, to the RDRC for review and approval prior to submission to the IRB. The IRB will not approve research subject to the RDRC without prior written approval from the RDRC.
 13. Institutional Biosafety Committee: The UIC IBC reviews all research involving the use of rDNA in compliance with the [*NIH Guidelines for Research Involving Recombinant DNA Molecules*](#). The IBC is also responsible for the safe conduct of research involving infectious agents, including select agents and toxins. The IRB will not approve research subject to the IBC without prior written approval from the IBC.
 14. Investigational Drug Service: This unit is a component of the UIC Medical Center. All drugs that are the focus of the research or that are prescribed solely because the subject is enrolled in the research must be registered with IDS via Appendix E before IRB review. If IDS services will be used, IDS registers the research, makes arrangements for distribution, and coordinates matters with the PI and coordinator. IRB approval of the particular protocol is communicated to IDS. Currently, the receipt, storage, distribution and control of investigational drugs for inpatients at UIC are handled by the IDS. For research performed in the clinics or other outpatient settings, the investigator may assume the responsibility themselves or delegate to IDS the handling of investigational drugs. When the investigator assumes this responsibility, a plan for storage, handling, dispensing and control of the investigational drug must be submitted for review and approval by the IRB in consultation with IDS.
 15. Office of Research Services: ORS is responsible for providing general grant, contract, and agreement administration with project sponsors. In addition, ORS is responsible for the following HSPP functions: monitoring funding agency assurance/certification requirements and ensuring compliance; posting federal and state regulatory guidelines relevant to sponsored research; coordinating with the IRB to ensure accuracy of completed assurances and certifications through the grant matching process; maintaining agency-required documentation; and

maintaining a working knowledge of the types of projects needing IRB review. ORS is responsible for negotiating the terms of all sponsored agreements, including clinical study agreements on behalf of UIC. ORS also prepares subagreements with collaborators, which include provisions for adherence to human research protections, the research protocol, and applicable federal and state regulations. ORS utilizes an internal Protocol Approval Form, which ensures that the proposed project has been reviewed by Department chairs, and/or deans; identifies the use of human subjects, rDNA or infectious agents, or radioactive materials in the research; and requires the disclosure of investigators who have a significant financial conflict of interest. The PAF contains investigator certifications that he/she will adhere to University policies on conflict of interest, ethical standards in the conduct of research, intellectual properties, and the use of human subjects in research. The PAF number serves as a link between ORS (UleRA) and OPRS (RiSC) information management systems.

16. **Clinical Research Center:** The CRC is part of the Center for Clinical and Translational Sciences. The CRC offers services to investigators, such as protocol and informed consent development services. The CRC also offers services to investigators such as nursing support, laboratory testing, bionutrition services, education, biostatistical support, informatics support, and administrative support. The CRC review process provides an additional support mechanism for the IRB to address whether the research is using sound scientific design. Please look for additional information this summer about the status of the CRC as it is in flux.
17. **JBVAMC R&D Committee:** The JBVAMC R&D Committee reviews all research under the auspices of the JBVAMC, initially and at least once a year, including research determined exempt by the Collaborative IRB. All NU, UIC, or JBVAMC research that engages the JBVAMC as a recruitment or performance site must have the approval of the JBVAMC R&D Committee and its appropriate subcommittees before the research may begin.
18. **VA Central Office COACH:** This VA office provides informal regulatory assistance and interpretation to UIC OPRS.
19. **VA Central Office Counsel:** This VA office provides OPRS with language and required wording for applicable documents.
20. **VA Regional Counsel:** This VA office provides OPRS with language and appropriate wording for applicable documents.
21. **Office of University Counsel:** IRB members, staff and investigators have access to the University Counsel for legal guidance and interpretation of local, state and federal laws and regulations as they relate to research. The HPA or the OPRS Director serves as the liaison between the IRB and the HSPP and University Counsel. The University Counsel also informs IRBs of educational matters.
22. **Conflict of Interest Office:** This UIC office is responsible for identifying, reporting, and creating a management plan, if applicable, as to potential conflicts of interest that may affect human subject studies. The COI office provides information pertaining to the protocol specific

conflict and makes a recommendation for management through the Statement of Explanation and Management (SEAM) form to the IRB for approval.

23. Associate Director of Research Compliance: This individual directs for-cause and not-for-cause on-site audits. This individual aids the HSEIC/HSIC and guides inquiries and investigations of complaints and allegations of non-compliance in research.
24. UIC HIPAA Privacy Officer: Responsible for HIPAA privacy oversight at UIC.
25. JBVAMC HIPAA Privacy Officer: Responsible for HIPAA privacy oversight for VA Research. The JBVAMC Privacy Officer attends the Collaborative IRB meetings to advise the IRB on privacy and functions as an advisor who does not vote with the IRB.
26. JBVAMC Information Security Officer: Responsible for Information Security for VA Research at the JBVAMC. The JBVAMC Information Security Officer attends the Collaborative IRB meetings to advise the IRB on information security issues as an advisor who does not vote with the IRB.
27. JBVAMC Patient Rights Advocate: Subjects in research involving the JBVAMC have access to this resource for any complaints. When patients are research subjects and the complaints involve a human subjects protection issue, this individual notifies the ACOS for R&D. A summary of the complaint and recommended resolution is forwarded to the JBVAMC R&D Committee with a copy to the UIC Collaborative IRB (IRB #4).
28. OVCR Tech Support/ RiSC Support: Responsible for updating the RiSC application to meet new regulatory or internal requirements, to improve the efficiency and compliance of the HSPP, and/or to improve sorting and auditing capabilities for quality assurance and response to external agency requests. The RiSC application is the electronic database storage system for OPRS and the IRBs.
29. UIC Medical Center Continuous Quality Improvement Program: The UIC Medical Center has an office for Continuous Quality Improvement.
30. UI Auditors: University auditing department that periodically audits units on campus for adherence to standards, policies, and procedures that govern that particular department or office. The University Auditors periodically audits OPRS and the IRBs and the VCR receives a report.

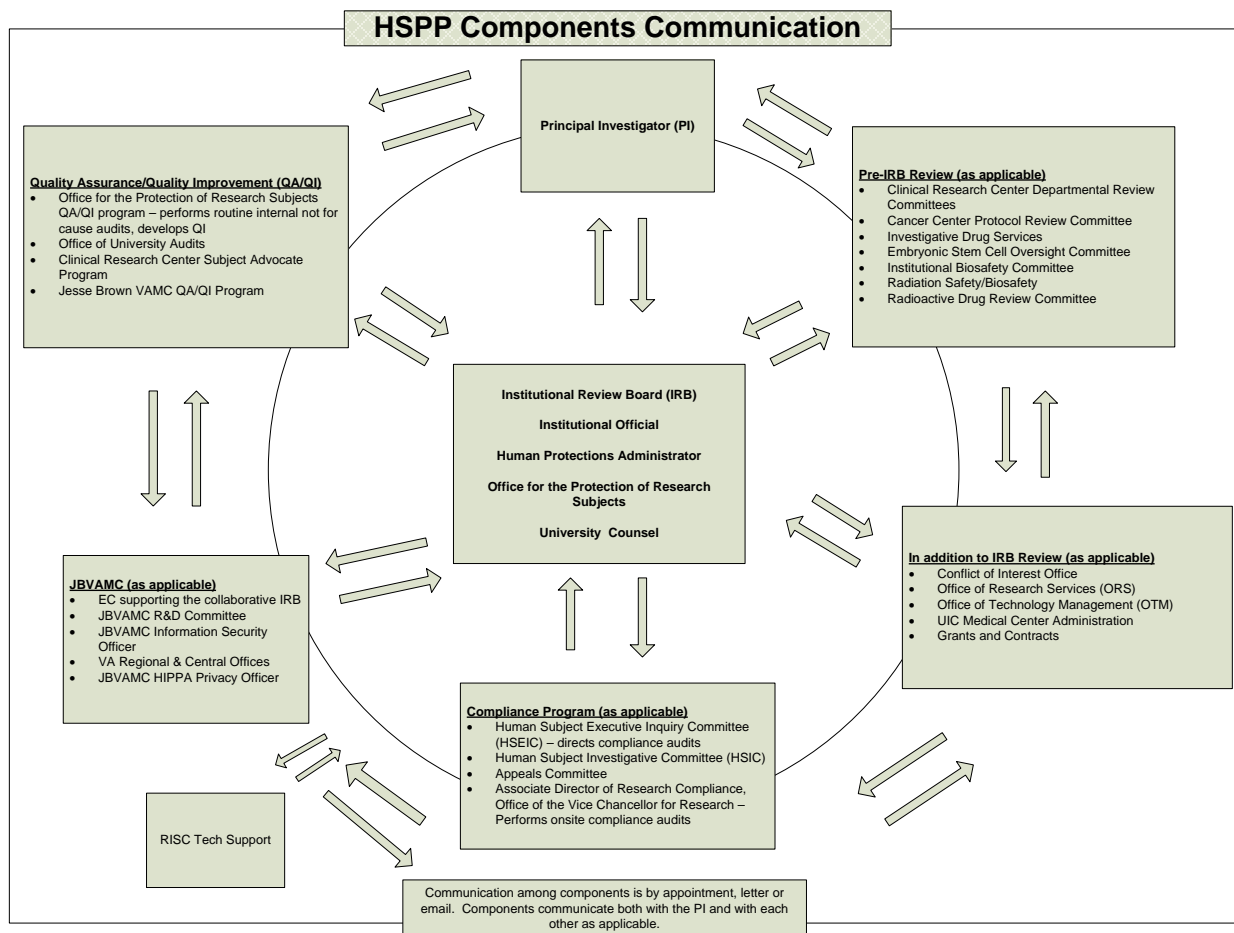
C. Relationships among the HSPP Components.

1. The above components of the UIC HSPP work together across a continuum of research needs in accordance with the core Belmont Report principles of respect for persons, beneficence, and justice.
2. IRB coordinators and Assistant Directors are available for questions about study conceptualization, as well as questions regarding whether a research activity involves human subjects.
3. Potential principal investigators and their key research personnel are required to successfully meet educational requirements as a prerequisite to conducting research.

4. Study feasibility and scientific validity are considered by several components of the HSPP, depending on the subject matter of the protocol. Protocols generally undergo a departmental review, unless the protocol qualifies for UIC Cancer review. The IBC CC-PRC and/or RSC review protocols as applicable.
5. As applicable, the PI must submit registration of applicable drugs to the IDS.
6. When a funded protocol is submitted, coordination between ORS and OPRS and ORS staff match the research protocol(s) approved protocols to the applicable grant application. OPRS records the PAF number corresponding to all protocols, with the exception of protocols with intramural, departmental funding or studies with no funding source. The ORS works in conjunction with OPRS to ensure that funding is released to PIs only after the match has occurred.
7. PIs are required to submit a protocol specific Statement of Explanation and Management form to the COI Office. The SEAM is evaluated by a subcommittee and recommendations of an approved SEAM are forwarded to the IRBs, for consideration in approval of the research.
8. IRB Coordinators and/or Assistant Directors at OPRS perform pre-reviews of applications for completeness, adherence to basic ethical and regulatory requirements, and use the review guides to assist with accuracy.
9. IRB Coordinators and/or Assistant Directors communicate with and educate investigators when needed to enhance the quality of applications prior to IRB review.
10. IRB Coordinators and/or Assistant Directors verify whether additional required organizational review, such as IBC, RSC, Conflict of Interest, IDS, etc., are either approved or in process, and will notify investigators of deficiencies. When the IRB Coordinators or Assistant Directors receive proof of organizational review, applications are then forwarded for IRB review.
11. IRB members have different expertise as well as different levels of experience with the regulatory framework associated with research; however, the members each contribute their strengths and assist each other in ensuring the protection of human research subjects, as well as additional protections for special populations, when applicable.
12. Assistant Directors, the Assistant Director of Quality Assurance/ Quality Improvement, and/or IRB Coordinators provide regulatory support to IRB members during the meeting.
13. Continuing education is provided on a regular basis to IRB members and OPRS staff by guest speakers such as the Director of OPRS, the University Counsel, the Conflict of Interest Officer, and speakers that increase the IRBs awareness of important issues. IRB Coordinators and/or Assistant Directors may also present educational items to the IRB.
14. Final IRB approval is not provided until documentation of approval through the organizational review committees is provided to OPRS and the IRB, as applicable.

15. The OPRS provides copies of correspondence to the review committees (IBC, IDS, CC-PRC, RDC).
16. JBVAMC R&D Scientific review, if applicable, occurs after IRB approval.
17. IRB Coordinators or Assistant Directors notify PIs of IRB decisions by letter, which is sent both via email and the postal service or campus mail.
18. The PI must re-submit required materials if the IRB requires modifications.

CHART:



REFERENCES:

NA

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 3/18/09	1.0, 10/15/08	Addition of subjects in Procedure Section I; Addition of AAHRPP standards in Procedure Section II.F.; Clarifications throughout

		regarding the Clinical Research Center; Deletion of the Clinical Research Center Scientific Advisory Committee; Clarification regarding Investigational Drug Service in Procedure Section IV.12; Addition of Chart representing the HSPP Component Communications.
1.2, 06/18/09	1.1, 03/18/08	Addition of educational program and Assistant Director of Quality Assurance/ Quality Improvement position.