

Institutional Oversight and Assurance

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POLICY:

- I. No UIC official has the authority to approve research that has not been approved by a UIC Institutional Review Board.
- II. UIC holds a Federalwide Assurance (FWA) (#00000083) from the Office for Human Research Protections in the Department of Health and Human Services. The FWA is maintained at the Office for the Protection of Research Subjects and is established in accordance with the following guidelines:
 - A. UIC's institutional authority for the Human Subjects Protection Program 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 Vice Chancellor for Research, who serves as the Institutional Official. The VCR is generally responsible for the UIC HSPP. The VCR has assigned the role of the Human Protections Administrator to the Director of OPRS. In the absence of an Associate VCR, the VCR may retain the role of HPA or designate someone else. The HPA is the primary contact person 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 the FWA.
 - B. The FWA is an agreement between DHHS and UIC that UIC will review and approve federally funded research involving human subjects in accordance with the ethical principles outlined in *The Belmont Report* and the DHHS regulations [45 CFR 46].
 - C. UIC is subject to this FWA, including but not limited to faculty, adjunct faculty, staff, students, certain consultants, departments and facilities. In the event that another FWA or agreement, such as an MOU, indicates a UIC IRB as an IRB of record, this research is also subject to the principles of this FWA.
 - D. The UIC IRBs also meet the membership requirements of the U.S. Food and Drug Administration regulations [21 CFR Parts 50 and 56], the U.S. Department of Education regulations [34 CFR Parts 350 and 356], and the requirements of VA regulation 38 CFR 16, VA Handbook 1200.05, and other applicable VA directives and guidance.
 - E. Where applicable, the UIC IRBs meet the requirements of the International Conference for Harmonization in so far as they are consistent with FDA regulations.

- F. Through a Memorandum of Understanding with the Jesse Brown Veterans Administration Medical Center, UIC IRBs 1 and 3 (IRB00000115, IRB00000117) serve as the IRBs of record for the JBVAMC (FWA #00000290).
- G. After the recently established Collaborative JBVAMC/Northwestern University/UIC IRB (UIC IRB #4) is operational, UIC IRB #1 and UIC IRB #3 will no longer be the IRBs of record for the JBVAMC and UIC IRB #4 will be the sole IRB of record for the JBVAMC.
- H. UIC IRB #4 operates independently, but is supported by the Executive Committee, an oversight body whose membership includes representatives from JBVAMC, UIC and Northwestern University (NU), and its determinations are reviewed by the JBVAMC R&D Committee.
- I. The Collaborative IRB is established and registered under UIC's FWA with OHRP. The JBVAMC and NU rely on this Collaborative IRB through the execution of three Memorandums of Understanding between NU and UIC, UIC and the JBVAMC, and NU and the JBVAMC. The individual FWAs are amended to reflect this reliance.
- J. In its FWA, UIC has elected to not extend OHRP's authority to all human subjects research conducted at UIC; however, the general protections of the *Belmont Report* and the Common Rule [45 CFR 46] will be applied to all research reviewed and approved at UIC either in the same way or in a variation.
- K. The UIC FWA is available upon request in the UIC OPRS office.
- L. UIC applies Illinois State law. The appropriate state law applies to research conducted in a different state. In the event that two laws govern a matter, the more specific of the two and/or the higher standard will govern.
- M. IRB members or OPRS staff who feel they may be experiencing undue influence should report this behavior to their respective IRB Chair or the OPRS Director, who will act as a mediator and consult the IO as necessary. The IO may form an investigative committee of impartial UIC employees as necessary to evaluate the allegation. An IRB Chair who experiences undue influence should report this behavior to the OPRS Director or IO. The IO may form an investigative committee of impartial UIC employees as necessary to evaluate the allegation. (Refer to UIC HSPP policy *Undue Influence Policy and Procedures*).

PROCEDURE:

- I. The responsibility for the protection of human research subjects is shared among the investigator, the institution, the IRB, the OPRS, and a variety of other entities and committees. (Refer to UIC HSPP policy *Human Subjects Protection Program Plan*). The mission of the UIC HSPP is to protect the rights, safety, and welfare of all human subjects involved in research regardless of funding status.
 - A. Investigator Responsibilities
 - 1. Investigators must not perform human subjects research without prior written IRB approval or an exemption determination and all other required approvals or documentation, as applicable.

2. Investigators must not initiate JBVAMC Research until the JBVAMC Research & Development Committee approves the research. Therefore, upon initial approval, the UIC OPRS will forward the stamped, IRB-approved JBVAMC consent documents to the JBVAMC R&D Office for release.
3. All investigators must read the Belmont Report and understand their ethical responsibilities in conducting human subject research that are outlined in this pamphlet. The Belmont Report is available at the OPRS website.

The core principles of the Belmont Report are the following:

- (1) Respect for persons,
 - (2) Beneficence, and
 - (3) Justice.
4. Investigators must ensure that the research is conducted according to the IRB approved research protocol. The principal investigator is responsible for the actions of all co-investigators and research staff involved with the research.
 5. Principal investigators and appropriate research staff must fulfill educational requirements as outlined in the appropriate educational policy and procedure and the UIC HSPP policy *Dissemination of New Information* policy and procedure and disclose any financial or other conflicts of interest in accordance with the UIC HSPP policy *Investigator Conflict of Interest Disclosure Policy for Human Subjects Research*.

B. IRB Responsibilities

1. For research requiring IRB review, the appropriate IRB must always review and approve the research before human subjects research may begin.
2. IRBs have the authority: to approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the organization; to suspend or terminate approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants; to observe, or have a third party observe, the consent process; and to observe, or have a third party observe, the conduct of the research.
 - a) IRBs #1 and #3 serve to review biomedical human subjects research and JBVAMC Research until JBVAMC Research protocols are transferred to IRB #4; and
 - b) IRB #2 serves to review social and behavioral human subjects research.
 - c) IRB #4 serves to review VA Research at the JBVAMC.
3. UIC, as well as any institution at which an UIC IRB is an IRB of record following an assurance or MOU with the UIC IRB, may choose not to accept the UIC IRB determination and thereby reject the initiation of the research.
4. No IO may approve research that has been disapproved by any UIC IRB. Only the IRBs may approve the research.

5. The IRB must record and document its research determinations in sufficient detail, including on review guides provided by OPRS Staff, and provide this documentation to the appropriate OPRS Staff.

C. OPRS Staff Responsibilities

1. OPRS staff will process IRB determinations, provide regulatory guidance and support to the UIC IRBs, and support investigators.
2. OPRS staff is responsible for maintaining a current FWA for UIC. The FWA must be updated at least every 36 months with the most recent information, even if no changes have occurred in the FWA.
3. OPRS must notify OHRP promptly of any changes to the FWA, including but not limited to changes in the composition of any UIC IRB or changes in UIC facilities.

D. Grants and Contracts/ OVCR Administration

- The Office of Business and Financial Services and the Office of Research Services will not release funding until the applicable IRB has approved the human subjects research or an exemption determination has been issued by OPRS.

REFERENCES:

[21 CFR 56.103\(c\), 21 CFR 56.109\(e\), 21 CFR 50 and 56, 312, 812](#)
[38 CFR 16](#)
[45 CFR 46.101\(a\), 45 CFR 46.101\(b\) or \(i\), 45 CFR 46.101\(e\), 45 CFR 46.101\(f\), 45 CFR 46.103\(a\), 45 CFR 46.103\(b\), 45 CFR 46.103\(b\)\(1\), 45 CFR 46.103\(b\)\(2\), 45 CFR 46.103\(b\)\(3\), 45 CFR 46.103\(d\), 45 CFR 46.109\(e\), 45 CFR 160 and 164](#)
[OHRP Compliance Activities: Common Findings and Guidance #52, #71\(p\), #72, #76](#)
[The Belmont Report](#)

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 9/17/09	1.0, 12/19/08	Clarified that only the IRBs may approve the research.