

**Scientific and Scholarly Review of
Research**

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POLICY:

- I. UIC policy requires that research involving humans undergo review by individuals with relevant scientific or scholarly expertise. Review by individuals with the knowledge to evaluate the rationale, aims, experimental design and methods of the research may occur at several steps in the HSPP review process depending on the research area and level of review, including Departmental Review Committees, Department Heads, and Cancer Center Protocol Review Committee (CC-PRC). Research submitted to the IRB also frequently receives scientific review from external sources, for example NIH study sections and private foundation or professional association review panels. These reviews are considered by the IRB in its scientific evaluation and in making the determination of whether the following regulatory criteria for approval are met:
 - A. Risks to participants are minimized by using procedures consistent with sound research design and which do not unnecessarily expose participants to risk.
 - B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- II. UIC policy does not allow the IRB to delegate its responsibility to judge whether the above criteria for approval are met.
- III. For Department of Defense sponsored research, a substantive amendment to approved research must undergo scientific review prior to IRB review.

PROCEDURE:

- I. Scientific or Scholarly Evaluation by Other Components of the HSPP.
 - A. Departmental Review Committee: Written evaluations of the merit, acceptability and feasibility of the study design and procedures, risks and benefits (refer to UIC OPRS form *Appendix F: Unit/Departmental Review Committee for Research Involving Human Subjects*) from two faculty or staff appointed by the head of the investigator's Department/Unit accompany protocols submitted for initial convened IRB review.
 - B. Department Head: The Department Head confirms by signing the initial and

continuing review applications that the research meets the standards of the discipline.

- C. CC-PRC: Scientific and feasibility review of cancer-related protocols are performed by the CC-PRC prior to initial IRB review for research not previously peer-reviewed by NCI and simultaneously with initial IRB review for NCI peer-reviewed protocols. Continuing review of cancer-related protocols by the CC-PRC occurs at the same time as IRB continuing review. Written copies of the CC-PRC reviews are provided to the IRB.
- D. CRC: Scientific and feasibility review (refer to UIC OPRS form *Appendix G: CRC Application*) by the CRC occurs for all proposals requesting use of the CRC as a performance site. For protocols requesting use of the CRC, approval from the CRC is required prior to IRB initial review approval or approval of an amendment reflecting the involvement of the CRC in the research. Written copies of the CRC reviews are provided to the IRB.
- E. Other committees that may review research before the IRB and supplement the IRBs' expertise include the IBC, Radiation Safety Committee, Radioactive Drug Review Committee (RDRC) and Embryonic Stem Cell Research Oversight (ESCRO) Committee. (Refer to UIC SOP *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB* for VA research information).

II. IRB: Scientific and Scholarly Review.

- A. Board Expertise. The composition of each UIC IRB is assessed annually by the Chairs and Director of OPRS to assure that the scientific or scholarly expertise and clinical or research experience is representative of the research activities reviewed by the IRB, including knowledge and experience with the classes of vulnerable populations encountered by the Board. When a deficiency is identified, the OPRS Director recruits individuals with the needed expertise, soliciting UIC Colleges and Departments and past and current members of the UIC IRB (refer to UIC SOP *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB*). The Director recommends potential candidates for appointment to the IO.
- B. Board Assignment: Protocols are assigned to a specific IRB for review based upon:
 - 1. Date of receipt;
 - 2. Type of research (i.e., Social/Behavioral [IRB #2] versus Health Science/Biomedical [IRBs #1,3,4];
 - 3. Performance site (e.g., JBVAMC to IRB #4); and
 - 4. Research population (e.g., prisoner research to IRBs #2 and 3).
- C. Assignment of Protocols for Convened IRB Review (initial review, continuing review, amendments): The UIC IRBs use a reviewer system with at least two voting members of the IRB assigned as primary reviewers. Note that the term "primary reviewer" is not intended to indicate a difference of importance. For initial review of protocols, an unaffiliated, non-scientist member (community member) may be assigned as a third reviewer. Assignment of the primary reviewers is performed by the IRB Assistant Director in consultation with the Chair. The Assistant Director designates the primary reviewers with the

expertise to conduct an in-depth review of the protocol and inform the IRB in addressing the following:

1. Does the research use procedures consistent with sound research design?
 2. Is the research design sound enough to yield the expected knowledge?
- D. Criteria for selecting primary reviewers include their scientific or scholarly discipline, clinical expertise, regulatory knowledge, and understanding of or experience working with the study population, especially any vulnerable groups.
- E. If the Assistant Director can not identify a primary reviewer with the appropriate scientific or scholarly review, the Assistant Director in consultation with the Chair arranges to either defer review of the protocol to another meeting, refer the protocol to another IRB or obtain an *ad hoc* consultant (refer to UIC HSPP policy *Identification and Use of Ad Hoc Consultants*).
- F. The Assistant Director also identifies protocols involving populations vulnerable to coercion or undue influence (i.e., children, prisoners, pregnant women, the handicapped, decisionally and cognitively impaired, or economically or educationally disadvantaged persons) and determines whether the IRB for the scheduled meeting will include persons knowledgeable about or experienced in working with these participants. If no individual with knowledge and experience with the relevant categories of vulnerable participants is available for the meeting, the Assistant Director in consultation with the Chair will either defer review of the protocol to another meeting, refer the protocol to another IRB or obtain an *ad hoc* consultant (refer to UIC HSPP policy *Identification and Use of Ad Hoc Consultants*).
- G. In accordance with VHA handbook 1200.05 and FDA guidance, UIC policy requires that a licensed physician be present and eligible to vote at meetings in which protocols involving FDA regulated articles are reviewed.
- H. In accordance with 34 CFR Parts 350 and 356, if an IRB reviews research that is supported by the U.S. Department of Education and subject to 34 CFR 97 and that purposefully includes children with disabilities or individuals with cognitive impairment and decisional impairment as research subjects, the IRB will include at least one person primarily concerned with the welfare of these research subjects.
- I. Expedited Review: The IRB Chair designates members to conduct expedited reviews. IRB members are assigned by the Assistant Director to expedited review of research protocols based on the nature of the research and their expertise. If the IRB member does not feel qualified to evaluate the protocol, the Assistant Director in consultation with the Chair appoints another expedited reviewer.

REFERENCES:

[21 CFR 56.107](#), [21 CFR 56.111\(a\)\(1\)\(i\)](#), [\(a\)\(2\)](#)
[38 CFR 16.107](#), [38 CFR 16.111\(a\)\(1\)\(i\)](#), [\(a\)\(2\)](#)
[34 CFR 350.4\(c\)](#), [34 CFR 356.3\(c\)](#)
[45 CFR 46.107](#), [45 CFR 46.111\(a\)\(1\)\(i\)](#), [\(a\)\(2\)](#)

[VHA Handbook 1200.05., section 7.f\(1\)](#)
[FDA Guidance for Institutional Review Boards and Clinical Investigators, Appendix H: A self-evaluation checklist for IRBs, 1998.](#)

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 8/12/09	1.0, 3/18/09	Added information as to Policy section III about Department of Defense requirements for scientific review.