

**IRB: Evaluation of Resources and
Workload**

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

Version: 1.2
Date: 06/18/2009
Approved by: Interim Vice Chancellor for Research
AAHRPP REF#: 151
AAHRPP Elements: 1.2.B

POLICY:

- I. Through its operational procedures, UIC OVCR strives to provide the appropriate number of IRBs for the volume and types of human research reviewed to ensure reviews are accomplished in a thorough and timely manner.

PROCEDURE:

- I. IRB Structure.
 - A. As of the most recent update to this policy and procedure, UIC's Assurance, FWA00000083, lists the following IRB panels as linked to the assurance:
 1. UIC IRB #1: 00000115;
 2. UIC IRB #2: 00000116;
 3. UIC IRB #3: 00000117;
 4. UIC IRB #4: 00006412 (JBVAMC/NU/UIC Collaborative IRB);
 5. National Cancer Institute Central NCI CIRB: 00000781 (pediatric);
 6. National Cancer Institute Central NCI IRB: 00004296 (adult).
 - B. Each of the IRBs listed above review all human subject matters within their jurisdiction, including but not limited to initial review, continuing review, amendments, final reports, unanticipated problems and/or events requiring prompt reporting, and protocol deviations or exceptions.
 - C. Boards #1 and #3 review health sciences and biomedical research for both VA Research and non-VA Research. Board #2 reviews social and behavioral science research for non-VA Research. Board #4 primarily reviews biomedical and social and behavioral research for VA Research involving the JBVAMC and, typically, NU. Prisoner research is reviewed by Boards #2 and #3.
 - D. VA Research is defined as research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time, utilizing VA resources, and/or on VA property including space leased to, and used by, VA. The research may be funded by VA, by other sponsors, or be unfunded. (Refer to VHA Handbook 1200.1). The Collaborative IRB is responsible for reviewing all applicable VA Research involving human subjects (as defined in 38 CFR 16.102 (f) or 21 CFR 812.3(p) and 50.3 (g)) and/ or human biological specimens (as defined in VHA Handbook 1058.03) prior to its initiation either through convened or expedited review or a

determination that the research is exempt from IRB review or is not human subjects research. (Refer to VA [FAQ: Banking of Human Biological Specimens for Research](#), dated 1/10/07). The JBVAMC relies on the Collaborative IRB to make the exemption determination and the not human subjects research determination. If research involving only human biological specimens is found to be exempt, only the R&D Committee is responsible for reviewing all applicable VA research involving human biological specimens prior to its initiation.

- E. Through existing MOUs with the JBVAMC, two UIC IRBs (UIC IRB #1 and #3) and three NU IRBs (NU IRB #3, #5 and #6) currently serve as IRBs of record for the JBVAMC until the Collaborative IRB becomes fully operational. Protocols active at the JBVAMC at the time of the establishment of the Collaborative IRB will be transferred from their original NU or UIC IRB to the Collaborative IRB at their next continuing review cycle. During the transition period, the term "Collaborative IRB" means the appropriate IRB of record, which may include UIC IRB #1, UIC IRB #3, NU IRB #5, NU IRB #6, or UIC IRB #4.
- F. An IRB Authorization Agreement exists between NU and UIC as to IRB #4.
- G. A commercial IRB must never be used to review VA Research. (VHA Handbook 1200.05).
- H. The NCI CIRB must not be used to review VA Research.

II. IRB Workload Monitoring.

- A. The Director of OPRS and the Associate Director of OPRS are presented with the following information, which is generated by a designee monthly, to evaluate the workload of each IRB and guide adjustments in the volume and level of research reviewed by and staff resources assigned to each board to maintain a thorough and timely review process on a regular basis, and periodically assesses
 1. Number of studies submitted by review type (initial review, amendments, continuing review) and review level (convened, expedited, exempt) overall and per IRB;
 2. Tracking list of individual protocols for each board;
 3. An efficiency report as to the timeliness for IRB reviews as measured by the number of letters completed within specified timelines by IRB and individual staff;
 4. An efficiency report of the timeliness and volume of reviews that can be viewed on a monthly basis and/or within the context of a 12-month period;
 5. Time required for approval of each type of application; and
 6. Copies of the final meeting minutes from each IRB on a regular basis after they are approved by the IRB Chair.
- B. The above reports are also provided to the HPA and IO.
- C. The Director and Associate Director of OPRS meet with the IO bi-monthly to review workload issues, including the timeliness of IRB reviews, the number, types and complexity of recent IRB submissions, and any perceived

deficiencies, such as the number of IRBs or IRB members, necessary reviewer expertise, information technology resources, or OPRS staff allocations.

- D. The Director and Associate Director of OPRS meet with the IRB Chairs monthly to discuss compliance, regulatory and operational issues. At least annually, the HPA and/or IO attend this meeting to obtain feedback from the Chairs concerning the time IRB members devote to the IRB activities and assess the complexity of the protocols and resource needs.
- E. The Director of OPRS and IO meet with members of the UIC research community as the need arises to obtain feedback as to the timeliness of reviews.
- F. At least once a year, the HPA as part of the budget planning process evaluates whether the resources, staff, number of IRBs, and IRB member expertise are sufficient for the volume and types of human subject research being reviewed and for the review process to be accomplished in a thorough and timely manner.
 - 1. The JBVAMC provides UIC OPRS, NU OPRS and the UIC IO and HPA, with the results of the required annual VA review and evaluation of the Collaborative IRB. This evaluation of the structure, function, and performance of the IRB is completed by the JBVAMC R&D Committee for the JBVAMC Medical Center Director. The report may include recommendations for improvements of OPRS and the Collaborative IRB made by the JBVAMC R&D Committee.
 - 2. The VA annual review and evaluation of the Collaborative IRB will be shared in its entirety with the following individuals:
 - a) UIC Director of OPRS;
 - b) IRB Chair;
 - c) IRB members;
 - d) IRB Assistant Director;
 - e) IRB Coordinators;
 - f) Assistant Director for Quality Assurance/ Quality Improvement;
 - g) OVCR Associate Director for Research Compliance;
 - h) Executive Committee; and
 - i) Other OPRS staff as necessary.

The Director of OPRS works with the EC in the evaluation and planning of appropriate action based on the VA annual review and evaluation and delegates the implementation of the actions as appropriate to OPRS staff. Possible actions include, but are not limited to: the development and implementation of additional educational sessions for appropriate OPRS staff and IRB members, the development, or updating, of policies and procedures, and/or the development of additional quality improvement measures.

- 3. The JBVAMC R&D Committee also evaluates the Collaborative IRB and documents in the IRB's consideration of the following in accordance with the same procedures as the VA annual review above:

- a) Assessment of qualifications and experience of a new Collaborative IRB chair;
 - b) Appropriateness of the Collaborative IRB and Collaborative IRB membership given the research being reviewed;
 - c) Collaborative IRB representatives include either members or alternates interested in, or who have experience with, vulnerable populations involved in research; or *ad hoc* consultants who will supplement the Collaborative IRB's expertise in specific research areas; and
 - d) Adequacy of the Collaborative IRB's policy and procedures.
4. UIC agrees to allow the JBVAMC to evaluate the Collaborative IRB and document these findings. The UIC OPRS reviews the JBVAMC R&D Committee's findings and requests for improvements and responds to the JBVAMC R&D Committee's findings in a timely manner, including the requests for improvements.
 5. The UIC OPRS and the Collaborative IRB may make changes based on for quality assurance and improvement recommendations from the JBVAMC when needed or if required following an oversight visit by a federal agency (i.e., OHRP, FDA, etc.) or an accrediting organization. All requests or recommendations for improvement between the two entities are handled through the Director of UIC OPRS and the Executive Committee Supporting the Collaborative IRB.
 6. UIC OPRS, the Assistant Director of Quality Assurance/ Quality Improvement, and the OVCR Associate Director for Research Compliance have the authority to perform quality assurance and quality improvement audits on, and assessments of, the Collaborative IRB files. Additionally, the UIC quality assurance and improvement program extends to the members and support staff of the Collaborative IRB, and they are evaluated within the scope of the Collaborative JBVAMC/NU/UIC human subjects protection program.

REFERENCES:

N/A

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 04/03/09	1.0, 05/19/08	Revised language regarding the UIC HPA to reflect position changes.
1.2, 06/18/09	1.1, 04/03/09	Added Assistant Director of Quality Assurance/ Quality Improvement title.