

**Investigator and Research
Personnel Education Program and
Training Requirements**

203 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-1711 Fax: 312 413-2929
www.research.uic.edu/protocolreview/irb

Version: 2.1
Date: 04/29/2012
Approved by Human Protections Administrator,
Director of OPRS, and Executive IRB Chair
AAHRPP REF#: 176
AAHRPP Elements: I.1.E., I.6.B., III.1.B.

POLICY:

- I. The UIC HSPP includes ongoing educational requirements for the research community (i.e., investigators, department heads, faculty, staff and students). The HSPP education program consists of initial and continuing mandatory training sessions for all individuals who are engaged in the research, including but not limited to, being involved in the conduct, review, or oversight of human subject research as well as a HIPAA research training requirement for all individuals involved in research using PHI.
- II. No individual identified as key research personnel on a protocol will be allowed to conduct research activities involving human subjects without meeting the HSPP training requirements.
 - A. Key research personnel are engaged in the research and include:
 1. Principal investigators;
 2. Co-investigators;
 3. Individuals listed on the grant or contract application;
 4. Individuals listed on a FDA form 1572 (for UIC sites);
 5. Individuals who are named as contact persons in the informed consent documents or recruitment materials for research;
 6. Individuals who provide supervision of the persons who are obtaining informed consent to participate in research;
 7. Individuals who obtain informed consent or authorization; and
 8. Individuals who have access to PHI.
 - B. PIs are responsible for the ongoing monitoring of the educational requirements of all research personnel, paying special attention when research personnel are promoted or are given additional responsibilities. A promotion or broadening of duties may trigger new educational requirements from which personnel were previously exempt.
 - C. Key research personnel are listed on the IRB application and Appendix P and must be reviewed and approved according to their role in the research by the IRB.
 - D. If students or other individuals are not engaged in the research and are not listed in Section II.A above, then they are not required to be listed on the research protocol. However, the Principal Investigator is responsible to

ensure that these individuals receive both adequate training, including human subjects protection training, and oversight in accordance to the roles these individuals perform in the research.

- E. Individuals who are designated as “RiSC Web View Only” must be listed on Appendix P with this designation, but human subjects protection education is not required for these individuals.
 - F. Individuals who use research information/data from a study for their own research must be included as key research personnel on the original protocol application or must submit a separate application.
 - G. Applications will not be accepted by OPRS for IRB review if a PI or faculty sponsor lacks the required human subject protection training. Key research personnel will be excluded from participating in the conduct of the research until they have met the training requirements.
 - H. Final approval may be withheld if it is determined that an individual, who has not met the HSPP training requirements, is key to the conduct of the research.
 - I. For further information on who is required to take HSPP training, see the OPRS Website Education and Training page:
<http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/education/index.shtml>.
- III. Other entities that are components of the UIC HSPP (UIC Medical Center, JBVAMC, College of Medicine, etc.) have their own research training mandates that are separate from those described in this policy and procedure. UIC OPRS is not responsible for the management or record-keeping for these courses.
- IV. The educational program at UIC OPRS also extends to UIC OPRS staff and IRB members.

PROCEDURE:

- I. Initial Training Requirement.
 - A. The initial training requirement may be fulfilled by completing the live UIC OPRS Investigator 101 course or the on-line Collaborative Initial Training Initiative (CITI) course. The CITI is also available in Spanish language.
 - B. OPRS should be contacted for other training options available for individuals with limited capacities and lesser roles in the research (e.g. community liaison) or for other non-English language options.
 - C. Educational offerings from other institutions will be evaluated on a case-by-case basis for equivalency to UIC standards. To submit outside training for approval, submit proof of training along with the course description to OPRS.
- II. HIPAA Training Requirement.
 - A. If the research involves the use of PHI, all key research personnel must complete the UIC HIPAA research training course.
- III. Continuing Education Requirement.

- A. All investigators and other key research personnel involved in human subject research are also required to complete a minimum of two contact hours of UIC HSPB-approved CE in human subject protections every two years.
- B. Educational opportunities may be found by attending approved educational offerings on campus (i.e., OPRS, departmental or college programs) or approved conferences or educational courses dealing with human subject protections within and outside of the institution.
- C. Individuals must submit external educational offerings for consideration for HSPB CE credit to OPRS using the "Requesting Continuing Education Credit" forms available on the OPRS website - <http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/index.shtml>.

IV. UIC OPRS maintains individual training attendance records for all research personnel who have attended training presented or authorized by OPRS/OVCR, completed the CITI Course, or have completed and submitted external training. Research personnel may receive their training record by:

- A. Logging into RiSCWeb and checking the education system;
- B. Sending an email to oprstraining@uic.edu; or
- C. Contacting OPRS reception.

V. New IRB Members:

- A. In addition to CITI/ Investigator 101 training and HIPAA training requirements, new IRB Members for all UIC IRBs must attend a one on one training session conducted by the Assistant Director for Education and/or the Associate Director of External Relations and Quality Assurance or complete this course independently. This introductory course is specifically tailored by UIC OPRS for the unique considerations faced by members of each IRB. The course includes the following:
 - How a typical IRB meeting works
 - What their role is on the IRB
 - Orientation to the life of a protocol in the UIC HSPB or JBVAMC HSPB, as applicable
 - Explanation and definitions of the range of IRB actions
 - Practical introduction to the range of review guides through various case studies
 - Practical orientation to each of the 45 CFR 46.111 criteria and what they mean when applied to research
 - Introduction to the concepts and procedures related to conflict of interest
 - Introduction to the concepts and procedures related to scientific expertise and review
 - Orientation to the applicable undue influence policy and procedure
 - Practical review of informed consent requirements
 - Orientation to email addresses and telephone numbers of people in UIC OPRS who can help with any questions or undue influence issues

- Notification of general IRB term and what types of circumstances cause non-renewal
 - Discussion of attendance expectations and meetings
 - Quorum
- B. New IRB members are provided the following information:
- UIC New Member Training handout
 - Belmont Report
 - Review Guides
 - UIC OPRS Tip Sheet Booklet
 - Directory information with people to contact depending on the issue
 - Copy of IRB Roster
 - Blank IRB member evaluation form
- C. New community IRB members receive tailored one on one instruction by either the Assistant Director for Education and/or the Associate Director of External Relations and Quality Assurance based on a curriculum targeted to their role on the IRB.
- With the exception of scientific review instruction, community members are provided with the same information as listed above, as well as specific information during the orientation on their unique and important role on the IRB.
- D. New non-community IRB members must observe the IRB meetings for a time as determined by the IRB Chair until they are permitted to begin to vote and review IRB materials within the areas delegated to them by the IRB Chair.

VI. Other IRB Members:

In addition to minimum IRB member (individuals who are not considered “new” by the IRB Chair) education requirements, the Assistant Director for Education and/or the Associate Director of External Relations and Quality Assurance, or other guests, also provide education as needed to provide updates on new policies and procedures, regulatory updates, or updates to VHA Handbooks. These educational presentations generally consist of PowerPoint presentations based on case studies, as well as any source materials and are generally held at the start of IRB meetings and last for approximately 15-30 minutes. Topics may also include updates on government audits or corrective actions that are needed due to quality assurance/ quality improvement audits. Educational topics may also be presented by the Director of OPRS that refresh the memory of the IRB as to UIC OPRS or JBVAMC policies and procedures as needed. The Chair or other IRB member may also bring journal materials to the attention of the individual creating the IRB agenda for inclusion in discussion.

VII. JBVAMC R&D Office

UIC OPRS staff, including but not limited to, the Director of UIC OPRS, the Assistant Director for Education, the Associate Director of External Relations and Quality Assurance, and the Assistant Director of the Collaborative IRB/ VA Liaison, provide constant education on a day to day basis concerning regulatory and procedural matters to the JBVAMC R&D Office for which UIC OPRS receives reimbursement. Formal educational sessions are also provided by OPRS staff during town hall meetings. Formal educational sessions on a more intensive schedule are also provided if significant regulatory changes occur.

VIII. UIC OPRS Staff

UIC OPRS staff are provided with educational updates and operational updates at regular staff meetings and staff retreats by a variety of UIC OPRS and OVCR individuals. For new policies and procedures, all UIC OPRS staff undergo training as a group, as well as complete a short graded quiz following the training.

IX. Training Updates

The Assistant Director for Education and the Associate Director of External Relations and Quality Assurance both review the educational materials at least an annual basis for any updates needed, but at a minimum significant regulatory or operational changes must be updated immediately in the educational materials.

REFERENCES:

[Engagement of UIC in Human Subjects Research](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 5/05/09	1.0, 12/22/08	Linked to the engagement policy and procedure, Determining Whether a Performance Site or an Institution is Engaged or Not Engaged in Research
1.2, 06/18/09	1.1, 05/05/09	Clarified that individuals who engage UIC in human subjects research must complete the required training.
2.0, 04/29/11	1.2, 06/18/09	Inclusion of IRB Member, JBVAMC R&D Office, and OPRS Staff training requirements.
2.1, 04/29/12	2.0, 04/29/11	Correction of title within policy. .