



**Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL. 60612**

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**SOP: Required Education and
Training for Human Research
Activities At the Jesse Brown VA
Medical Center**

PURPOSE

To describe the required education and training criteria for investigators and their research teams involved in human research activities, R&D Committee members, Collaborative IRB VA representatives, and R&D Office staff dealing with human subject protection program at the Jesse Brown VA Medical Center.

POLICY

To ensure that all Principal Investigators, key research personnel, R&D Committee Members, Collaborative IRB VA Representatives, and R&D Office Staff involved in Human Subject .Protection Program who participate in research activities are properly trained to conduct and/or review studies in a compliant, safe, ethical manner.

RESPONSIBILITIES

1. The Associate Chief of Staff for Research and Development (ACOS for R&D) is responsible for communicating education and training requirements to researchers and for making training programs available to all individuals involved in the conduct of human research, including R&D Committee Members, Collaborative IRB members, and R&D Office Staff.
2. All individuals involved in the conduct of human research at the JBVAMC must receive training in human subjects protection and GCP in accordance with VHA Handbook 1200.05 and ORD Guidance from the 2003 Stand Down Memorandum. This requirement is met by components of the CITI course as developed by ORD and CITI. The CITI course is mandatory for PIs, co-investigators, and research staff at JBVAMC and is accepted in place of UIC and NU CITI training requirements; however, the UIC specific portions of CITI must also be completed for UIC personnel. CITI training for human subjects protection is required before participating in human subjects research **and every two years thereafter**. Please note that "two years" is defined as within the second full calendar year

after the previous training. In addition to the CITI curriculum, other VA educational requirements, including **annual VHA privacy policy training**, **annual VA security awareness training**, and one-time Information Security 201 for Research Personnel, must also be completed along with one-time completion of UIC-IRB's additional training modules, HSPP 108 and HSPP 109.

The JBVAMC R&D staff provides information to UIC OPRS regarding any new VA training or updates required for individuals.

Additional VA-research specific training that may be required includes:

- i. Research (Laboratory) Safety Training** is required for all staff involved in laboratory-related activities; the type and extent of this training will be evaluated and provided by the facility Safety Officer; this training must be renewed on an annual basis.
 - ii. Radiation Safety Training** is required for all research staff whose duties will involve using radio-isotopes in laboratory space; the type and extent of this training will be evaluated and provided by the Radiation Safety Officer; this training must be renewed on an annual basis.
 - iii. Animal Care and Welfare Training** is required for staff involved in animal research protocols working with the VA IACUC.
 - iv.** UIC policy and procedure found in the *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4)* concerning expirations in education will be followed.
3. **Applicability:** This training requirement applies to all individuals involved in the conduct of VA human subjects research regardless of pay status, appointment type (title 38, title 5, IPA, or WOC), and length of time at the VA facility, including, but not limited to:
- a. Investigators;
 - b. Study coordinators;
 - c. Research assistants;
 - d. Other members of the research team;
 - e. Trainees, such as house officers and students;
 - f. All members of the research office whose responsibilities include involvement with human research (e.g., the ACOS for R&D and the AO for R&D);
 - g. VA representatives to external IRBs (e.g., Collaborative IRB);
 - h. All voting, and ex officio, nonvoting members of R&D Committees; and
 - i. Members of other research committees or subcommittees that review research involving human subjects.

This training requirement also applies to investigators and research team members conducting studies involving human subjects that are exempt from IRB review, as well as those conducting human research for which the IRB has granted a waiver of informed consent or a waiver of documentation of informed consent.

Exceptions to Applicability. This training requirement does not apply to:

- a. Secretarial support staff,
- b. Research office staff whose responsibilities do not involve human research (e.g., those who deal only with research involving animals),

- c. Community members of the IRB. However, community members of the IRB must complete specific training for IRB members as defined in the facilities' SOPs.
- d. Facility Directors are not required to complete this training, but are required to complete the required Assurance training.

Academic Affiliate. The Collaborative IRB members are encouraged to complete the VA required human subjects protection training, or its equivalent. The JBVAMC is not required to track such training.

DMC. Members of a DMC for a VA research study are encouraged to complete VA required human subjects protection training or its equivalent. The JBVAMC is not required to track such training.

Individuals Outside VA. Individuals outside VA (e.g., phlebotomists, x ray, and laboratory technicians) who are not VA employees (paid, WOC, or IPA), and whose work occurs exclusively outside the JBVAMC (e.g., at affiliated academic institution), must meet their own institutions' requirements for training, but the JBVAMC is not required to track such training.

Clinical Service Providers. Individuals who provide services for the research study in the course of their routine clinical duties (e.g., an x-ray technician who performs a chest x-ray, or clinical laboratory technician who performs a routine blood count), but have no other role or responsibility for the research study, are not required to complete VA human research protection training.

PROCEDURES

Step 1

The JBVAMC R&D staff indicates to the Collaborative IRB at the time of submission of an initial review, continuing review, amendment, or exempt submission whether the education and training requirements for PIs and other research personnel are up to date via the JBVAMC R&D IRB Protocol Submission Checklist. The Collaborative IRB will not approve research for performance at the JBVAMC unless the PI is current with required VA training. If training is deficient at the time of continuing review even prior to the expiration date, IRB approval is considered to have lapsed and the procedures described in section III.D.3.ii. of the *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4)* are followed.

Step 2

JBVAMC R&D Committee annually assesses VA training and education requirements for investigators and other research personnel involved in JBVAMC research. Failure by the PI to have met the annual and biennial training requirements results in a lapse of approval of any ongoing research at the JBVAMC. The R&D office immediately notifies the Collaborative IRB and the PI in writing of the lapse of R&D

approval. The PI is instructed to stop all research activities and to submit to the IRB Chair a list of subjects who are still active in the research and for whom research interventions or interactions must be continued to prevent harm. The IRB Chair in consultation with the VA COS determines if it is in the best interest of the subject(s) to continue in the research. The failure to complete the required educational programs is considered by the Collaborative IRB as non-compliance and will trigger the non-compliance review process as described in the UIC HSPP policy Handling Complaints and Allegations of Potential Non-Compliance with Human Subjects Protection Regulations. If the noncompliance is found by the IRB to be serious and/or continuing, the UIC reporting policy to investigators, institutional officials and the department or agency heads, the UIC HSPP policy Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance, is followed.

Step 3

Co-Investigators or other research personnel who are deficient in training and education requirements at the time of submission of an initial or continuing review or at the annual R&D review must be removed from the research before IRB review and approval may proceed. If research personnel are removed, submission of an amendment is needed to restore them to the protocol after the training deficiency is corrected.

REFERENCES

VHA handbook 1200.05
 VHA handbook 1200.01

REVISION LOG:

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Version (#, date)	Replaces (#, date)	Summary of changes
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