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Jesse Brown VA Medical  
Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

R&D 537/151  
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Version 1.0

**SOP: Use of VA Central IRB**

**PURPOSE:**

To establish the scope, policy, and procedures for the use of the VA Central IRB (CIRB). In 2008, the Office of Research and Development (ORD) established a Central IRB in order to be the official IRB of record for VA Cooperative Studies (CSPs). All review of the research by the VA Central IRB must be approved by the R&D Committee.

**SCOPE:**

The CIRB reviews certain VA funded multi-site trials which intend to include human subject research; this may include human subjects, biological samples from humans, or their medical records. This review is intended to ensure that human subjects are protected. All JBVAMC applicable R&D SOPs and IRB SOPs will apply to protocols using the CIRB, with this SOP providing the applicable exceptions to the JBVAMC's SOPs.

**BACKGROUND:**

A Memorandum of Understanding is in place between JBVAMC and the VHA Central Office Institutional Review Board (VA CIRB) for select multi-site VA research projects involving human subjects. The VA CIRB review will include initial review, continuing review, review of amendments, reporting, monitoring and other relevant requirements.

As per the MOU, both institutions will adhere to 38 CFR 16 and 17, 45 CFR 46 subpart A, and 21 CFR 50 and 56, as well as other pertinent VA and federal regulations and requirements applicable to human subject research.

The VA Central IRB has been added to our Federal-wide Assurance (FWA) with the Office for Human Research Protections as an IRB of record for our facility.

## DEFINITIONS:

Assurance. An Assurance is also called an Assurance of Compliance, or a Federal-wide Assurance (FWA). It is a written commitment by an institution to protect human subjects participating in research. Under federal regulations, any institution conducting or engaged in federally supported research involving human subjects must obtain an Assurance in accordance with 38 CFR 16.103. NOTE: All research conducted under VA auspices is considered to be Federally-supported. This requirement also applies to any collaborating “performance site” institutions. Under 38 CFR 16.102(f), an institution is engaged in human subject research whenever its employees or agents: intervene or interact with living individuals for research purposes; or obtain, release, or access individually-identifiable private information for research purposes. Assurances are filed through the VA Office of Research Oversight (ORO) with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). The FWA replaces previous types of OHRP and VA assurances.

Federal-Wide Assurance (FWA). A Federal-wide Assurance is also referred to as an Assurance (see the definition of Assurance in paragraph 3.C).

Investigator. An investigator is any individual who conducts research involving human subjects including, but not limited to, the PI, co-PI, and Local Site Investigator (LSI). The investigator must uphold professional and ethical standards and practices, adhere to all applicable Federal requirements, and comply with applicable local policies and procedures (see par. 9).

(1) VA Investigator. A VA investigator is any individual who conducts research approved by the VA R&D committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970. In addition, a VA investigator must comply with all applicable VA and VHA requirements, and comply with applicable local VA facility policies and procedures.

(2) Principal Investigator (PI). The PI is a qualified person or persons designated by an applicant institution to direct a research project or program and who usually writes the grant application. The PI oversees scientific, technical, and day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team. **NOTE: FDA considers Investigator and PI to be synonymous.**

(3) Co-Principal Investigator (Co-PI). A Co-PI is when one of two or more PIs share equally in the accountability for a study. A Co-PI must meet the same qualifications of a PI.

(4) Site Investigator or Local Site Investigator (LSI). The Site Investigator or LSI is an investigator at a site participating in a multi-site research project. The LSI oversees scientific, technical, and day-to-day management of the research at the local site. (VHA Handbook 1200.05, dated October 15, 2010).

Memorandum of Understanding (MOU). A Memorandum of Understanding is a cooperative agreement between two parties. There are two MOU's in place for the purposes of human subject's protection in research. The Memorandum of Understanding

(MOU) between the Institution (JBVAMC) and the JBVAMC/NU/UIC IRB 4 concerns the VA's utilization of its affiliate IRB for human subject protection in research. The MOU establishes the terms of the cooperative agreement between these entities. According to the MOU, neither the JBVAMC nor the Universities may enter into collaborative human research with VA support with an institution that does not hold a FWA. The Memorandum of Understanding (MOU) between the Institution (JBVAMC) and the VA Central IRB establishes the terms of the cooperative agreement for human subject protection in research between these two entities. This agreement outlines the requirement for both institutions to adhere to VA and other federal requirements for the protection of human subjects in research.

Office for Human Research Protections (OHRP). The OHRP is an office within the Department of Health and Human Services (DHHS) that monitors human research subject's protections through educational efforts, clarification and guidance, site visits, and reporting requirements. The OHRP has the authority to suspend research for failure to adhere to the regulations. OHRP replaces the earlier Office for Protection from Research Risks (OPRR).

Office of Research and Development (ORD). Within VHA Central Office, ORD is the office responsible for the overall policy, planning, coordination, and direction of VA research activities.

Office of Research Oversight (ORO). ORO serves as the primary VHA office in advising the Under Secretary for Health on all matters of compliance and assurance regarding human subject protections, animal welfare, research safety and security, research information protection, and research misconduct.

Safety Reports. Safety Reports are written reports from sponsors notifying the FDA and all participating investigators of any adverse experience associated with the use of a drug, biologic or device that is both serious and unexpected.

Unanticipated Problem. Refers to a problem, event or information item that is unexpected, given the nature of the research procedures and the subject population being studied; related or possibly related to participation in research and suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.  
. (VHA Handbook 1058.01, vs. May 21,2010)

## **PROCEDURES:**

The Local Site Investigator Application package as well as the Compliance packet is submitted by the JBVAMC investigator to the JBVAMC R&D Office for review by the local site liaison and ACOS for Research and Development. After review, the ACOS for Research submits the application to the VA CIRB through the local site liaison.

The Compliance packet for VA central IRB studies includes the same documents as for studies utilizing the Collaborative IRB 4.

When the VA Central IRB has reviewed the Principal Investigator application as well as the Local Site Investigator application, the local investigator and the local VA facility are sent a copy of the application package requiring that they review the application package to ensure the project conforms to all local requirements. This process includes making sure the CIRB consent form, as well as other submission documents, meet local site criteria. The local site and the local investigator have 30 calendar days to address initial CIRB review considerations. This response will be sent to the VA Central IRB through the local site liaison.

If the ACOS-R or the R&D Committee have any additional concerns about the study, or would like changes made to any study documents, the local site liaison will notify the local site investigator, along with the VA Central IRB study-specific Coordinator within the 30 day window.

Once the local site investigator receives official approval from the VA Central IRB, JBVAMC has 10 days to determine whether it wishes to be a local site for this study under these final conditions. This determination is made by a review of the IRB submission by the Research HSPP Coordinator and the ACOS-R and will be communicated with both the local site investigator and the VA Central IRB study-specific Coordinator. If the decision to participate is made, a copy of the VA Central IRB minutes will be forwarded to JBVAMC by the VA Central IRB.

These minutes will then be forwarded to the R&D Committee for approval as per normal procedures for JBVAMC research projects.

Once the R&D Committee approves the study and the Central IRB minutes at which the study was discussed, the official notification of approval from the ACOS-R will be sent by the R&D office to the local site liaison, to the local site investigator and to the VA Central IRB study-specific Coordinator. **NOTE: The study cannot start until the PI has received the approval letter from both the VA Central IRB and the ACOS-R.**

Continuing Reviews: The VA Central IRB will conduct continuing review of approved projects at least once per year, or more often if determined appropriate. The R&D Committee will approve the Central IRB minutes at which the continuing reviews were discussed and approved.

Please refer to the VA Central IRB website: (<http://www.research.va.gov/programs/pride/cirb/sop/default.cfm> ) for information on specific reporting requirements and procedures.

**REVISION LOG:  
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Version (#, date)	Replaces (#, date)	Summary of changes
1.0; September 29, 2010		