

January 30, 2012

RESEARCH STANDARD OPERATING PROCEDURES
Use of the VHA Office of Research and Development Central IRB (CIRB)

1. **PURPOSE:** To establish the scope, policy, and procedures for the use of the CIRB. The Office of Research and Development (ORD) has established a CIRB in order to be the official IRB of record for VA Cooperative Studies (CSPs). The South Texas Veterans Health Care System (STVHCS) Federal Wide Assurance (FWA) includes the CIRB as a second IRB of record for this facility. Research reviewed and approved by the VA CIRB must be approved by the Research and Development (R&D) Committee prior to conducting the research at the STVHCS.

2. **POLICY:** 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 STVHCS applicable R&D SOPs and IRB SOPs will apply to protocols using the CIRB, with this SOP providing the applicable exceptions to the STVHCS SOPs.

3. **ACTIONS:**

a. The CIRB serves as a subcommittee of the STVHCS R&D Committee. The STVHCS will maintain a Memorandum of Understanding (MOU) with the CIRB. The MOU outlines, in detail, the respective authorities, roles, and responsibilities of the CIRB and the STVHCS.

(1) 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 subjects research.

(2) The CIRB review will include initial review, continuing review, review of amendments, reporting, monitoring and other relevant requirements.

(3) CIRB will provide timely written notice (usually within 10 working days of a CIRB action) to the STVHCS of any action requiring the STVHCS institutional response. Such actions include CIRB's initial review considerations and approvals/disapprovals, results of continuing reviews and amendments, any lapses of approval, and its final termination of a project.

(4) Additional information on specific reporting requirements and procedures of the CIRB are located on the CIRB website:

<http://www.research.va.gov/programs/pride/cirb/sop/default.cfm>.

b. Procedures for the use of the CIRB include the following:

(1) STVHCS investigators are responsible for completing the Local Site Investigator Application package for review by the CIRB. The local site application must be submitted to the CIRB via the ACOS for Research, through the local site liaison.

POLICY MEMORANDUM 12- 28

- (2) The CIRB will provide the R&D office and the local site investigator with initial review considerations following its review of the Principal Investigator and the Local Site Investigator application. The STVHCS and the local investigator have 30 calendar days to address initial CIRB review considerations. The local review is to ensure the project conforms to all local requirements. The response of this review will be sent to the VA CIRB through the local site liaison.
- (3) The local site application as well as all required R&D paperwork will be submitted to the R&D office for review by the Data Security and Privacy Subcommittee, Research Safety Subcommittee, and other appropriate STVHCS committees (i.e. Radiation Safety Committee). If any concerns or changes are noted they will be sent to the CIRB through the local site liaison within the 30 calendar day review window.
- (4) Once the local site investigator receives official approval from the CIRB, STVHCS 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 the ACOS for Research or designee and will be communicated with both the local site investigator and the CIRB.
- (5) Once written notification of approval by CIRB is received, the protocol will be forwarded to the STVHCS R&D Committee for review and approval as per normal procedures.
- (6) Once the R&D Committee approves the study, the official notification of approval from the ACOS for Research will be sent to the local site investigator and through the local site liaison to the CIRB. NOTE: The study can not be initiated until the PI has received the approval letter from both the CIRB and the ACOS for Research.
- (7) CIRB minutes with initial approvals and continuing reviews will be forwarded to the STVHCS R&D Committee for approval as per normal procedures for STVHCS research projects.

4. **REFERENCES:** VHA Handbook 1200.05; MOU between CIRB and STVHCS

5. **RESPONSIBILITY:** ACOS for Research and Development (151)

6. **RECESSION:** None

7. **RECERTIFICATION:** January 2017


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