



# Stratton VA Research & Development Committee Standard Operating Procedure

## **Procedural Protocol: Stratton VAMC Institutional Use of the VHA Office of Research & Development Central IRB (CIRB)**

**Purpose:** To establish the scope, policy, and processes for the use of the 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). The Stratton VAMC Federal wide Assurance (FWA) was amended to add this IRB as a second IRB for the facility. All Stratton VAMC research is the ultimate responsibility of the Stratton VAMC HRPP. The 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 Stratton VAMC applicable R&D SOPs and IRB SOPs will apply to protocols using the CIRB, with this SOP providing the applicable exceptions to the Stratton VAMC's SOPs.

**References:** VHA Handbook 1200.05  
MOU between CIRB and Stratton VAMC

**Policy and Procedures:** The CIRB serves as a Stratton VAMC's R&D Committee subcommittee. The Stratton VA Medical Center Research Service will maintain a Memorandum of Understanding (MOU) with the CIRB. This MOU outlines, in detail, the respective authorities, roles, and responsibilities of the CIRB and the Stratton VA Medical Center.

### **Activities Considered Subject to IRB Review.**

- CIRB will perform initial review of selected multi-site research projects.
- CIRB will require the use of an informed consent document for all research involving human subjects unless this requirement is waived by the CIRB. The informed consent document and process, waiver of documentation of informed consent, or waiver of informed consent, must meet all requirements in VHA Handbook 1200.05.
- CIRB will provide a timely written notice (usually within 10 working days of a CIRB action) to the Stratton VA Medical Center of any action requiring the Stratton VA Medical Center's response. Such actions include CIRB's initial review considerations and its final approval or disapproval of a project.
- CIRB will conduct meaningful and substantive continuing review of approved projects at a minimum of once per year or more often if determined appropriate to the degree of risk to subjects. The continuing review will evaluate information submitted by the Principal

Investigator (PI) including, but not limited to, the continuing review application containing all the elements required by VHA Handbook 1200.05 and all interim reports.

- CIRB will remain cognizant of local issues throughout the duration of the project and may request additional information from local sources or ad hoc advisors to supplement its review.
- CIRB will provide a timely (within 10 working days), written notice of the results of the continuing review to the Stratton VA Medical Center, including any lapses of approval, in accordance with CIRB SOPs.
- CIRB will evaluate any requests to amend or modify a previously approved protocol. CIRB will notify all participating local sites in writing within 10 working days after it approves any amendment or modification to a protocol. CIRB will provide a copy of the approval and the amendment or modification to the Stratton VA Medical Center.
- CIRB oversight of approved projects will include, but not be limited to:
  - Requiring all CIRB-approved projects that present greater than minimal risk to contain a specific data safety monitoring plan that includes a means of communication between the PI and local site investigators to ensure adherence to the plan.
  - Working closely with the Stratton VA Medical Center to investigate any complaints from subjects or others, incidents of investigator noncompliance or unanticipated problems, and to coordinate required reporting to regulatory agencies in accordance with CIRB SOPs, local site SOPs, and all VA and other Federal requirements.
  - Sending any of its members or administrative staff to a participating local site if determined necessary to complete any investigation or if requested by the Stratton VA Medical Center.
- If the CIRB determines that a given project is exempt from IRB review, it will provide a written letter with its decision to the PI who will be responsible for providing the letter to all Local Site Investigators to share with their respective participating local VA facilities.
- CIRB will review the PI's Initial Application for each protocol to determine which sites are engaged and, therefore, require a Local Site Investigator and a Local Site Application.

## **Responsibility:**

### **Medical Center Director (MCD) is responsible for:**

- The MCD is the Institutional Official (IO) responsible for ensuring that the Human Research Protection Program at the facility has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all

Assurances, and assumes the obligations of the institution's Assurances. The Medical Center Director ensures that the use of a commercial IRB is prohibited.

**Associate Chief of Staff for Research (ACOS/R) or his/her designee is responsible for:**

- Maintaining a current Federal Wide Assurance (FWA).
- Maintaining a formal written agreement (MOU) with the CIRB.
- Educating the members of the research community about the requirements of all aspects of the human research protection program
- Providing the CIRB access to the research subjects' clinical records and/or case files if required as part of any CIRB oversight or monitoring activity.
- Maintain a file on each CIRB approved project that will include the PI's Initial Application, the Stratton VA Medical Center's Local Site Application, CIRB-approved consent form that will be used locally, other documents associated with the initial application, CIRB final approval documents, Stratton VA Medical Center R&D Committee approvals, local audits and monitoring reports, and any subsequent correspondence, amendments, continuing review reports and approvals, and any other pertinent documents.
- Act as liaison between the CIRB and the local site investigator.

**Research Compliance Officer is responsible for:**

- Fulfilling all auditing and reporting requirements related to the oversight and implementation of the continuous quality improvement program, including projects approved by the CIRB.
- Promptly notifying the CIRB of any complaints from subjects or others; unanticipated problems involving risks to subjects or others; serious adverse events that are unanticipated and related to the research; suspension or termination of research activities; or serious or continuing noncompliance encountered in VA human subjects research projects approved by VA Central IRB; results or outcomes of all audits of protocols approved by the CIRB.

**Research and Development Committee is responsible for:**

- Approval of ALL research conducted at the Stratton VA Medical Center.
- Provide comments and/or suggestions if applicable to the CIRB about CIRB's initial review considerations, in a timely manner, not to exceed 30 calendar days, from the date of receipt of the initial review considerations
- Notify the CIRB immediately of potential research impropriety, misconduct, suspension, debarment, or restriction of any local research team member associated with a CIRB-approved project.