Stratton VA Medical Center
IRB Standard Operating Procedure: Sponsored Research

POLICY

Research conducted in collaboration with industry will be governed by Veterans Health Administration (VHA) Handbook 1200.5 and the model for Clinical Trials - Cooperative Research and Development Agreements (CT CRADAs). CT CRADAs are used by the government to establish the terms [(including handling of intellectual property, statement of work (SOW), and budget)] of sponsored research collaborations, primarily with industry.

REFERENCES

VHA Handbook 1200.5, Requirement for the Protection of Human Subjects in Research, Department of Veterans Affairs, Veterans Health Administration, Washington, D.C.

VHA Handbook 1200.17, VA Research and Education Corporations, Department of Veterans Affairs, Veterans Health Administration, Washington, D.C.

VA regulations pertaining to research-related injuries: 38 CFR 17.85

VA regulations pertaining to Common Rule: 38 CFR 16.102(g)

Food and Drug Administration (FDA) regulations pertaining to rights and welfare of human subjects participating in research involving investigational drugs and devices: 21 CFR parts 40, 56 and 312

VHA Directive 2003-031 – Establishment of a Facility Human Protections Program

Title 38, United States Code (U.S.C.), Sections 7361-7368, VA Research and Education Corporations

Department of Veterans Affairs, Clinical Trial Cooperative Research and Development Agreement, Model 2005
http://www.research.va.gov/programs/tech_transfer/crada/default.cfm

RESPONSIBILITIES

Sponsor: The sponsor is the person or entity who takes responsibility for, or initiates a clinical investigation. The Stratton Veterans Administration Medical

Center (Stratton VAMC) seeks written assurances from sponsors via the CT CRADA that research is conducted according to applicable laws and regulations, good clinical practices and ethical standards.

Hospital Director: The Hospital Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the Stratton VAMC, including sponsored research agreements and activities. The Hospital Director is the signature authority for CT-CRADAs.

Associate Chief of Staff for Research and Development (ACOS/R&D): The ACOS/R&D will maintain responsibility for procedures, policies, and execution of the sponsored research program.

Research Compliance Officer (RCO): The RCO will conduct quality assurance audits on sponsored research, and will notify the Hospital Director, the ACOS/R&D and the IRB of any noncompliance issues or circumstances that appear to pose a risk to human subjects.

Principal Investigator (PI): Within VA, a Principal Investigator is an individual who conducts a research investigation, i.e., under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The FDA considers a PI and an investigator to be synonymous.

Investigator: An investigator is an individual under the direction of the Principal Investigator (PI) who is involved in some or all aspects of the research project, including the design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts. An investigator must be either compensated by VA, be appointed to work without compensation (WOC), or may be an employee assigned to VA through the Intergovernmental Personnel Act (IPA) of 1970. The FDA considers an investigator and a PI to be synonymous.

Non-Profit Research Institutes: Non-profit research institutes created pursuant to sections 7361-7368 of Title 38, United States Code (U.S.C.) may administer funds received for research studies conducted at VA Medical Centers provided that the R&D Committee and any required subcommittee approve the studies. The Stratton VAMC R&D Committee and its subcommittees provide oversight of these studies. Stratton VAMC is associated with the Albany Research Institute (ARI), located at the Stratton VAMC.

The Albany Research Institute takes the lead in working with the PI in negotiating terms of the CT CRADA. ARI works with the Stratton VAMC's Research and Development Office to advance the CT CRADA through the VA approval process, and upon execution ARI administers the research project including the funds. ARI is a signatory on the CT CRADA with the Stratton VAMC Director and the Sponsor/Collaborator. ARI is responsible for insuring that any research conducted on behalf of the Institute has received R&D Committee approval and that the approval is filed with the Institute.

OVERSIGHT

Human Research Protection Program (HRPP): VHA Directive 2003-031 establishes a Facility Human Protections Program to support ongoing quality assurance at every VA research site. An HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of a variety of individuals and committees such as: the Medical Center Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, compliance officers, etc., the R&D Committee, the IRB, other committees or subcommittees addressing human subjects protection, investigators, IRB staff, research staff, health and safety staff and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principals and regulatory requirements for the protection of human subjects in research.

Research and Development (R&D) Committee: The R&D Committee will review and approve all sponsored research conducted at the Stratton VAMC, including assurance of human research protections. The R&D Committee oversees the activities of the IRB by reviewing the IRB meeting minutes, IRB reports and recommendations, and other communications from the IRB regarding human studies. No human research project is granted final written approval by the R&D Committee until it has been approved by the IRB (and all other appropriate subcommittees), ensuring that the rights, safety and well-being of human subjects are protected.

Minutes of the R&D Committee meetings are signed by both the chairperson and the ACOS/R. Minutes are provided to the facility Director and the Chief of Staff, through their membership on the committee. Minutes are also posted on the facility research website.

Institutional Review Board (IRB): The IRB is a board established in accordance with and for the purposes expressed in the Common Rule (38 CFR 16.102(g).) At VA medical centers, the IRB is a subcommittee of the R&D Committee. The Stratton VAMC IRB is formally designated by Stratton VAMC to review, to approve the initiation of, and to conduct periodic review of biomedical research involving human subjects. The IRB is charged with the protection of human subjects in all human studies research regulated by the R&D Committee.

The IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Information that may impact on the risk benefit ratio such as adverse events (AE's), unanticipated problems, and complaints regarding the research will be documented and communicated with subjects as contained in the SOP for Human Studies Research, Informed Consent – IRB. No research may commence until there is final written approval by the R&D Committee. The HRPP SOP provides further guidance on this matter.

PROCEDURE

The Human Research Protection Program and all VA statutes, regulations and policies at the Stratton VAMC will apply to sponsored research, as well as, all research conducted at the Stratton VAMC. Compliance activities are conducted in accordance with VA requirements.

CT CRADAs will be maintained with sponsors that require adherence to VHA Handbook 1200.5 for human subjects and all other applicable policies, regulations, and laws. In agreements with sponsors, the VHA guidelines for Clinical Trial Cooperative Research and Development Agreements will be followed, including the explicit language regarding the protection of human subjects, dissemination of knowledge and health care to injured research subjects.

CT CRADA Section 3.6 Human Subject Protection, will specify that the Collaborator and Stratton VAMC shall immediately notify each other of any findings that could affect the safety of subjects or their willingness to continue participation, influence the conduct of the study, or alter the status of the protocol at the IRB. When participant safety or medical care could be directly affected by study results, Stratton VAMC will send study subjects a written communication about the results.

CT CRADA Section 12.3, stipulates that the Collaborator shall be responsible for reasonable and customary costs incurred for treatment of physical injury to the subject if the Collaborator reasonably determines, after consulting with the VA, that the Adverse Event was reasonably related to administration of the Test Article or Protocol.

CT CRADA Section 7.4, Presentations and Publications, will require agreement from the sponsor regarding the dissemination of findings from research and the roles that investigators and sponsors will play in publication or disclosure of study results. With regard to affiliates, the agreement regarding publication and disclosure will be addressed in a Cooperative Technology Administrative Agreement.

SPONSOR RESPONSIBILITIES

FDA regulations: (21 CFR 312.23(a)(1)(iv)) require that a sponsor assure the FDA that a study will be conducted in compliance with the informed consent and IRB regulations (21 CFR parts 50 and 56). The sponsor is responsible for assuring the FDA (IND application-Form 1571 or IDE application 812.20) and the investigator assures the sponsor (Form 1572) that the study will be reviewed by an IRB and is functioning in compliance with regulations.