

RESEARCH SERVICE

April 1, 2008

RESEARCH STANDAND OPERATING PROCEDURES (SOP)

Contracts and Agreements with Sponsors of Human Subject Research

1. **PURPOSE:** To clarify policy and procedures for conducting human subject research that is sponsored by a commercial company that owns an investigational new drug or device, designs the protocol, and/or funds the project.
2. **POLICY:** All human subject research conducted at the STVHCS must adhere to all regulations and directives related to the protection of human subjects in research as required by the VA and all other responsible Federal agencies. All individuals involved in the HRPP, including sponsors, must understand and apply their obligation to protect the rights and welfare of human research subjects. Research conducted in collaboration with a commercial company will be governed by Veterans Health Administration (VHA) Handbook 1200.5, the model for Clinical Trials Cooperative Research and Development Agreements (CT-CRADAs), and Memorandum of Understanding (MOU) for Utilization of the Institutional Review Board (IRB) between the South Texas Veterans Health Care System (STVHCS) and the University of Texas Health Science Center at San Antonio (UTHSCSA), and the UTHSCSA Clinical Trials Agreement Template.

3. ACTION:

a. Responsibility:

- (1) Hospital Director: The Hospital Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the STVHCS, including sponsored research agreements and activities.
- (2) 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.
- (3) Research and Development (R&D) Committee: The R&D Committee will review and approve all sponsored research conducted at the STVHCS, including assurance of human research protections.
- (4) Research Compliance Officer (RCO): The RCO or his/her designee will monitor all sponsored research, will conduct quality assurance audits, and will notify the Hospital Director and the ACOS/R&D of any noncompliance issues or circumstances that appear to pose a risk to human participants.

b. Procedures:

- (1) The STVHCS Human Research Protection Program (HRPP) and all research policies at the STVHCS will apply to sponsored research, and there will be a written agreement with the sponsor fully addressing human research protections, and requiring adherence to VHA Handbook 1200.5 and all other applicable policies, regulations, and laws, prior to the initiation of research involving human participants within the STVHCS.

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- (2) When the agreement is between the sponsor and the STVHCS, the VHA template for Clinical Trials CRADAs will be followed, which includes explicit language regarding the protection of human participants.
- (3) When the agreement is between the sponsor and the University affiliate, the agreement will be in accordance with the MOU for Utilization of the UTHSCSA IRB, which also requires adherence to applicable regulations regarding the protection of human participants, and the UTHSCSA Clinical Trials Agreement Template, which addresses research-related injury, reporting of findings to the IRB, publication or disclosure of results, and communication of results to study participants.
- (4) Agreements with sponsors, or the University affiliate that negotiates with sponsors, will:
 - (a) Address the issue of medical care for research participants who may sustain a research-related injury according to VHA Handbook 1200.5.
 - (b) Specify that there will be prompt reporting of any findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the status of the protocol at the IRB.
 - (c) Address dissemination of findings from research and the roles that investigators and sponsors will play in publication or disclosure of results.
 - (d) Address how results will be communicated to study participants when participant safety or medical care could be directly affected by study results.

4. REFERENCES:

VHA Handbook 1200.5, *Requirement for the Protection of Human Subjects in Research*, Department of Veterans Affairs, Veterans Health Administration, Washington, DC

Cooperative Technology Administrative Agreement (CTAA)
http://www.research.va.gov/programs/tech_transfer/crada/affiliates.cfm

Clinical Trials Cooperative Research and Development Agreement
http://www.research.va.gov/programs/tech_transfer/crada/default.cfm

UTHSCSA Clinical Trial Agreement Template

5. RESPONSIBILITY: The ACOS/R&D is responsible for the follow-up of this SOP.

6. RECISSIONS: None.

7. RECERTIFICATION: April 2011.

//Signed//
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ACOS for Research & Development