

April 3, 2018

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 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 administered through the Foundation for Advancing Veterans' Health Research (FAVHR) and governed by Veterans Health Administration (VHA) Handbook 1200.05, 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 South Texas Veterans Health Care System (STVHCS) and the University of Texas Health at San Antonio (UT Health), and the UT Health 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 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 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.
- (5) Foundation for Advancing Veterans' Health Research (FAVHR): The FAVHR will administer all funds provided by the collaborator in support of the research study and will verify the budgets and expenses are appropriate for the approved research.

b. Procedures:

- (1) STVHCS Human Research Protection Program (HRPP) and all research policies at STVHCS will apply to sponsored research, and there will be a written agreement with the sponsor fully

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addressing human research protections, and requiring adherence to VHA Handbook 1200.05 and all other applicable policies, regulations, and laws, prior to the initiation of research involving human participants within STVHCS.

- (2) When the agreement is between the sponsor, the FAVHR, and STVHCS, the VHA template for Clinical Trials CRADAs will be followed, which includes explicit language regarding the protection of human participants.

4. REFERENCES:

VHA Handbook 1200.05, *Requirements for the Protection of Human Subjects in Research*, <https://www.research.va.gov/pride/120005.cfm>

Cooperative Studies Program (CSP)
<https://www.research.va.gov/programs/csp/default.cfm>

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

6. RECISSIONS: Research Service Policy Memorandum 12-45, November 14, 2012.

7. RECERTIFICATION: April 2023


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