

## **SPONSORED RESEARCH**

### **1. POLICY**

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to applying its HPRR to all sponsored research. Research conducted at the TVAMC in collaboration with a commercial company or sponsor is to be governed by VHA Handbook 1200.5, the model for Clinical Trials Cooperative Research and Development Agreements (CT-CRADAs) and a study related protocol provided by the sponsor.

It is the policy of the TVAMC HRPP to ensure that the applicable Federal, state, and local regulations are carried out in protecting the rights and welfare of subjects who voluntarily participate in investigational studies within this Medical Center, including when the research is sponsored by a commercial company. This Standard Operating Procedures (SOP) is a written documentation of the plan for the TVAMC to apply its HRPP to all sponsored research. This policy establishes procedures that ensure sponsored-research at the TVAMC is conducted in accordance with the requirements of the TVAMC HRPP,

### **2. RESPONSIBILITIES**

**TVAMC Medical Center Director:** The Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the TVAMC, including sponsored research agreements and activities.

**Coordinator for Research and Development (C/R&D):** The C/R&D maintains responsibility for procedures, policies, and execution of the research program (including sponsored research) conducted at the TVAMC.

**Executive Director of Tuscaloosa Research and Education Advancement Corporation (TREAC):** The executive director of TREAC is responsible for ensuring sponsor awareness of necessary provisions and ensuring the inclusion of required elements in the contract.

**Research and Development (R&D) Committee and Institutional Review Board (IRB):** The R&D Committee and IRB reviews and approves, approves with stipulations, or disapproves all research conducted at the TVAMC, (including sponsored research).

**Principal Investigators (PI):** The PI must abide by written agreements with the sponsor to conduct the research in accordance with the written protocol, applicable law, and the TVAMC ethical standards and provide prompt reporting of adverse events or safety issues.

### 3. DEFINITIONS

- a. **Sponsor** means the company, institution, individual donor, or organization responsible for the initiation, management or financing of a research study.
- b. **Sponsored research** means research funded by external entities through a grant or contract that involves a specified statement of work (e.g., the research proposal) with a related transfer of value to the sponsor, including clinical trials involving investigational drugs.
- c. **Tuscaloosa Research and Education Advancement Corporation (TREAC)** is a non-profit flexible funding mechanism established pursuant to 38 U.S.C. sect 7361, et seq., and as such facilitates approved VAMC research. The Corporation shall facilitate the conduct of the studies which have been approved by the TVAMC R&D Committee and IRB and shall use all reasonable efforts to ensure performance of the CRADA agreements.
- d. **Clinical Trial Cooperative Research and Development Agreement (CRADA) or Clinical Trial Agreements (CTA)** are written agreements that are signed by the TVAMC Director, the sponsor, the TREAC Executive Director, and the PI that include agreements that the TVAMC will conduct the research in accordance with the written protocol, applicable laws and the TVAMC ethical standards. The agreements also address staffing, financial and material obligations, inventions and intellectual property, licensing, ownership and rights of access to data and publication, confidentiality, representations and warranties, expiration and termination, disputes, liability and arrangements for medical care for research participants with a research-related injury, and prompt reporting of findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.

### 4. PROCEDURES

- a. All HRPP policies at the TVAMC apply to sponsored research. Specifically, there is a case-by-case assurance that either CT-CRADAs or Clinical Trial Agreements (CTAs) fully address human research protections before research with human participants can proceed within the TVAMC.
- b. Written agreements (i.e. CRADA) are maintained with sponsors that require adherence to VHA Handbook 1200.5 for human participants and all other applicable policies, regulations, and laws. In agreements with sponsors, the VHA guidelines for Clinical Trials CRADAs are followed, including the explicit language regarding the protection of human participants.
- c. The CRADA provides written agreement with sponsors that address the issue of medical care for research participants who may sustain a research-related injury.

- d. The CRADA provides written agreement with sponsors that specify that there will be prompt reporting to the TVAMC IRB 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.
- e. Before initiating research, the TVAMC HRPP requires agreement in the CRADA from the sponsor regarding the dissemination of findings from research and the roles that investigators and sponsors play in publication or disclosure of results.
- f. When participant safety or medical care could be directly affected by study results, the written CRADA addresses how results will be communicated to study participants.
- g. The CRADA provides written assurances from the sponsor that the manufacture and formulation of investigational or unlicensed test articles conform to federal regulations, i.e. the FDA's current Good Manufacturing Practice set out in 21 C.F.R. §§ 210-211 and ICH QA7, and meets the specifications cited in Investigator's Brochure, as defined in 21 C.F.R. § 312.23(a)(5) (CRADA Section 9.2.4).
- h. If the sponsor refuses any of these positions, the agreement must be reviewed by general counsel and receive approval from the Medical Center Director.

## 5. **REFERENCES**

- VHA Handbook 1200.5, *Requirement for the Protection of Human Subjects in Research*
- Cooperative Trials Agreement  
[http://www.research.va.gov/programs/tech\\_transfer/crada/default.cfm](http://www.research.va.gov/programs/tech_transfer/crada/default.cfm)
- Clinical Trials Cooperative Research and Development Agreement  
[http://www.research.va.gov/programs/tech\\_transfer/crada/default.cfm](http://www.research.va.gov/programs/tech_transfer/crada/default.cfm)

## 6. **ATTACHMENTS**

- Clinical Trials Cooperative Research and Development Agreement (CRADA)

## 7. **RESCISSIONS**

IRB Standard Operating Procedures dated July 1, 2004.

## 8. **REVIEW DATE**

January 1, 2012

Signature on File in R&D Office

Lori L. Davis, MD

Coordinator of Research and Development