SPONSORED RESEARCH

1. POLICY

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to applying its HRPP to all sponsored research. Research conducted at the BVAMC in collaboration with a commercial company or sponsor is to be governed by VHA Handbook 1200.05, and VHA Handbook 1200.17 Nonprofit Corporations. Additionally, all sponsored research must utilize the model contract for clinical trials entitled, Cooperative Research and Development Agreements (CRADAs) and a study related protocol provided by the sponsor.

It is the policy of the BVAMC 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 BVAMC to apply its HRPP to all sponsored research. This policy establishes procedures that ensure sponsored-research at the BVAMC is conducted in accordance with the requirements of the BVAMC HRPP.

2. RESPONSIBILITIES

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

**Associate Chief of Staff, Research and Development (ACOS/R&D):** The ACOS/R&D maintains responsibility for procedures, policies, and execution of the research program (including sponsored research) conducted at the BVAMC.

**Executive Director of VISTAR:** The executive director of VISTAR is responsible for ensuring sponsor awareness of necessary provisions and policies to ensure the inclusion of required elements in each CRADA signed and with all regulatory requirements involving the Nonprofit Corporation and its operations.

**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 BVAMC, (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 BVAMC ethical standards and provide prompt reporting of adverse events or safety issues.

3. **DEFINITIONS**

See HRPP SOP #24 – **HRPP Definitions**

4. **PROCEDURES**

a. All HRPP policies at the BVAMC 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 BVAMC.

b. Written agreements (i.e. CRADA) are maintained with sponsors that require adherence to VHA Handbook 1200.05 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 BVAMC 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 BVAMC 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 1200.05, Requirement for the Protection of Human Subjects in Research
- Cooperative Trials Agreement
  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
- VHA Handbook 1200.17 Department Of Veterans Affairs Nonprofit Research And Education Corporations Authorized By Title 38 United States Code (U.S.C.) Sections 7361 Through 7366

6. ATTACHMENTS

Clinical Trials Cooperative Research and Development Agreement (CRADA)

7. RESCISSIONS


8. REVIEW DATE

February 1, 2021

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ACOS, Research and Development