



**Department of Veterans Affairs  
Jesse Brown VA Medical Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

R&D 537/151  
April 20, 2009  
Version 1.2  
Revised July 13, 2011

## **SOP:SPONSORED RESEARCH**

### **PURPOSE**

To clarify policies and procedures for conducting a clinical research trial sponsored by a commercial company (Sponsor) who owns an investigational new drug or device, designs the protocol, and/or funds the project.

### **POLICY**

Research conducted in collaboration with a commercial company will be subject to Veterans Health Administration (VHA) policies, especially VHA Handbook 1200.05; the procedures related to Clinical Trial Cooperative Research and Development Agreements (CT-CRADAs); Jesse Brown VAMC (JBVAMC) policies and guidelines for conducting research; VHA Handbook 1200.2; and the IRB MOU entered into with the University of Illinois at Chicago (UIC),. Sponsored Research utilizing VA resources and/or involving Intellectual Property may not be undertaken without prior review and approval of the responsible committees and officials.

### **RESPONSIBILITIES**

- a. The Hospital Director is the responsible Institutional Official who has overall responsibility for all research at JBVAMC, including sponsored research.
- b. The Associate Chief of Staff for Research and Development (ACOS) is responsible for the management of the research program.
- c. Research and Development (R&D) Committee is responsible, through the Chief of Staff (COS) to the medical center Director, with the assistance of the ACOS, for the oversight of the research program. The R&D committee will review all research conducted at JBVAMC to ensure the scientific and ethical quality of VA research projects, the protection of human subjects in research, the safety of personnel

engaged in research, the welfare of laboratory animals, security of VA data, and the security of VHA research laboratories.

d. The Human Subject Research Coordinators (HSRC) are responsible for reviewing compliance with the Human Research Protection Program (HRPP). HSRC will conduct quality assurance audits and notify the ACOS and R&D Committee of any signs of non-compliance that appear to pose a risk to human participants.

e. Regional Counsel is responsible for reviewing and approving sponsored research agreements as well as any related legal documents such as the Conflict of Interest survey.

## **PROCEDURES**

a. The Human Research Protection Program and JBVAMC's research policies will apply to sponsored research. There will be a case-by-case review of the agreement to determine if it addresses protections of human research subjects, can proceed within JBVAMC or its satellite clinics, and can utilize VA resources.

b. Procedures outlined in the Clinical Trial Cooperative Research and Development Agreements (CT-CRADAs) will be used for agreements with Sponsors, including those involving the University affiliates.

c. Agreements shall address, but is not limited to, the following: protections of human research subjects; medical care for research participants who sustain a research related injury; and prompt reporting to JBVAMC and IRB committee 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 level.

## **REFERENCES**

a. VHA Handbook 1200.05, Requirement for the Protection of Human Subjects in Research, Department of Veterans Affairs, Veterans Health Administration, Washington, DC.

b. [Cooperative Trials Agreements and Clinical Trials Cooperative Research and Development Agreement \(Attached\)](#)

c. VHA Handbook 1200.2, Research Business Operations, Department of Veterans Affairs, Veterans Health Administration, Washington, D.C.

d. [Conflict of Interest Survey \(Attached\)](#)

**REVISION LOG:**

<b>Version (#, date)</b>	<b>Replaces (#, date)</b>	<b>Summary of changes</b>
1, 4/20/09		
1.1, 04/25/11	1, 4/20/09	
1.2, 07/13/11	1.1, 04/25/11	Clarification of CRADA use