

DEPARTMENT OF VETERANS AFFAIRS
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, Missouri

HPM 589A4-364
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Issued by: Research

SPONSORED RESEARCH

1. **PURPOSE:** To clarify policy and procedures for conducting research that is sponsored by a commercial company when the sponsor desires commitment of ownership and licensing rights in advance of an invention being made.
2. **POLICY:** Research conducted in collaboration with a commercial company will be governed by Veterans Health Administration (VHA) Handbook 1200.05, VHA Directive 2007-044 "Use of a Cooperative Research and Development Agreement (CRADA)," and, in the case of human subject research, a Memorandum of Understanding (MOU) for Utilization of the Health Sciences Institutional Review Board (HS-IRB) between the Truman VA and the University of Missouri; a MOU between the Truman VA and the Central-IRB; or other MOUs established for research oversight.
3. **RESPONSIBILITY:**
 - a. Hospital Director: The Hospital Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the Truman VA, including sponsored research agreements and activities.
 - b. 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. The ACOS/R&D ensures:
 - (1) The use of a CRADA for all sponsored research conducted at the Truman VA when the sponsor desires commitment of ownership and licensing rights in advance of an invention being made.
 - (2) The Research and Development (R&D) Committee verifies the use of a CRADA appropriate for the research being proposed.
 - (3) The Research and Development Committee conducts an annual quality assurance review of active CRADAs.
 - (4) For dually appointed Principal Investigators that the specifications regarding intellectual property ownership and licensing in each CRADA are consistent with the applicable Cooperative Technology Administration Agreement (CTAA) with the academic affiliate.

c. Research and Development (R&D) Committee: The R&D Committee will review and approve all sponsored research conducted at the Truman VA, including assurance of human research protections when applicable, and the appropriate use of a CRADA.

d. Research Compliance Officer (RCO): The RCO will closely monitor all sponsored research, will conduct quality assurance audits, and will notify the Hospital Director of any noncompliance issues or regulatory deficiencies..

e. University of Missouri HS-IRB or other IRB of record: The HS-IRB or other IRB of record will review and approve all human subject sponsored research conducted at the Truman VA, including assurance of human research protections. The HS-IRB or other IRB of record will ensure that the Principal Investigators communicate promptly with the study sponsor when requested.

5. PROCEDURES:

a. The Human Research Protection Program (HRPP) and all research policies at the Truman VA will apply to sponsored research involving human subjects. All human subject research performed under a CRADA must be reviewed by the University of Missouri HS-IRB or other IRB of record.

b. The Executive Director of the Missouri Foundation for Medical Research will work with the Research Office to negotiate CRADAs. Clinical Trial CRADAs (CT-CRADAs) will be negotiated with the Principal Investigator, the sponsor, and regional counsel. If an agreement can be reached the CRADA will be forwarded to Technology Transfer in Washington, D.C. Basic science CRADAs are negotiated by the Principal Investigator, Technology Transfer, and the sponsor. A master CRADA (pre-negotiated CRADA) is used when one exists.

c. The Research and Development Committee must approve all research conducted under a CRADA before the research can commence at the Truman VA.

REFERENCES:

a. VHA Handbook 1200.05, Requirement for the Protection of Human Subjects in Research, dated October 15, 2010

b. VHA Directive 2007-044, Use of a Cooperative Research and Development Agreement, Veterans Health Administration, Washington, D.C.

c. Cooperative Trials Agreement
http://www.research.va.gov/programs/tech_transfer/crada/default.cfm

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

e. National Association of Veterans Research and Education Foundations
<http://www.navref.org>

6. **FOLLOW-UP RESPONSIBILITY:** ACOS/R&D.
7. **RECISSIONS:** HPM 589A4-364 dated March 9, 2010

APPROVED:

Sallie Houser-Hanfelder, FACHE

SALLIE HOUSER-HANFELDER, FACHE
Director

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