

Department of Veterans Affairs  
Harry S. Truman Memorial Veterans' Hospital  
800 Hospital Drive  
Columbia, Missouri

HPM 589A4-042  
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Issued by: Research

REVIEW OF RESEARCH PROPOSALS

1. **PURPOSE:** To describe the procedures and criteria for the scientific review of research proposals by the Research and Development (R&D) Committee and appropriate subcommittees.

2. **POLICY:** To stimulate a high-quality research program that is responsive to investigators and that maintains compliance with all applicable regulations.

3. **DEFINITIONS:**

a. **Human Research** is research involving human subjects as defined below or one or more identifiable human biological specimens.

b. **Human Subject** is defined by:

(1) Title 38 CFR Part 16 as a living individual about whom an investigator conducting research obtains either (a) data through intervention or interaction with the individual or (b) obtains identifiable private information.

(2) Per FDA regulations, as an individual who is or becomes a participant in a clinical investigation, either as the recipient of a test article or a control.

(3) Per FDA device regulations, as an individual on whom or whose specimen and investigational device is used or as a control.

c. **Research** is a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalized knowledge (38 CFR 16.102[d]).

d. **VA Research** is research that has been approved by the Research and Development Committee and conducted by VA investigators on VA time, utilizing VA resources, or on VA property regardless of funding source or status.

(1) Under FDA regulations, activities are considered "research" when they involve use of a drug, other than the use of an approved drug, in the course of medical practice; use of a medical device, other than the use of an approved medical device, in the course of medical practice; or involve gathering data that will be submitted to, or held for inspection, by the FDA in support of an FDA-marketing permit for a food, including a dietary supplement that bears a nutrient content claim or a health claim, an infant formula, a food or color additive, a drug for human use, a medical device for human use, a biological product for human use, or an electronic product.

(2) Systematic Investigation in human research includes, but is not limited to the following:

Surveys and questionnaires,  
Interviews and focus groups,  
Analyses of existing data or biological specimens,  
Epidemiological studies,  
Evaluations of social or educational programs,  
Cognitive and perceptual experiments,  
Medical chart review.

(3) Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(4) Interaction includes communication or interpersonal contact between the investigator and subject.

(5) FDA regulations define a subject as a participant in research either as the recipient of a test article or as a control [21 CFR 50.3(g), 21 CFR 312.3(b)]. If the research involves a medical device, individuals are considered "human subjects" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

(6) Activities are human subject research and subject to VA regulations when (a) they meet the definition of "human subjects research" and (b) meet any of the following criteria:

(a) Any research involving human subjects that is performed at a VA facility;

(b) Any research involving human subjects (in any location) that is conducted by a VA investigator if the investigator conducts research on VA time or uses VA resources;

(c) All studies that have Institutional Review Board (IRB) approval from other organizations, including approval from other government entities if the investigator conducts research on VA time or uses VA resources.

e. **Biomedical Research** refers to research that may not directly involve humans or animals, but may use tissues, cells, blood, or bone from both.

f. **Animal Research** refers to research that may use live vertebrate animals or tissues, cells, and/or blood samples from an animal within a research project.

g. **Principal Investigator (PI)** is a qualified person or persons designated by an applicant institution to direct a research project or program. The PI oversees scientific, technical, and day-to-day management of the research. The PI assumes primary responsibility for the conduct of the research.

h. **Co-Principal Investigators (Co-PI)** refers to two or more principal investigators who share equally in the accountability for a project.

i. **VA Protected Information** (VAPI) is VA sensitive information, Privacy Act information, Protected Health Information (PHI), or other VA information that has not been deliberately classified as public information for public distribution.

j. **VA Sensitive Information** is all Department data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and information that can be withheld under FOIA.

k. **Investigational device** as defined by the FDA is a device that is the object of an investigation.

l. **Investigational drug** is a chemical or biological drug that is used in a clinical investigation.

m. **Test article** is any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

n. **Investigational new drug** is an application to the FDA that allows an investigational drug or biological products to be studied in humans.

#### 4. **REQUESTS TO CONDUCT RESEARCH PROCEDURES:**

a. All human, biomedical, and animal research must be reviewed by the R&D Committee and all applicable subcommittees; all human research will be reviewed by the University of Missouri-Columbia Health Sciences Institutional Review Board (HS-IRB) or the VA Central IRB. In some cases, human research may prove to be exempt from applicable federal, state and local regulations. However, "exempt" status will be determined by the HS-IRB or VA Central IRB, not by the investigator.

b. The PI will be referred to the IRB of record for a determination of whether an activity is human subject research or is not human subject research.

c. Research team members who will access VA patients, data, research animals, or utilize VA resources and/or VA space for research purposes are required to have either a VA paid or Without Compensation (WOC) appointment. To obtain WOC applications, contact the Research Secretary at 573-814-6550.

d. Obtain and complete a "Request to Conduct Research" application, which can be obtained on the Research website located at <http://www.va.gov/columbia-mo>.

e. An "Authorization to Transport and Utilize VA Sensitive Information Outside Protected Environments" (Attachment 1) is required for research protocols that transport VA sensitive information outside protected environments unless a HIPAA authorization allows for transport of VA sensitive data outside the VA.

f. Submit two paper copies and an electronic version of the completed application to the Research Secretary in Room B044 by the posted deadlines. Prior to submission, the applicant will be responsible for providing documentation of all required training and for initiating all staff appointments required to conduct the study.

#### **5. R&D COMMITTEE AND SUBCOMMITTEE PROCEDURES FOR APPROVAL OF REQUESTS TO CONDUCT RESEARCH:**

a. Applicable subcommittees (e.g., HS-IRB, VA Central IRB, Subcommittee for Research Safety, Subcommittee Animal Studies, Institutional Biosafety Committee) will conduct reviews and make recommendations prior to the R&D Committee meeting. In the case of the IRB of record, the results of protocol reviews by the HS-IRB will be communicated to the VA Research Office, PI, and R&D Committee in writing. The VA Research Office will transmit HS-IRB actions or VA Central IRB actions to the R&D Committee for review.

b. Memoranda of Understanding (MOU) are maintained between the Truman VA and the University of Missouri for the use of the HS-IRB and between the Truman VA and the VA Central IRB for VA protocols designated for review by the VA Central IRB. Therefore, applicants proposing human research studies must submit a separate application to the HS-IRB or VA Central IRB. The policy of the Truman VA is to require strict adherence to all HS-IRB and VA Central IRB related policies. These policies are located on the HS-IRB website <https://irb.missouri.edu/> and with the VA Central IRB at <http://www.research.va.gov/programs/pride/cirb/default.cfm>.

c. An initial review of projects will be conducted by a convened meeting of the R&D Committee at which there is a quorum present.

(1) In conducting an initial review, the R&D Committee will evaluate scientific quality, the relevance to both the VA's mission and the facility's research program, adequacy of design, appropriateness from an ethical standpoint, the ability of the investigator to perform and complete the research, and compliance with applicable policies, regulations, and laws (both state and federal) as related to each research application. In addition, the review will include information on (a) the use, storage, and security of VA data and VA sensitive information including VA private information (VAPI), (b) budgetary information, (c) requirements for space, personnel, equipment, and supplies, (d) the role of the investigator at the facility, (e) the investigator's qualifications, and (f) other information deemed relevant by the R&D Committee.

(2) In conducting an initial review, the R&D Committee will consider the findings by other applicable committees such as the Subcommittee for Animal Studies (SAS), the Subcommittee for Research Safety (SRS), the Radiation Safety Committee, the Biosafety

Committee, and the IRB of record. The initial approval of research requires a majority vote of the convened quorum.

(3) The initial review of research projects that involves the use of veterans' data or another person's data (identified or de-identified) must include an assessment of the mechanisms in place to ensure:

- (a) Security of data and all files in accordance with VHA Directive 6500;
- (b) Confidentiality of data, including data derived from research subjects;
- (c) Release of data in accordance with VHA regulations and policies; and
- (d) Control of the data so that reuse of the data is within an approved research protocol and in compliance with VHA procedures.

d. The VA Offices of Regional or General Counsel will be consulted if a legal opinion regarding either state or federal laws is needed in relation to the VA research program. When requested by either the R&D Committee, the HS-IRB, or the VA Central IRB the Associate Chief of Staff for Research and Development (ACOS/R&D) will request legal assistance from the Medical Center Director, who will transmit the request to the appropriate VA counsel. Final approval of research applications will not occur until policy, regulatory, and/or legal issues are fully resolved.

e. The R&D Committee will carefully monitor research applications that involve Investigational New Drug Applications (INDs) or Investigational Device Exemptions (IDEs) in order to ensure that the Principal Investigator (if assuming the sponsor function) and/or other sponsoring organizations provide sufficient information (and give attestation) to assure knowledge of the regulatory requirements that govern sponsored research using INDs or IDEs. Information regarding INDs and IDEs will be obtained in the course of the HS-IRB or VA Central IRB application (which is a component of the Application to R&D Committee) and provides additional information to judge the adequacy of the knowledge of the sponsor regarding policies and regulations. At the discretion of the R&D Committee, additional information regarding sponsor knowledge of applicable regulations and policies of the Food and Drug Administration (FDA) will be solicited prior to protocol approval. In addition, if the investigator plans to serve as the sponsor, the R&D Committee will require the investigator to utilize one or more outside auditors (approved by the R&D Committee) to evaluate whether policies and procedures are in place to fully comply with FDA sponsor requirements.

f. Special precautions are required in the review of research applications in situations where state and federal laws may be in conflict. The VA Offices of Regional or General Counsel will consider potentially conflicting issues and offer a legal opinion. In general, federal law is followed unless state law is more restrictive. Other general guidelines are that the VA definition of legally authorized representative is accepted; guardianship issues are determined by state law; procedures for protection of children are determined by state

law; privacy matters are determined by VA policy; and state laws are followed where federal laws and regulations do not exist, such as in the case of genetic testing, genetic information, or reporting of child, elder, or spousal abuse.

g. The R&D Committee may approve, approve with modifications, disapprove, or table an application. The final approval of the R&D Committee will occur after all applicable subcommittees have granted final approval.

h. Once approved by the R&D Committee, the research becomes VA-approved research. Note: Research may be initiated only after R&D Committee approval has been obtained.

i. If a subcommittee of the R&D Committee disapproves a research project or program the R&D Committee may not approve it.

6. **DOCUMENTATION:** Complete documentation of the application process, communication with the investigators, and R&D Committee actions (including subcommittees) will be maintained in the Research Office.

a. All applicants will receive notification of R&D Committee actions in writing prior to initiating research.

b. The HS-IRB and VA Central IRB will receive, in writing, R&D Committee decisions regarding all human research projects.

c. The Animal Care Quality Assurance/Animal Care and Use Committee (ACUC) will receive a copy of R&D Committee decisions regarding all animal research projects.

d. Applicants will annually update a progress report and will be responsible for obtaining subcommittee approval for all necessary project amendments, adverse events, serious adverse events, unanticipated problems, or personnel changes.

e. The ACOS/R&D will report the actions of the R&D Committee to the Principal Investigator, IRB of record, Chief of Staff, and the Medical Center Director. The R&D meeting minutes will be signed by the Chief of Staff and Medical Center Director.

## 7. **INDEPENDENCE OF REVIEW PROCESS:**

a. In the context of compliance with policies, regulations, and laws, independence of the R&D Committee will be maintained without inappropriate outside influence, with the exception that the R&D Committee may not approve research activities that have been disapproved by other independent committees such as the HS-IRB, VA Central IRB, the Subcommittee for Animal Studies, the Subcommittee for Research Safety, or the Radiation Safety Committee.

b. Likewise, the independence of the IRB of record will be maintained, and decisions made by the IRB of record will serve as the final disposition for the human research components of VA research applications. No other institutional representative, committee,

or governing body will have the authority to approve any research activities that have been Disapproved by the IRB of record.

c. Any attempt to exert outside influence on the decision-making authority of research review committees will be promptly reported to the RCO, ACOS/R&D, R&D Chair, HS-IRB Chair, VA Central IRB, COS and/or the Hospital Director.

**8. REFERENCES:**

- a. VHA Handbook 1200.01 dated June 16, 2009
- b. VHA Handbook 1200.05 dated October 15, 2010
- c. VHA Directive 6500 dated August 4, 2006
- d. 21 CFR 50.3(g)
- e. 21 CRF 56.103(3)
- f. 21 CRF 813.3(p)

g. Harry S. Truman Memorial Veterans' Hospital Research and Development Committee Standard Operating Procedures

**9. FOLLOW UP RESPONSIBILITY:** ACOS/R&D

**10. RESCISSION:** HPM 589A4-042, dated June 22, 2009

APPROVED:



SALLIE HOUSER-HANFELDER, FACHE  
Director

Date: March 28, 2011

Key Words: Research  
FDA  
DHHS  
HRPP

Attachment 1

## Department of Veterans Affairs

# Memorandum

**Date:**

**From:** <Requestor's Title>

**Subj:** Authorization to Transport and Utilize VA Sensitive Information Outside Protected Environments

**To:** Field Information Security Officer

**Thru:** <Requestor's Service/Department Chief>

1. In order to accomplish my duties, I require the capability to store, transport, and utilize Department of Veterans Affairs (VA) sensitive information outside protected environments, as defined by VA Handbook 6500. VA information refers to all information, either electronic or paper-based. My personal information follows:

<Requestor's Full Name>  
<Title>  
<Home Address>  
<City, State, Zip>  
<Home Phone number>

2. Justification for the removal of VA sensitive information outside of protected environments (include where and how information will be used):

3. The sensitive information, as defined in VA Handbook 6500, I intend to store, transport, and utilize includes (check all that apply):

- Individually identifiable medical, benefits or personnel information
- Information that can be withheld under the Freedom of Information Act
- Financial information
- Research information
- Investigatory information
- Commercial information
- Quality assurance information

- Law enforcement information
- Information that is confidential or privileged in litigation
- Information that could adversely affect the national interest or conduct of federal programs

4. The timeframe I will store, transport, and utilize VA sensitive information outside protected environments is:

- 30 days
- 180 days
- One Year

5. I acknowledge that the above statements are accurate and are in compliance with VA Handbook 6500, "Removable Storage Media and Restrictions on Transmission, Transportation and Use of, and Access to, VA Information Outside Protected Environments".

6. I acknowledge this document requires renewal upon expiration of the approval timeframe requested above.

<requestor signature>

### Required Concurrence and Approval

CONCUR/DO NOT CONCUR

CONCUR/DO NOT CONCUR

\_\_\_\_\_  
Information Security Officer      Date

\_\_\_\_\_  
Chief Information Officer      Date

CONCUR/DO NOT CONCUR

APPROVED/DISAPPROVED

\_\_\_\_\_  
Chief of Staff      Date

\_\_\_\_\_  
Director      Date