

Department of Veterans Affairs
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, MO 65201

HPM 589A4-391
December 11, 2007
Issued by: Research

REVIEW OF RESEARCH PROPOSALS FOR COMPLIANCE WITH PRIVACY AND INFORMATION
SECURITY REQUIREMENTS

1. **PURPOSE:** To describe the policy and procedures for review of research proposals at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH) by the Information Security Officer (ISO) and Privacy Officer (PO).
2. **POLICY:** This component of the HSTMVH Research Program is designed to ensure that all privacy and information security requirements have been met in order to use or disclose protected health information.
3. **DEFINITIONS:**
 - a. Department of Veterans Affairs (VA) research is any research that has been approved (or requires approval) by the HSTMVH Research and Development (R&D) Committee. Generally, this includes research that is conducted utilizing VA resources including funds, staff, equipment, and/or space.
 - b. Research data consists of information that has been collected for, used in or derived from the conduct of VA research.
 - c. Sensitive information is defined as all 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.

This term includes information whose improper use or disclosure could adversely affect the ability of the agency to accomplish its mission, proprietary information, or records about individuals requiring protection under various confidentiality provisions such as the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. It also includes information that can be withheld under the Freedom of Information Act (FOIA).

- d. Sensitive VA research information consists of information that has been collected for, used in, or derived from the conduct of VA research that fits the definition of VA sensitive information.
- e. Individually-identifiable Information consists of any information, including health information maintained by the Veterans Health Administration (VHA), pertaining to an individual that identifies the individual and, is retrieved by the individual's name or other unique identifier.
- f. De-identified Health Information is health information that does not identify an individual and to which there is no reasonable basis to believe that the information can be used to identify an individual.

g. 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.

4. **RESPONSIBILITIES:** It is the expectation that everyone involved with research at the HSTMVH will ensure the security and confidentiality of any sensitive research information collected, used, transmitted, transported, or stored as part of that research. It is also expected that the appropriate safeguards will be put into place to protect the privacy of research subjects. The specific responsibilities are described below:

a. Hospital Director:

(1) Ensure the security and confidentiality of sensitive VA research data at the HSTMVH.

(2) Certify to the Veterans Integrated Services Network (VISN) 15 Director, on an annual basis, that all principal investigators have met the certification requirements related to storage and security of sensitive VA research data.

(3) Review and approve/disapprove any requests to take sensitive VA research data outside of the HSTMVH.

b. Associate Chief of Staff for Research and Development (ACOS/R&D):

(1) Notify principal investigators on an annual basis of the need to complete the Investigator's Checklist and Certification.

(2) Annually, compile Investigator's Certification and submit a written certification of compliance to the Hospital Director.

c. Principal Investigators:

(1) Complete and submit an HSTMVH "Application to Conduct Research" packet including a "Data Security Checklist for Principal Investigators" (Attachment 1) and "Principal Investigator's Certification: Storage and Security of VA Research Information" (Attachment 2).

(2) If the research includes the storage, transfer, or transmission of VA research data (whether that data is sensitive or not), completion and submission of an HSTMVH "Request for Approval of Off-site Storage/Transfer of VA Research Data" (Attachment 3).

(3) In the case of human subjects research, obtain written approval from the University of Missouri-Columbia's Health Sciences Institutional Review Board (HS-IRB) prior to submission of an HSTMVH research application.

d. Privacy Officer (PO):

(1) Ensure that HSTMVH investigators are compliant with privacy policies and requirements.

(2) Conduct an independent review of all VA research protocols for compliance with privacy requirements. This review will be conducted in a timely manner after HS-IRB

approval has been obtained, but before the project is reviewed by the R&D Committee and before the PI initiates the project.

(3) Serve as an Ex-officio member of the HSTMVH R&D Committee. When appropriate, the Privacy Officer will discuss privacy issues or concerns as part of the R&D Committee's review of the protocol.

(4) Provide approval of the research protocol when all VA privacy criteria have been met.

e. Information Security Officer (ISO):

(1) Review and approve/disapprove any requests to take sensitive VA research data outside of the HSTMVH.

(2) Review and, when appropriate, approve PIs' requests for storing VA research data outside the HSTMVH (Note: approval must also be obtained from the Chief Information Officer, Chief of Staff, and the Hospital Director).

(3) Review all policies and procedures pertaining to transportation, transmission, remote access, and use of VA Information Technology (IT) equipment.

(4) When appropriate, conduct physical inspections of non-VA systems used to store VA research information.

(5) Serve as an Ex-officio member of the HSTMVH R&D Committee. When appropriate, the Information Security Officer will discuss information security issues or concerns as part of the R&D Committee's review of the protocol.

(6) Provide approval of the research protocol when all VA Information Security criteria have been met.

4. PROCEDURES:

a. Principal Investigators must complete and submit the Application to Conduct Research to the Research Office. In the case of human subjects research, the HS-IRB approval letter must be submitted as part of the protocol.

b. The following reviews will be conducted in accordance with the Research Review Routing Form (Attachment 4): Research Secretary, Administrative Officer (AO) for Research, Human Research Compliance Officer (HRCO), Radiation Safety Officer (RSO), ISO, PO, and the ACOS/R&D.

c. Individuals involved in human subjects research will receive appropriate training in the ethical principals and good clinical practices for human subjects research on an annual basis.

5. RESCISSION: None.

6. REFERENCES:

a. VA Directive 6502, Privacy Program

- b. VA Directive 6504, Information Security Program
- c. VHA Handbook 1605.1, Privacy and Release of Information
- d. VA Handbook 6500, Information Security
- e. Memorandum from Deputy Under Secretary of Operations and Management (10N), Appointment of Facility Information Security Officers and Privacy Officers to Institutional Review Board (IRB), dated September 7, 2007

APPROVED:

SALLIE HOUSER-HANFELDER, FACHE
Director

Key Words:

Off-site
Research
Sensitive
Waiver

Data Security Checklist for Principal Investigators

Date:

Name of Protocol:

Name of PI:

PI's Phone Number and e-mail address:

Name of Privacy Officer (PO): Paul Young

PO's Phone & e-mail address: (573) 814-6446, Paul.Young@va.gov

Name of ISO: Chrys Higginbotham

ISO's Phone Number and e-mail address: (573) 814-6319,

Chrysann.Higginbotham@va.gov

Instructions: If you answer NO to any one of the statements, you may not remove or transmit the data outside the VA and you must consult with your supervisor, ISO and Privacy Officer. If the research will not obtain any VA sensitive information/data the statements below should be marked as not applicable (N/A).

Yes	No	N/A	Specific Requirement
			All VA sensitive research information is used and stored within the VA
			All copies of VA sensitive research information are used and remain within the VA

If you have answered yes or N/A to both statements above, stop here.

If the original or copies of VA research information are removed from the VA the following apply: See Appendix A for definition of terms used in this document.

Yes	No	N/A	Specific Requirements
			Permission to remove the data has been obtained from 1) your immediate supervisor, 2) your ACOS/R&D, 3) the VA Information Security Officer (ISO), and 4) the VA Privacy Officer.
			A property pass for the equipment (Laptop etc.) has been obtained.
			The laptop or other portable media is encrypted and password protected. Note: Contact the VA ISO at your facility for encryption issues.
			Data are not transmitted as an attachment to unprotected e-mail messages.
			Names, addresses, and Social Security Numbers (real and scrambled) have been replaced with a code. Note: Names, addresses, and Social Security Numbers (real or scrambled) may only be maintained on a VA server and documentation of the procedure by which the data were coded must remain within the VA
			Data sent via mail or delivery service have been encrypted. Note: It is preferable to send data on CDs or other media by a delivery service where there is a "chain of custody".
			For data that will reside on a non-VA server: The server has been certified and accredited as required by Federal Information and Security Management Act of 2002 (FISMA). Note: your facilities ISO should be consulted.
			Access to the data is only by those who are authorized to access it and the access is related to VA-approved research.
			Procedures for reporting theft or loss of sensitive data or the media such as a laptop, containing sensitive data are in place and familiar to the researcher and all others who have access to, use, store, or transport the data.

Principal Investigator's Certification: Storage & Security of VA Research Information

Instructions:

- 1. This certification must be completed by all Principal Investigators (PI) and submitted to their facility's ACOS/R&D no later than April 15, 2007. It must also be completed and submitted to the ACOS/R&D by April 15th annually there after. If you are PI on more than one research protocol, you may a) complete a form for each protocol, b) list additional protocols and date of R&D approval on the bottom of this form, or c) attach a separate list.*
- 2. This form must be completed for each new protocol and a copy of this form must remain with the research protocol file.*
- 3. This form must be submitted to ORD during the Just-In-Time process if you will be funded by ORD for a research project.*

I certify to the best of my knowledge that all VA sensitive information associated with the research study entitled _____ and approved by the Research and Development Committee on _____ is being used, stored and security in accordance with the applicable VA and VHA policies and guidance.

Name: _____

Signature: _____

Title: _____

Date: _____

Phone: _____

E-mail: _____

Signature: _____

Title: HSTMVH Information Security Officer

Signature: _____

Title: HSTMVH Privacy Officer

Attachment 3
HPM 589A4-391
December 4, 2007

Department of Veterans Affairs

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>

RESEARCH APPLICATION REVIEW ROUTING FORM

Principal Investigator Name: _____
Project title: _____

SECRETARY

Date received/stamped: _____

Entered in research log book Yes No

Routing slip attached Yes No

File created (1st copy) Yes No

Completed staff training Yes No

Completed staff appts. Yes No

Is VetPRO credentialing required for any staff? Yes No

Initiate office routing Yes No

Filed in Pending: Yes No

Entered in HR Database: Yes No N/A

AO REVIEW

IP Agreement in Place? Yes No N/A

Commercial Sponsor? Yes No

If Sponsored, Copy of Agreement? Yes No

If Sponsored, HRPP Clause? Yes No

If Sponsored, Injury Clause? Yes No

If Sponsored, Safety Clause? Yes No

If Sponsored, Dissemination Clause? Yes No

If Sponsored, Results Clause? Yes No

Fee (\$1200) Apply? Yes No

CT Registration Needed? Yes No

Research Billing Needed? Yes No

Confidential Data or PHI? Yes No

If confidential data, adequate plan? Yes No

Appropriate VA PI/Co-PI? Yes No

Sign-off by SLD? Yes No

SRS Review Needed? Yes No

SRS Materials Complete? Yes No

SAS Review Needed? Yes No

SAS Materials Complete? Yes No

Refer to HRCO?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Financial Analysis Prepared?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Date: _____

Projected R&D Committee Date? _____

<i>HRCO REVIEW</i>		<input type="checkbox"/> NOT APPLICABLE
IRB #:		
IRB Status:		
IRB Approval Letter	<input type="checkbox"/> Yes	<input type="checkbox"/> No
IRB Applications & Signature Page:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
IRB Approved Consent:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
IRB Approved HIPAA Authorization:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
IRB Notified - Approval Needed for R&D Review:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Non-Veterans recruited?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Director Notified?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Nursing Review Needed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Pharmacy Review Needed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10-1086 Consent	<input type="checkbox"/> Yes	<input type="checkbox"/> No
HIPAA Authorization	<input type="checkbox"/> Yes	<input type="checkbox"/> No
10-9012 Investigational Drug	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Investigator-held IND?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
FDA Auditing Required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
CPRS Flagging Note Required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sent to Donna Kraus?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:		

<i>RADIATION SAFETY OFFICER REVIEW</i>	
Does protocol require review by Radiation Safety Committee?	<input type="checkbox"/> Yes <input type="checkbox"/> No

<i>PRIVACY OFFICER REVIEW</i>	
Does all VA sensitive information reside within the VA?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the Data Security Plan adequate?	<input type="checkbox"/> Yes <input type="checkbox"/> No

INFORMATION SECURITY OFFICER REVIEW

Does all VA sensitive information reside within the VA?

 Yes No

Is the Data Security Plan adequate?

 Yes No**ACOS/R&D REVIEW**

Protocol scientifically adequate/sound?

 Yes No

COI for all members of the research team?

 Yes No N/A

Any ethical concerns? If yes, describe.

 Yes No**PROGRAM ASSISTANT REVIEW**

Entered into Agenda section of PROMISE?

 Yes No

Subcommittee review:

SRS Yes N/ASAS Yes N/ARSC Yes N/ANursing Yes N/APharmacy Yes N/A

Routing date:

Protocol status:

 Pending Ongoing

Assigned R&D reviewers:

(1) _____

(2) _____

Additional notes: _____

SUBCOMMITTEE FOR RESEARCH SAFETY (SRS) REVIEW NOT APPLICABLE

(All research [except chart reviews] must be reviewed by this subcommittee)

Protocol review date: _____

Status:

 Approve Disapprove Tabled (documentation or revisions required)

Approval memorandum date: _____

Minutes reflect decision:

 Yes No**SUBCOMMITTEE FOR ANIMAL STUDIES (SAS) REVIEW** NOT APPLICABLE

ACORP review date: _____

Status:

 Approve Disapprove Tabled (documentation or revisions required)

Approval memorandum date: _____

Minutes reflect decision:

 Yes No

RADIATION SAFETY COMMITTEE (RSC) REVIEW NOT APPLICABLE

Protocol review date: _____

Status: Approve
 Disapprove
 Tabled (documentation or revisions required)

Approval memorandum date: _____

Minutes reflect decision: Yes No**PHARMACY REVIEW** NOT APPLICABLE

Protocol Sent on (date): _____

Status: Approve
 Disapprove
 Tabled (documentation or revisions required)

Approval memorandum received (date): _____

Form 10-9012 sent: Yes No N/AForm 10-1223 sent: Yes No N/AIRB Approval letter provided: Yes No N/A**NURSING REVIEW** NOT APPLICABLE

Protocol Sent on (date): _____

Status: Approve
 Disapprove
 Tabled (documentation or revisions required)

Approval memorandum received (date): _____

FINAL ADMINISTRATIVE CHECK (PROGRAM ASSISTANT)All Staff Appointments Completed Yes NoAll Required Training Completed Yes NoFinancial Analysis Completed Yes NoISO Approval Completed
(Must have approval prior to R&D letter to PI) Yes NoPO Approval Completed
(Must have approval prior to R&D letter to PI) Yes NoAll Preliminary Issues Addressed Yes NoCT Registration Confirmed Yes No N/A**RESEARCH AND DEVELOPMENT (R&D) COMMITTEE REVIEW**Protocol review results returned for distribution: Yes No

Reviewers reviewed protocol and submitted results:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
R&D Committee results:	<input type="checkbox"/> Approve	
	<input type="checkbox"/> Disapprove	
	<input type="checkbox"/> Tabled (documentation or revisions required)	
R&D Approval Date:	_____	
Approval Letter Sent to PI:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Approval Copy Sent to IRB:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Approval Copy Sent to Pharmacy:	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
Minutes reflect decision:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Initialized in PROMISE?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Date initialized:	_____	

<i>Final Document Review (Program Assistant) (Within 7 days of R&D)</i>			
Permanent Folder Constructed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Original Signature (All Documents)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
VA10-9012 Pharmacy In File (Original to Inv. Pharmacist)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
VA Consent 10-1086 in File (IRB Stamped)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
VA Consent 10-1086 Sent to Inv. Pharmacist (If Applicable)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
VA HIPAA Authorization in File (IRB Stamped)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
CPRS Flagging Note in File (For Human Protocols)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
VA Form 10-1223	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
ACORP Cover Page in File (For Animal Protocols)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Safety Form in File	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Radiation Safety Approval in File	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Pharmacy Approval Memorandum in File	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Nursing Approval Memorandum in File	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Copy of Approval Letter in File	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

<i>QA Review for Human Studies (HRCO) (Within 14 day of R&D)</i>		<input type="checkbox"/> NOT APPLICABLE
Human Research Protocol Reviewed & Filed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Back-up Copy Recycled?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
HRCO Signature	_____	
Date	_____	

QA Review for Animal Studies (AO) (Within 14 day of R&D)		<input type="checkbox"/> NOT APPLICABLE
Animal Research Protocol Reviewed & Filed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Back-up Copy Recycled?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
AO Signature _____	Date _____	