

May 24, 2011

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Access to VA Research Data
Within Health Service Research at the
Veterans Evidence-Based Research
Dissemination Implementation Center (VERDICT)

1. PURPOSE: To establish procedures for research staff to access VA data that has been collected for Research & Development (R&D) Committee and Institutional Review Board (IRB)-approved research studies, data for Department of Veterans Affairs (VA) implementation projects in which Veterans Evidence-Based Research Dissemination Implementation Center (VERDICT) is involved, and data preparatory to research.

2. POLICY: It is the policy of VERDICT to comply with all applicable laws and all VA directives and policies relevant to patient data.

3. ACTION:

a. When a R&D Committee and IRB-approved research study begins and it will be using VA patient data or VERDICT agrees to be involved in a VA implementation project requiring collection of VA data or VA data is collected preparatory to research (such as for a grant proposal), a folder will be created on a research server (a server connected to the VA Intranet; [\\VHASTXRES2](#), [\\VHASTXRES3](#), [\\VHASTXSAS](#), [\\VHASTXVERD1](#), [\\VHASTXVERD2](#), and [\\VHASTXMUL4](#)) where protected health information (PHI) and other VA data will be kept.

b. The Principal Investigator (PI) will provide the VERDICT Data Manager with the names of all VA and without compensation (WOC) staff who are part of the project and will need access to the data. The PI certifies that all have current VA/VA WOC appointments, STVHCS credentialing and license, IRB human subject's protection and good clinical practice training (CITI). As per Research Service SOP entitled "Granting Research Privileges for Research Personnel Conducting Human Subjects Research" the Office of R&D is responsible for compliance to the training regimen.

c. Security for access to each folder will be set or directed by the VERDICT Data Manager for each person on the list provided by the PI through their VA Domain login access. In addition, the VERDICT Data Manager will have access to each folder.

d. The VERDICT Data Manager is responsible for quarterly audit of the list of access privileges. The current list will be reviewed with the PI to verify its accuracy. The folder access will be reviewed to verify that only those people currently approved for the study have access to the folder. Any discrepancies will be addressed by the PI, the Data Manager, and the System Administrator/Managers. When a staff person terminates their VA or WOC status, they will automatically lose access to all research folders because the VA Domain login access will be removed. However, the Data Manager will also change the access privileges associated with their name on the access list to reflect their discontinued access. If a staff person remains in a VA or WOC status but is no longer working on a particular research study, his/her access to the appropriate folder will be removed by the System Administrator/Managers and the changed status will be recorded in the access list by the Data Manager. When a new VA or WOC staff person joins a research project, the System Administrator/Managers will give him/her access to the appropriate research folder(s), once all training is completed and IRB approval has been obtained (via an amendment) to let that person access the PHI.

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e. Each person who has access to a folder as described above may also keep relevant patient and other VA data on their VA-connected, encrypted desktop PCs, provided (a) they have obtained Data Security and Privacy Subcommittee approval adding their VA desktop PC as a data storage location for that study's PHI, and (b) the VERDICT system administrator has limited sign-on capability on their VA desktop PC to that person alone (plus System Administrators).

f. The Data Manager will keep a log of the quarterly reviews at \\vhastxres2\data\folder_access_list.xls.

g. On an annual basis, the Data Manager will monitor that no VA PHI is kept on VA or non-VA desktop computers or laptops or removable media. This will be accomplished by asking all members of VERDICT to aver that (a) they have no VA PHI data stored anywhere other than the servers or approved encrypted limited-access VA desktop computers described in 3e above, and (b) they understand where VA PHI may and may not be stored.

4. **REFERENCES:** All applicable VA directives, policies, and standard operating procedures as well as specifically, STVHCS Policy Memorandum 151--03 Protection of Human Subjects in Research and STVHCS Research SOP 062 Granting Research Privileges for Research Personnel Conducting Human Subjects Research at the STVHCS.

5. **RESPONSIBILITY:** ACOS for Research and Development (151)

6. **RESCISSION:** Policy Memorandum 151-08-09, Access to VA Research Data

7. **RECERTIFICATION:** May 2016


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