

November 21, 2002

**PROTOCOL FOR SHARING VA REHABILITATION OUTCOMES DATA WITH VA  
AND NON-VA RESEARCH INVESTIGATORS**

1. **PURPOSE:** This Veterans Health Administration (VHA) Notice describes the protocol by which the Department of Veterans Affairs (VA) and non-VA researchers may access data stored in the Functional Status and Outcomes Database (FSOD) (for Rehabilitation) at the Austin Automation Center (AAC).

2. **BACKGROUND:** The FSOD was established in June 1997, through a cooperative agreement between the VHA Central Office of Physical Medicine and Rehabilitation (PM&R), the Uniform Data System for Medical Rehabilitation (UDSmr), and the AAC. The database is stored on the AAC mainframe and is accessible through local personal computer connectivity to the AAC mainframe. This database includes all VA rehabilitation records previously stored at the UDSmr in State University of New York (SUNY), Buffalo, NY, since 1987. The FSOD supports three levels of data entry: acute inpatient rehabilitation, subacute inpatient rehabilitation, and the rehabilitation continuum of care across multiple care settings, including facilities without rehabilitation bed units. Functional status is measured using the Functional Independence Measure (FIM) and entered into the database through the VA FIMware data management software. Special facility reports are also included within the software system in addition to the regular quarterly reports issued to UDSmr acute or subacute subscribers.

3. **POLICY:** It is VHA policy to permit VA and non-VA researchers access to data stored in FSOD, subject to approval of PM&R VHA Central Office.

4. **ACTION**

a. Approval Process for VA Investigators

(1) Access to use of the FSOD must be approved by the PM&R VHA Central Office utilizing policy established by the field-based FSOD Steering Committee. The researcher's VAMC must use the research component of its Veterans Equitable Resource Allocation (VERA) medical care funds to cover any cost accrued by VHA for access or use of the database.

(2) VA Investigators with approved proposals for VA research funding may request access to VA FSOD. A written request to the PM&R VHA Central Office is required for consideration of all access requests. If an investigator requires access to patient specific identifiers, the Steering Committee will consider the merits of the research. Upon concurrence, the committee will forward the request to the National Director, PM&RS for approval. National Level Real Social Security Number (SSN) access requires signature approval from the National Director, PM&RS. The following information should be submitted to Clifford R. Marshall, Rehabilitation Planning Specialist, PM&R Central Office (117C), VA Medical Center, Room CWG-20, 1030 Jefferson Ave., Memphis, TN 38104:

**THIS VHA NOTICE EXPIRES NOVEMBER 30, 2007**

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(a) A formal written and signed request (memo or letter format) from the principal investigator containing the following:

1. The specific FSOD variable/s needed to accomplish the objectives within the approved VA research protocol. Specify patient admission or discharge date range, impairment group, an estimated duration (time) this access is needed, and facilities of interest. **NOTE:** *Approved applicants will have access to all FSOD variables, excluding patient's name, address, and telephone number.*

2. If the patient SSN disclosure is required for the effective use of the database, provide special documentation for the need (e.g., the principal investigator requires linking of the database to the VA Patient Treatment File (PTF)). Approval for access to National Level Real SSN data begins with the requesting facility submitting VA Form 9957 (ACRS Time Sharing Request Form) and a Memo of Justification via the local Information Security Office. Both documents should be mailed for concurrence to the National Director, Physical Medicine & Rehabilitation Service (117C), VA Medical Center, Room CWG-20, 1030 Jefferson Ave., Memphis, TN 38104. Following concurrence, the PM&R Program Office will forward the documents to the Department of Veterans Affairs, Veterans Health Administration, Veronica Graves (19E), VHA FOIA Office, Washington, D.C. 20420.

3. Complete, sign and return the attached Privacy Act And Data Security Statement (see Attachment. A-1).

(b) A one page document describing the project (Executive Summary or Abstract is acceptable), cover sheet of the approved Merit Review or Pilot Application, and a copy of the letter of approval from the VA Research Office or other appropriate research agency.

(c) A copy of the Institutional Review Board approval, if required for the project.

### b. Approval Process for non-VA Investigators

(1) Non-VA Investigators' requests will be considered on a case-by-case basis. A written request to the PM&R VHA Central Office is required for consideration of all access requests. If an investigator requires access to patient specific identifiers, the Steering Committee will consider the merits of the research for approval. Upon concurrence, the Steering Committee will forward the request to the National Director, PM&RS and to the VHA Privacy Officer to determine whether the request meets the requirements of the Privacy Act, VA confidentiality statutes, and VHA Handbook, Privacy and Release of Information for approval. The following information should be submitted to Clifford R. Marshall, Rehabilitation Planning Specialist, PM&R Central Office (117C), VA Medical Center, Room CWG-20, 1030 Jefferson Ave., Memphis, TN 38104:

(a) A formal written and signed request (memo or letter format) from the principal investigator containing the following:

1. The specific FSOD data sought.

2. The names of the research subjects for whom data is requested.

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(b) A one page document describing the project (Executive Summary or Abstract is acceptable), cover sheet of the approved Merit Review or Pilot Application, and a copy of the letter of approval from the VA Research Office or other appropriate research agency.

(c) A copy of the Institutional Review Board approval, if required for the project.

(d) A copy of the prior authorizations of researcher subjects, if applicable.

***NOTE:** Denial of requests for access by Non-VA researchers to the FSOD must also be given under the Freedom of Information Act (FOIA). Any such denials should be forwarded to the VHA FOIA Officer for processing at the address given above.*

**5. RESPONSIBILITY:** The Physical Medicine and Rehabilitation Program Office (117C) is responsible for the contents of this Notice. Questions concerning its contents should be directed to Clifford R. Marshall at (901) 523-8990, Ext. 1-2508.

**6. RESCISSIONS:** This VHA Notice expires November 30, 2007.

Robert H. Roswell, M.D.  
Under Secretary for Health

Attachment

DISTRIBUTION: CO: E-mailed 11/25/02  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 11/25/02



**ATTACHMENT A**

**SAMPLE OF  
PRIVACY ACT AND DATA SECURITY STATEMENT  
FOR RESEARCH, AUDIT AND EVALUATION ACTIVITIES INVOLVING RELEASE OF  
IDENTIFIABLE PATIENT DATA GOVERNED BY THE PRIVACY ACT,  
TITLE 38 UNITED STATES CODE (U.S.C.) 5701 AND/OR U.S.C. 7332**

**1. Title of Research, Audit or Evaluation Activity:**

**2. Patient Data Elements to Be Used:**

**3. Name(s) of Database(s) for Which Access is Required:**

**4. Delimiting Dates of Access for Research, Audit or Evaluation Activity:**

**5. Limitation on Use and Rediscovery:** All identifying data will be kept strictly confidential by the Department of Veterans Affairs (VA) and non-VA personnel and will be used only for the research, audit or evaluation purposes described herein. At the end of the project all data files with veteran identifiers will be erased or destroyed. Results generated from this research, audit or evaluation containing identifiers may be disclosed only back to VA, and no identity will be made of any individual patient in any report of the research, audit or evaluation or otherwise disclose patient identifiers.

**6. Data Security:** Data containing patient names or identifiers will be securely stored and protected from theft by the use of passwords (when data are stored on hard disks) and locked cabinets (when the data are stored on floppy disks or any other transportable medium). Patient level data will not be disclosed, copied, or transmitted in total or in part to anyone not connected with the approved protocol.

**7. Penalty Provisions:** Penalties for misuse of the data provided is set at not more than \$5,000 for the first offense and not more than \$20,000 in the case of any subsequent offense. (5 U.S.C. 552a, Title 38 Code of Federal Regulations (CFR) 1.576 (e) and 1.463).

**CERTIFICATION:** As principal investigator, I hereby acknowledge that I am responsible for the research data and understand and agree to the provisions as set forth above. I am responsible for ensuring all individuals participating in this investigation study comply with the provisions as set forth above. This release of identifying patient information is approved, only for the purposes and under the conditions described above, under the provisions of the Privacy Act, 5 U.S.C. 552a(a)(8)(B)(ii) and (b)(3), and routine use #15 as set forth in the VA System of Records Notice. "24VA136, Patient Treatment Records" and Title 38 U.S.C. 5701 (e) and 38 U.S.C. 7332(b)(2)(B) and VA regulations Title 38 CFR 1.488 through 1.489.

**RESPONSIBLE RESEARCH OFFICIAL(S)**

**Name:**

**Title:**

**Address:**

**Phone Number:**

**Signature and Date:**

**REVIEWING AND APPROVING VA OFFICIALS**

**Name:** Clifford R. Marshall

**Title:** Rehabilitation Planning Specialist

**Business Address:** VA Medical Center, PM&R/VACO (117C),  
Room CWG-20, 1030 Jefferson Ave., Memphis, TN 38104

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**Phone Number:** (901) 523-8990, Ext. 1-2508

**Date:**