Office of Health Data and Informatics
VHA Privacy Office

Privacy Fact Sheet

June 2006 ***Volume 06, No. 4***

Privacy Requirements for Disclosures for Research to Non-VA Researchers

There are several Federal privacy laws and regulations that must be satisfied prior to the disclosure of VHA individually identifiable information for research purposes or a research study conducted by Non-VA Researchers.

A prior written authorization signed by the research subject that complies with VHA Handbook 1605.1 Para 14 would satisfy all of the applicable Federal privacy laws and regulations. In the absence of a timely, compliant authorization, the requirements Federal and Non-Federal Researchers must satisfy under each of the Federal privacy laws and regulations are:

Laws & Regulations	Federal Researcher	Non-Federal Researcher
38 USC 5702	Written request stating records sought and purpose for the records that is dated and signed by the Researcher.	Written request stating records sought and purpose for the records that is dated and signed by the Researcher.
38 USC 5701 (Applicable to Names and Addresses)	No special requirement. Federal Researcher may be provided name and address under 38 USC 5701(b)(3) without having to provide the names of the subjects.	Must provide the names and addresses of the research subject in order to obtain identifiable information on individuals.
38 USC 7332 (Applicable to Drug Abuse, Alcohol Abuse, HIV Infection, and Sickle Cell Anemia Records)	Assurance in writing from the Researcher that the purpose of the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. **NOTE:** This assurance may be documented in the research protocol.	Assurance in writing from the Researcher that the purpose for requesting the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. **NOTE:** This assurance may be documented in the research protocol.
38 CFR 1.488 (Applicable to Drug Abuse, Alcohol Abuse, HIV Infection, and Sickle Cell Anemia Records)	The Under Secretary for Health or designee determines that the requester of the patient identifying information: (1) Is qualified to conduct the research. (2) Has an approved research protocol under which the information will be maintained in accordance with the security requirements of Sec. 1.466; and will not be redisclosed except back to VA. (3) Has furnished a written statement that the research protocol has been reviewed by an IRB who found that the rights of patients would be adequately protected and that the potential benefits of the research outweigh any potential risks to patient confidentiality posed by the disclosure of records.	The Under Secretary for Health or designee determines that the recipient of the patient identifying information: (1) Is qualified to conduct the research. (2) Has a research protocol under which the information will be maintained in accordance with the security requirements of Sec. 1.466; and will not be redisclosed except back to VA. (3) Has furnished a written statement that the research protocol has been reviewed by an IRB who found that the rights of patients would be adequately protected and that the potential benefits of the research outweigh any potential risks to patient confidentiality posed by the disclosure of records.

Privacy Act of 1974 (Applicable to Individually Identifiable Information)	Routine use in the applicable system of records must be present. Usually the routine use requires approval of VHA's participation in the research study by leadership, including the Under Secretary for Health.	Routine use in the applicable system of records must be present. Usually the routine use requires approval of VHA's participation in the research study by leadership, including the Under Secretary of Health.
HIPAA Privacy Rule (Applicable to Health Information)	Documented approval of waiver of authorization from an Institutional Review Board (IRB) or Privacy Board that includes the following elements: • A statement identifying the IRB or Privacy Board and the date on which the waiver of authorization was approved. • A statement that the IRB or Privacy Board has determined that the waiver of authorization satisfies the following criteria: o The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals under criteria specified in the Privacy Rule; and o The research could not practicably be conducted without access to and use of the protected health information. • A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board in order to conduct the research. • A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures. The documentation must be signed by the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.	Documented approval of waiver of authorization from an IRB or Privacy Board that includes the following elements: • A statement identifying the IRB or Privacy Board and the date on which the waiver of authorization was approved. • A statement that the IRB or Privacy Board has determined that the waiver of authorization satisfies the following criteria: o The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals under criteria specified in the Privacy Rule; and o The research could not practicably be conducted without access to and use of the protected health information. • A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board in order to conduct the research. • A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures. The documentation must be signed by the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

Once all of these legal requirements have been determined to be satisfied based on a review by the VHA Privacy Office for national-level data or the VISN/Facility appropriate person for network or local-level data, the Researcher may be provided the information requested as it is described in the Research Protocol that was approved by the IRB. The VISN/Facility should determine how this review will be conducted prior to disclosing the requested network or local-level data.

Note: This Fact Sheet does not provide guidance on requirements for human subjects research or for securing and safeguarding research information. Its intent is to clarify VHA Handbook 1605.1 Para 13b.

Privacy Office at a glance…
VHA-specific privacy questions: VHA personnel should contact the VHA Privacy Office at 727-320-1839 or 321-504-4574.
A list of facility Privacy Officers may be obtained at http://vaww.vhaco.va.gov/privacy.