



Privacy Fact Sheet

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Privacy Requirements for Use of VHA Data by VHA Researchers

There are several Federal privacy laws and regulations that must be satisfied prior to the use of VHA individually identifiable information (III) for a research study or research purpose by VA Researchers.

An authorization signed in advance 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 properly executed prior written authorization by the patient, VA Researchers must satisfy the requirements of each of the Federal privacy laws and regulations as follows:

Laws & Regulations	VA Researcher
38 USC 5701 (Applicable to Names and Addresses)	VA Researcher may be provided name and address under employee need-to-know.
38 USC 7332 (Applicable to Drug Abuse, Alcohol Abuse, HIV Infection, and Sickle Cell Anemia Records)	Assurance in writing from the VA 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.
Privacy Act of 1974 (Applicable to III)	VA Researcher may be provided VHA individually identifiable information (III) as needed in the performance of his/her official VA duties under 5 USC 552a(b)(1).
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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 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 ○ 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 local-level data, the VA 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 a Data Steward or Data Owner providing access to the requested local-level data.

Note: This Fact Sheet does not provide guidance on requirements for human subjects research, securing and safeguarding research information, or for disclosing health information to outside individuals or entities for research purposes. Its intent is to clarify VHA Handbook 1605.1 Para 13a.

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 is available at <http://vaww.vhaco.va.gov/privacy>.