

SOP# HRP 01.12/PM #049

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COMPLIANCE WITH VHA PRIVACY REQUIREMENTS

PURPOSE:

1. To ensure all of the legal privacy requirements have been met in order to use or disclose protected health information (PHI) or individually identifiable information (II) for the purposes of a research project. To accomplish this, a review of all of the documentation for research studies must be conducted prior to providing the protected information requested.
2. To ensure prompt reporting of incidents related to research information protection according the VHA Handbook 1058.01.

BACKGROUND:

The VA has codified its enforcement of the Health Insurance Portability and Accountability Act (HIPAA) through its VA Privacy Rule and VHA Handbook 1605.1. The conduct of research within HIPAA requirements presents special challenges. Both the UMB (through the IRB) and the VAMHCS (through the VAMHCS Privacy Officer review process) evaluate the privacy risks of research proposals and must approve HIPAA documents and privacy protection plans according to established policies and procedures.

In compliance with VA mandates, the VAMHCS has named a Privacy Officer (PO) who reviews research proposals prior to IRB review, to ensure that the privacy requirements have been satisfied before protocols can be initiated. The PO also sits on the R&D Committee as a consultant for privacy matters (non-voting).

In addition, VHA has instituted reporting procedures for noncompliance and other incidents related to research information protection (VHA Handbook 1058.01 [June 2015]). This handbook delineates the reporting requirements for investigators, privacy officers, ACOS/R&D, and facility directors.

POLICY:

- The VAMHCS Privacy Officer (PO) reviews each research proposal to determine what health or individually-identifiable information (III) will be accessed, used or disclosed for the research study, the risks of (if any) and safeguards for disclosures of PHI and III, the adequacy of HIPAA authorizations or waiver requests, and other required elements.
- The R&D Committee (RDC) seeks the PO's guidance on privacy matters.
- The RDC will not approve research studies until the PO has determined that all privacy requirements have been met.
- The VAMHCS R&D Service, Investigators and VAMHCS institutional officials shall comply with all VHA reporting requirements for incidents related to research information protection.

DEFINITIONS

Comprehensive Institutional Evaluation of Research Online (CICERO) - the electronic protocol management system currently used by the IRB.

Individually-identifiable Information (III) – any information, including health information maintained by VHA, pertaining to an individual that also identifies the individual and, except for individually-identifiable health information, is covered regardless of whether or not the information is retrieved by name. III includes a subset of information called “Individually-identifiable Health Information” (IIHI) further defined in 1605.1 par 4.aa.

Network Security Operations Center (NSOC) – the VA central reporting system for privacy events.

Protected Health Information (PHI) – individually-identifiable health information maintained in any form or medium; includes employment records held by a covered entity in its role as an employer. (1605.1 par 4.ss)

VA Data (or VA Information) – Information owned or in the possession of VA or any entity acting for or on behalf of VA.

VA Research Data – consist of information that has been collected for, or used in or derived from the conduct of VA research.

RESPONSIBILITIES:

Privacy Officer (PO)

1. Reviews the documentation of each human research project prior to IRB review, to ensure that privacy requirements have been met or identified.
2. Is a non-voting member of the Research & Development Committee (RDC);

3. Processes privacy-related incidents through the NSOC mechanism and VAMHCS procedures.
4. Includes these incidents in Privacy Office reports to the VAMHCS R&D Committee.

RDC Coordinator

Notifies the Privacy Officer when a human research study is submitted for RDC review

Investigators

1. Design their research protocols with VA privacy requirements in mind, or amend their protocols as recommended by the PO.
2. Completes the “Checklist for Reviewing Privacy, Confidentiality and Information Security in Research” as a component of the protocol submission to the RDC.
3. Follow approved procedures related to participants’ individually identifiable information and PHI.
4. Report incidents related to information protection to the VAMHCS ACOS/R&D, PO, and Human & Animal Research Protections Officer (HARPO) within 1 hour of becoming aware of the incident, and otherwise complying with R&D Process Module #045., “Reportable Events: RISP”.

ACOS/R&D

Reports incidents related to information protection to the Medical Center Director and other individuals as required by R&D SOP Process Module #045.

PROCEDURES:

1. Review of Research Protocols

- 1.1. All research projects involving human subjects are reviewed by the VAMHCS Privacy Officer to ensure that the privacy requirements have been satisfied and to document the findings of the review using the [“Checklist for Reviewing Privacy, Confidentiality and Information Security in Research”](#).
- 1.2. The privacy review will be in compliance with VAMHCS “Privacy Program Policy” (512-001/PO-002).
- 1.3. Prior to IRB review of the protocol, the PO accesses CICERO or the paper documents to review required documents, including but not limited to: the [“Checklist for Reviewing Privacy, Confidentiality and Information Security in Research”](#), the study protocol, Informed Consent Form, the HIPAA Authorization and, if applicable, the request for Waiver of HIPAA-Compliant Authorization).
- 1.4. The PO will review the documents for the following requirements:

- 1.4.1. Review the research protocol to determine what health information is specifically being requested for the research study and to determine whether the Researcher will be obtaining informed consents and HIPAA authorizations or if a waiver of HIPAA-compliant authorization is required. This information is normally listed in the research protocol under Methodology or Data Analysis.
- 1.4.2. Obtain supporting documents, i.e., signed HIPAA waiver, HIPAA authorization when required, VA Consent, IRB approval letter, and Certificate of Confidentiality when applicable.
- 1.4.3. Review the informed consent form and HIPAA authorization to determine if it contains all of the content requirements for an authorization as outlined in VHA Handbook 1605.1.
- 1.5. The Privacy Officer signs and dates the "[Checklist for Reviewing Privacy, Confidentiality and Information Security in Research](#)" upon review of the research project documents. This signed and noted checklist may serve as the PO summary report to the RB.
 - 1.5.1. The PO report is made available to the IRB prior to its review
- 1.6. If privacy issues are discerned, the Privacy Officer:
 - 1.6.1. Notes the issues on the "[Checklist for Reviewing Privacy, Confidentiality and Information Security in Research](#)",
 - 1.6.2. Notifies the Investigator and the RDC Coordinator,
 - 1.6.3. Follows up with the Investigator in a timely manner, to ensure the proposed research is in compliance with relevant privacy and confidentiality before the Investigator initiates the study.
 - 1.6.4. Reports to the IRB any issues regarding privacy requirements (see 1.5.1 above).
- 1.7. The RDC will not approve research studies until the PO has determined that all privacy requirements have been met.
 - 1.7.1. The facility may not provide the protected information to the Researcher until RDC approval is obtained and the study is initiated by the ACOS/R&D.
 - 1.7.2. The Researcher may not access or collect research related information until the R&D Committee has fully approved the protocol and the study is initiated by the ACOS/R&D.
2. Reportable Events
 - 2.1. Incidents reportable to NSOC: Members of the VAMHCS research community ensure that the following situations are reported to the ACOS/R&D, ISO, PO and HARPO within 1 hour of becoming aware of the situations below:
 - 2.1.1. Unauthorized access to VA sensitive information, (including unauthorized use, disclosure, transmission, removal, theft, or loss) related to research, including but not limited to protected health information, individually-identifiable private information, and confidential information protected by HIPAA;

- 2.1.2. Any research-related incident reportable to the Office of Information and Technology (OI&T) NSOC that impacts, inhibits, or compromises network security.
- 2.1.3. The PO proceeds according to NSOC requirements and periodically updates the PI and the HARPO of any determinations made by NSOC, and on any corrective actions that are to be taken.
- 2.2. Incidents not reportable to NSOC: Members of the VAMHCS research community ensure that the following situations are reported to the ACOS/R&D, ISO, PO and HAARPO within 5 days of becoming aware of the situations below:
 - 2.2.1. Any findings of noncompliance related to research information security or privacy by any VA office (other than ORO) or any other Federal or state entity;
 - 2.2.2. Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program;
 - 2.2.3. Any suspension or termination of research (e.g., by the ACOS for Research or other facility official) related to concerns about research information protection.
 - 2.2.4. The ISO, HARPO and PI ensure that any corrective actions are resolved.
- 2.3. Investigators must also report incidents involving human participants to the IRB through CICERO. R&DS PM #045 must be followed.
- 2.4. Within 5 business days of being notified, the MCD must report the research information protections incidents listed above according to R&DS PM #045.

SEE ALSO:

VAMHCS Policy Memorandum "Privacy Program Policy" (512-001/PO-002
VHA Handbook 1058.01 "Research Compliance Reporting
Requirements" (June 2015)

REFERENCES:

VHA Handbooks 1605.1 "Privacy and Release of Information"
1200.05 "Requirements for the Protection of Human
Subjects in Research"
Privacy Fact Sheets on Research, Vol 06, No 3&4