

OFFICE OF RESEARCH OVERSIGHT

Examples and a Brief Guide for Reporting Apparently Serious Research Information Security Problems That May Be Reportable to ORO under VHA Handbook 1058.01

September 14, 2015

VHA Handbook 1058.01: Research Compliance Reporting Requirements

§4.t. Serious Problem. A serious problem is a problem in human research¹ or **research information security** that may reasonably be regarded as:

- (1) **Presenting a genuine risk of substantive harm**, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or
- (2) **Substantively compromising a facility's HRPP** [Human Research Protection Program] or **research information security program**.

§10.a. Notification Requirements. VA personnel, including WOC and IPA appointees, must ensure notification of the ACOS/R&D, Information Security Officer (ISO), Privacy Officer (PO), and relevant investigators **immediately (i.e., within one hour)** upon becoming aware of any information security incidents related to VA research, including any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI.

IMPORTANT NOTE: It is the role and responsibility of the relevant **research review committee(s)** [i.e., Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Subcommittee on Research Safety (SRS), and/or Research and Development Committee (R&DC)] to determine whether a particular situation actually **constitutes** a serious research information security problem. However, VA personnel are required to **report** any situation that **appears** to represent a serious research information security problem. Examples are provided here to assist in identifying such problems, but the examples should be not considered either exhaustive or definitive. ORO strongly recommends that research review committees clearly **document case-specific determinations and justifications** related to their evaluations of apparently serious research information security problems.

A. Examples of Apparently Serious Problems in Research Information Security That May Be Reportable to ORO under VHA Handbook 1058.01 §10.a:

- (1) Inappropriate access, loss, or theft of protected health information (PHI); noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI. Issues for the research review committee to consider in evaluating any information security incident may include the following:
 - a. What level of subject identification was contained in the pertinent PHI (e.g., name, SSN, address, phone number)?
 - b. How sensitive and specific was the pertinent PHI (e.g., HIV diagnosis, alcohol/drug dependence)?
 - c. What is the likelihood of a permanent loss versus temporary displacement?
 - d. What is the likelihood of actual unauthorized access?
 - e. Who and how many (other Veterans, researchers, sponsors, etc.) accessed the PHI?
 - f. How many documents, individual subject records, and/or pieces of equipment were accessed/lost/stolen/stored/transmitted/removed/destroyed in this one incident?
 - g. Is this a repeated instance of noncompliance (same type, investigator, research group)?

OFFICE OF RESEARCH OVERSIGHT

Examples and a Brief Guide for Reporting Apparently Serious Research Information Security Problems That May Be Reportable to ORO under VHA Handbook 1058.01

September 14, 2015

- (2) Unauthorized destruction (accidentally or intentionally) of research documents or records. Additional issues for the research review committee to consider may include the following:
 - a. Was the sole copy of the record destroyed?
 - b. How many records were destroyed in this one incident?
 - c. Is the National Archives and Records Administration (NARA) required to be notified?
- (3) Loss, theft, or unauthorized destruction of equipment (e.g., laptops, other mobile devices, external storage media) containing VA research-related PHI. Additional issues for the research review committee to consider may include the following:
 - a. Was the equipment encrypted according to VA standards?
 - b. Did the equipment contain the only copy of the research record?
- (4) Transmission of VA research-related PHI not encrypted according to VA standards. Additional issues for the research review committee to consider may include the following:
 - a. Was the PHI transmitted outside of VA?
 - b. Was the PHI transmitted to its intended (authorized) recipient?
 - c. Was the PHI encrypted, but not according to VA standards?
- (5) Use or connection of unauthorized equipment (e.g., non-VA thumb drive, unauthorized personally owned equipment) to store, process, or transmit VA research-related PHI. Additional issues for the research review committee to consider may include the following:
 - a. Was the equipment connected to the VA network?
 - b. Was the equipment subsequently taken outside of the VA facility or connected to non-VA information systems?
- (6) Malicious attack on or unauthorized access to VA information system containing VA research-related PHI. Additional issues for the research review committee to consider may include the following:
 - a. Was VA PHI compromised or potentially compromised (confidentiality, integrity, and/or availability of the system affected)?
 - b. Was the attack/access isolated or widespread?

¹ For detailed requirements related to human research problems, see VHA Handbook 1058.01 §6.c. and ORO Decision Chart “Reporting Local Death, Local Serious Adverse Events (SAEs), and Serious Problems in VA Research” (Revised September 14, 2015). Examples of apparently serious problems in human research that may be reportable to ORO include the following:

- (1) Any situation that requires action to prevent an immediate hazard to subjects or others.
- (2) Any serious research-related injury to human research subjects, research personnel, or others.
- (3) Any problem described in a VA Pharmacy Benefits Management alert relevant to local human subjects.
- (4) Any problem described in a Data Monitoring Committee report.
- (5) Any combination of problems that collectively present a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, or substantively compromise a facility’s HRPP.

OFFICE OF RESEARCH OVERSIGHT

Examples and a Brief Guide for Reporting Apparently Serious Research Information Security Problems That May Be Reportable to ORO under VHA Handbook 1058.01

September 14, 2015

B. Brief Guide for Reporting Apparently Serious Information Security Problems in VA Research. *For detailed requirements, see VHA Handbook 1058.01 §10.*

