

VAMHCS RESEARCH & DEVELOPMENT SERVICE
RDS Process Module

PM-SRS-045

Effective Date: July 2016

REPORTING REQUIREMENTS FOR HUMAN RESEARCH PROTECTIONS EVENTS

Applicable Regulatory Context:

[VHA Handbook 1058.01]:

This Handbook describes requirements for reporting compliance events in VA research to research review committees, VHA officials, and ORO. These requirements do not alter or replace any additional requirements for reporting such events to other internal or external entities as mandated by law, regulation, policy, or agreement.

Paragraph 10 deals specifically with Research Information Security.

1. Applicable Events in the VAMHCS Research Information Security Program (RISP) must be reported to the Information Security Officer (ISO), Privacy Officer (PO), IRB, VAMHCS Director and ORO in compliance with VHA Handbook 1058.01, as outlined in the tables below. VAMHCS ACOS/R&D and HARPO must also be notified as outlined in the tables below.
2. The R&D Service/HARPO prepares any written reports from the Director to ORO. VAMHCS templates for memo/letter formats must be followed.
3. VA personnel, including WOC and IPA appointees, must ensure *notification of appropriate entities as below*:

	Event	Method	Timing	How
1	Any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of	oral and written notification of the VAMHCS ISO and PO	immediately (i.e., within one hour) upon becoming aware	<ul style="list-style-type: none"> • Phone/email VAMHCS ISO/PO vamhcsPrivacyOffice@va.gov or vamhcsISOstaff@va.gov. • Phone/email ACOS/R&D and HARPO • Follow IRB RNI <i>if</i>
		written notification of the ACOS/R&D and HARPO	within 5 business days after becoming aware of the death	

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	Event	Method	Timing	How
	equipment containing PHI ¹			<p><i>applicable</i> (RNI #5 or #13)</p> <p>(IRB then follows HRPO SOP 024 and other applicable procedures to make applicable determinations)</p>

4. The ACOS/R&D must ensure *notification of appropriate entities as below*:

	Event	Method	Timing	How
A	Records have been destroyed	oral and written notification of the VAMHCS Records Management Officer	immediately upon becoming aware	<ul style="list-style-type: none"> Phone/email xxxxxxxxrmoxxxxxxx Notify HARPO and other R&D personnel as applicable
B	Other incidents above	<p>written notification of the IRB, IACUC, SRS where relevant.</p> <p>OR, to the RDC if not relevant to at least one of the above committees.</p>	immediately upon becoming aware	<ul style="list-style-type: none"> Phone/email the applicable committee Chair(s) Notify HARPO and other R&D personnel as applicable

5. If the IRB determines that the incident constitutes a serious problem, it must notify the *VAMHCS MCD, the ACOS/R&D, and the HARPO* within 5 business days after the determination.

6. VAMHCS MCD must report *to ORO* in writing as below:

¹ Reports and questions related to HIPAA authorizations and deficiencies (such as invalid HIPAA authorizations, deficient waivers of authorization, and other uses and disclosures of PHI for research without legal authority) are to be reported to ORO in accordance with Process Module 041 (Human Research) rather than this PM.

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Event	Timing	How – Also Cc
Items A-B above	within 5 business days after receiving the committee’s notification	<ul style="list-style-type: none"> HARPO prepares letter or memorandum and submits to Executive Suite for review and signature. Encrypted email sent to ORO HRP Workgroup: ororisp@va.gov with Ccs to COS, ACOS/R&D, DACOS, RCO, VISN 5 Action Group.
Provision of an Issue Brief for VA Central Office regarding the incident	within 5 business days after taking or becoming aware of such action(s), regardless of any determination made by the IRB or R&DC:	<ul style="list-style-type: none"> HARPO prepares letter or memorandum and submits to Executive Suite for review and signature. Encrypted email sent to ORO with Ccs to COS, ACOS/R&D, DACOS, RCO, VISN 5 Action Group.
Any notification to individual(s) of an information breach or provision of credit monitoring as required by the Network Security Operations Center (NSOC)		
Any breach notification required under the Health Information Technology for Economic and Clinical Health (HITECH) Act		
Any notification to or from the Office of Inspector General (OIG) regarding the incident		

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