

VAMHCS RESEARCH & DEVELOPMENT SERVICE
RDS/SRS Process Module

PM-RDS/SRS-043

Effective Date: July 2016

REPORTING REQUIREMENTS FOR RESEARCH LABORATORY SAFETY 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 8 deals specifically with Research Information Safety.

1. Applicable Events in the VAMHCS Research Safety and Security Program (RSSP) must be reported to the SRS, MCD 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. See VAMHCS R&D Service SOP 151/R&D-002, "Service Safety Plan", for details on VAMHCS laboratory safety requirements.
3. The R&D Service/HARPO prepares any written reports from the Director to ORO. VAMHCS templates for memo/letter formats must be followed.
4. VA personnel, including WOC and IPA appointees, must ensure *notification of the SRS, ACOS/R&D and HARPO* as below:

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	Event	Method	Timing	How
1	Human Deaths	oral notification of the VAMHCS Subcommittee on Research Safety (SRS)	Immediately upon becoming aware of any human death that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area).	<ul style="list-style-type: none"> Also notify ACOS/R&D and HARPO immediately Contact SRS Chair directly or through ACOS/R&D or HARPO. Notify IRB if associated with an IRB-approved project (See "Reportable Events – Human" chart.)
		written notification of the SRS	within 5 business days of becoming aware of the death	Cc ACOS/R&D, DACOS, and HARPO
2	Human Accident, Injury, Illness, or Exposure	written notification of the SRS	Within 5 business days after becoming aware of any serious accident, injury, illness, or exposure (other than those that result in death) that may be the result of work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area)	<ul style="list-style-type: none"> Also notify ACOS/R&D, DACOS, and HARPO immediately Contact SRS Chair directly or through ACOS/R&D or HARPO. Emails should Cc SRS Chair, ACOS/R&D, DACOS, and HARPO.
3	Reportable Incidents Under Applicable Federal Standards	written notification of the SRS	Within 5 business days after becoming aware of any incident related to research safety that is reportable under relevant VHA Handbooks or applicable Federal requirements, including Occupational Safety and Health Administration (OSHA) requirements.	<ul style="list-style-type: none"> Also notify ACOS/R&D, DACOS, and HARPO immediately Contact SRS Chair directly or through ACOS/R&D or HARPO. Emails should Cc SRS Chair, ACOS/R&D, DACOS, and HARPO.
4 ¹	ORC audit findings reported by the RCO	ORC written report to SRS	Scheduled SRS meetings	<ul style="list-style-type: none"> See R&D Service Process Module 030

¹ Local R&D Service item. This is not specified in 1058.01.

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	Event	Method	Timing	How
5	Laboratory Decommissions and Reassignments	<u>Oral/email conversations</u> between PI and ACOS/R&D	<u>As soon as</u> PI decides to vacate laboratory space or becomes aware of a plan to decommission of reassign laboratory space	<ul style="list-style-type: none"> See R&D Service Process Module 026
		<u>written</u> decommissioning plan to SRS and ACOS/R&D	Within 1 week of notifying the ACOS/R&D and SRS	

5. For items 1-4 above, SRS discusses the events/findings and determines:
- whether the issue is reportable to ORO (via the Director)
 - whether the issue is reportable to other external entities (via the Director)
 - whether the issue is reportable to VAMHCS entities for action
 - whether the action is not reportable beyond the SRS
 - any combination of a-c above.

6. The SRS must report to the VAMHCS Director as below:

	Event	Method	Timing	How – Also Cc
A	Human Death	Alert ORO by e-mail or telephone	<u>within 2 business days</u> after receiving such notification.	<ul style="list-style-type: none"> ORO RSAW Group: ororsaw@va.gov VA facility Director and the ACOS/R&D, DACOS/R&D and HARPO must receive concurrent notification
B	When it reaches a determination that a reportable incident has occurred	<u>written</u> notification of the MCD	within <u>5 business days</u>	<ul style="list-style-type: none"> EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s)
C	When it reaches a determination that an incident brought to its attention under lines 1-3 above was not reportable.	<u>written</u> notification of the MCD	within <u>5 business days</u>	<ul style="list-style-type: none"> EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s)
D	If the SRS is unable to make a determination required under	<u>written</u> notification of the MCD	immediately	<ul style="list-style-type: none"> EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s)

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	Event	Method	Timing	How – Also Cc
	paragraph 8 within 60 calendar days after receiving notification of the relevant event			

7. The ACOS/R&D must notify the VA facility Director and the facility Safety Office of any **unauthorized decommissioning or reassignment of laboratory space** within 5 business days after becoming aware of the unauthorized decommissioning or reassignment.

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

Event	Timing	How – Also Cc
Items A, B above	within 5 business days after receiving the SRS's notification that a reportable incident has occurred	<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 RSAW Group: ororsaw@va.gov with Ccs to COS, ACOS/R&D, DACOS, RCO, VISN 5 Action Group.
Item D above	within 5 business days after receiving the SRS's notification that the SRS is unable to make a determination required under paragraph 8 within 60 calendar days after receiving notification of the relevant event	<ul style="list-style-type: none"> MCD must provide ORO with an acceptable justification for the delay and an acceptable completion timeline HARPO prepares letter or memorandum and submits to Executive Suite for review and signature. Encrypted email sent to ORO RSAW Group: ororsaw@va.gov with Ccs to COS, ACOS/R&D, DACOS, RCO, VISN 5 Action Group.
New or substantially revised MOUs related to research safety	within 5 business days after final concurrence or signature	<ul style="list-style-type: none"> ORO strongly encourages contacting ORO early in the development of new or revised MOUs.
Unauthorized decommissioning or reassignment of laboratory	within 5 business days after being notified	<ul style="list-style-type: none"> HARPO prepares letter or memorandum and submits to Executive Suite for review and

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Event	Timing	How – Also Cc
space		signature. <ul style="list-style-type: none"> Encrypted email sent to ORO RSAW Group: ororsaw@va.gov with Ccs to COS, ACOS/R&D, DACOS, RCO, VISN 5 Action Group.
The VA facility Director and others acting within their areas of responsibility may also investigate such incidents and make separate determinations as to reporting, but cannot reverse or overrule a determination by the SRS that a reportable incident has occurred.	(1) The VA facility Director must be notified within 5 business days after any such separate determination that a reportable incident has occurred. (2) The VA facility Director must report to ORO within 5 business days after making or receiving any separate determination that a reportable incident has occurred, and the SRS must receive a concurrent copy of the report.	<ul style="list-style-type: none"> The SRS must receive a concurrent copy of the report. ACOS/R&D, DACOS/R&D, HARPO must receive a concurrent copy of the report.

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