

VAMHCS RESEARCH & DEVELOPMENT SERVICE
SRS Process Module

PM-SRS-042

Effective Date: July 2016

REPORTING REQUIREMENTS FOR ANIMAL CARE AND USE 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 7 deals specifically with animal research.

1. Applicable Events in the VAMHCS Animal Care and Use Program (ACUP) must be reported to the IACUC, 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 the IACUC as below*:

	Event	Method	Timing	How
1	Unanticipated Death of Research Animals	oral notification of the Institutional Animal Care and Use Committee (IACUC)	within 5 business days after becoming aware of any apparent unanticipated death(s) of animals used for research including, deaths due to physical plant deficiencies, engineering failures, worker errors, test article toxicity, anesthetic or	<ul style="list-style-type: none"> • Follow UM IACUC procedures • Notify ACOS/R&D, DACOS/R&D and HARPO • Notify VAMHCS Veterinarian

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			surgical complications, and other mishaps	
2	Animal Theft, Escape, or Unexplained Disappearance	written notification of the IACUC	within 5 business days after becoming aware of any theft of research animals or of the escape or unexplained disappearance of research animals that could potentially pose a danger or risk to workers, the public, or the environment	<ul style="list-style-type: none"> Follow UM IACUC procedures Notify ACOS/R&D, DACOS/R&D and HARPO Notify VAMHCS Veterinarian
3	Human Deaths	oral notification of the IACUC	immediately upon becoming aware of any human death that may be the result of working with, caring for, or other contact with research animals.	<ul style="list-style-type: none"> Follow UM IACUC procedures Notify ACOS/R&D, DACOS/R&D and HARPO Notify IRB if associated with an IRB-approved project (See "Reportable Events – Human" chart.)
4		written notification of the IACUC	within 5 business days of becoming aware of the death	
5	Human Accident, Injury, Illness, or Exposure	written notification of the IACUC	within 5 business days of becoming aware of any serious accident, injury, illness, or exposure of a human (other than resulting in death) that may be the result of working with, caring for, or other contact with research animals	<ul style="list-style-type: none"> Follow UM IACUC procedures Notify ACOS/R&D, DACOS/R&D and HARPO Notify IRB if associated with an IRB-approved project (See "Reportable Events – Human" chart.)
6	Reportable Incidents Under Applicable Federal Standards	written notification of the IACUC	within 5 business days of becoming aware of any incident that is reportable under relevant VHA Handbooks or applicable Federal requirements related to laboratory animal welfare or research	<ul style="list-style-type: none"> Follow UM IACUC procedures Notify ACOS/R&D, DACOS/R&D and HARPO Notify VAMHCS Veterinarian

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		safety	
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4. The IACUC must report *to the VAMHCS Director* in writing as below:

	Event	Timing	How – Also Cc
A	When it reaches a determination that a reportable incident has occurred	within 5 business days	<ul style="list-style-type: none"> EMAIL to Director with Ccs to ACOS/R&D, DACOS/R&D, HARPO, and R&DC Chair(s)
B	When it reaches a determination that an incident brought to its attention under lines 1-6 above was not reportable	within 5 business days	<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	If the IACUC is unable to make a determination required under paragraph 7 within 60 calendar days after receiving notification of the relevant event	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)

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

	Event	Timing	How – Also Cc
<ul style="list-style-type: none"> Items A-C above Items 3-5 above (when notified by IRB) 		within 5 business days after receiving the IACUC'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.
<ul style="list-style-type: none"> Items A-C above Items 3-5 above (when notified by IRB) 		within 5 business days after receiving the IACUC's notification that the IACUC is unable to make a determination required under paragraph 7 within 60 calendar days after receiving notification of the relevant event	<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.
	New or substantially revised MOUs related to the use of animals in research	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.

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Any substantial revision to the PHS Animal Welfare Assurance that covers the facility's animal care and use program, whether held by the facility or an academic affiliate.	within 5 business days after the occurrence	<ul style="list-style-type: none"> • Revisions or submissions occur through the University • The University corresponds/collaborates with VAMHCS Director and R&D Service. • 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.
The submission to the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) of routine renewals of the Assurance.		
Any change in the status (e.g., expiration, restriction, suspension, or termination) of the Assurance		
Any failure of the facility to achieve or maintain the accreditation status that is required by VA, or after any change in the status of an affiliate institution upon which the facility relies.	within 5 business days after the failure	<ul style="list-style-type: none"> • The University corresponds/collaborates with VAMHCS Director and R&D Service. • 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.

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