

	Title: Reporting Adverse Events	SOP #	IACUC-11
		Version #	1
		Implementation Date	3/3/2017
Page #	1 of 3	Next Review Date	3/3/2020
Department	Institutional Animal Care and Use Committee		

Standard Operating Procedure

1. Purpose

Outline the process for reporting adverse events involving animals associated with an approved Animal Use Protocol (AUP).

2. Scope

Departments at Central Oregon Community College (COCC) which engage in the use of live, vertebrate animals for research or teaching must report serious adverse events experienced by animals associated with an AUP.

3. Prerequisites

The Adverse Event Report Form is available on the COCC website or from the Attending Veterinarian (AV) or IACUC Chair.

4. Responsibilities

The Principal Investigator is responsible for reporting adverse events to the Attending Veterinarian within 48 hours of the event.

The Attending Veterinarian will determine whether no action is needed, immediate action is needed to prevent hazards to animals associated with the AUP, AUP activities must be modified or suspended, and whether the adverse event must be reviewed by IACUC.

	Title: Reporting Adverse Events	SOP #	IACUC-11
		Version #	1
		Implementation Date	3/3/2017
Page #	2 of 3	Next Review Date	3/3/2020
Department	Institutional Animal Care and Use Committee		

5. Procedure

Adverse events involving Animal Use Protocol subjects must be reported, utilizing the Adverse Event Report Form, if:

Both criteria are true:	<ol style="list-style-type: none"> 1. The problem/adverse event is serious/life-threatening or involving risks to subjects or others 2. The problem/adverse event was an unanticipated incident.
OR:	The problem/adverse event involves death .
OR:	In the PI's judgment, prompt reporting of the event(s) is in the best interest of the subject (s) because it may affect the safety and/or welfare of subjects and/or change the risk level of the study.

All problems/adverse events that are serious or life-threatening AND unanticipated must be reported to the Attending Veterinarian and IACUC within 48 hours.

All other problems/adverse events must be reported to the Attending Veterinarian within 5 days.

6. References

References

1. Institute of Laboratory Animal Resources: Guide for the Care and use of Laboratory Animals, National Academy Press, Eighth Edition (http://www.nap.edu/catalog.php?record_id=12910).
2. Animal Welfare Act and Animal Welfare Regulations. United States Department of Agriculture (https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf).
3. National Institutes of Health: Public Health Service Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/phspol.htm>).



Title: Reporting Adverse Events

SOP #	IACUC-11
Version #	1
Implementation Date	3/3/2017
Next Review Date	3/3/2020

Page # 3 of 3

Department Institutional Animal Care and Use Committee

4. The Federation of Animal Science Societies: Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd Edition, 2010
(http://www.fass.org/docs/agguide3rd/Ag_Guide_3rd_ed.pdf).
5. Protocol Suspension (SOP# IACUC-06)
6. Reporting Animal Care and Use Concerns (SOP# IACUC-07)

7. Definitions

1. AV – Attending Veterinarian – responsible for the health and well-being of all laboratory animals used at the institution
2. SOP – Standard Operating Procedure – established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations
3. IACUC – Institutional Animal Care and Use Committee – responsible for assessment and oversight of the institution’s animal care program components and facilities
4. Chair – Chairperson of the IACUC
5. PI – Principal Investigator – a Central Oregon Community College employee having the background and training in scientific and administrative oversight necessary to conduct and manage the proposed study
6. Protocol – Animal Use Protocol – protocol created by the principal investigator of the proposed research, testing, or educational study
7. COCC – Central Oregon Community College
8. Guide – the *Guide for the Care and use of Laboratory Animals*
9. AWA – Animal Welfare Act – requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public
10. PHS – Public Health Service – establishes guidelines for the proper care of animals to be used in research

Revision	Author	Revisions Made	Effective Date	Approval
1	Cindy Elston	<ul style="list-style-type: none"> • New SOP 	3/3/2017	Cindy Elston (AV)
		<ul style="list-style-type: none"> • 		