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.
5. **Procedure**

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

| Both criteria are true: | 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. |
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<td>OR:</td>
<td>The problem/adverse event involves death.</td>
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<td>OR:</td>
<td>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.</td>
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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**


IACUC-11 Reporting Adverse Events

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. **COC** – 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

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<td>• New SOP</td>
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