Version: 1.0 **Effective Date:** 05/14/2025	**INVESTIGATING ANIMAL WELFARE AND POTENTIAL NONCOMPLIANCE**	**Supercedes** **Document Dated: N/A**

I. Background

The ACUC ensures humane care and use of vertebrate animals used in research, teaching, and testing, and ensures adherence to applicable federal and state regulations and institutional policies at UCB. For those purposes the ACUC monitors the animal care and use program for compliance.

This policy provides the framework for the reporting, assessment and/or evaluation of potential noncompliance with ACUC approved protocols, laws, regulations, policies, and guidelines.

II. Authority

The ACUC exercises authority granted by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the United States Department of Agriculture (USDA) Animal Welfare Act and Regulations (AWAR) to enforce policies and regulations as currently described in UC Berkeley's Assurance approved by the Office of Laboratory Animal Welfare (OLAW).

Under the PHS Policy on Humane Care and Use of Laboratory Animals, the ACUC must promptly report (via the Institutional Official) to the National Institutes of Health (NIH) OLAW the following[1]:

- Any serious or continuing noncompliance with the PHS Policy or the AWAR;
- Any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals (the Guide); and,
- Any suspension of an activity by the ACUC.

PHS Policy and the AWAR require that if the ACUC suspends an activity involving animals, the Institutional Official, in consultation with the ACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to applicable entities (e.g., OLAW, the USDA, and any Federal agency funding that activity).

III. Definitions

A. Animal –

[1] See *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html

1. The definition of "animal" differs slightly between different federal policies and regulations. In general, any live, vertebrate animal – homeotherm or poikilotherm - used or intended for use in research, research training, teaching, or biological testing is considered a research animal as per the PHS Policy.

2. The AWA restricts the definition of "animal" to any live or dead[2] warm-blooded vertebrate used or intended for use in biomedical research[3], teaching, testing, experimentation, or exhibition. The AWA excludes captive bred birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, as well as livestock not used for biomedical research and horses not used for research.

3. For purposes of review, ACUC considers animals to be vertebrates at or beyond the gestational point when neural development may allow pain sensation. This life stage varies among species, but the following non-exhaustive list of criteria are used:

    - Mouse, rat, and hamster fetuses ≥ 15 days gestation
    - Guinea pig fetuses ≥ 35 days gestation
    - Zebrafish at > 3 days post fertilization
    - Xenopus stage 44 (e.g. 3 days, 20-hour post fertilization @ 23°C for *x. laevis* L)
    - Avian or reptile embryos or eggs at ≥ 50% gestation

B. Animal Use Protocol (AUP) – A complete description of all proposed animal species, numbers and procedures to be used or conducted over three years.

C. Animal Care and Use Committee (ACUC) – The group responsible for assessment and oversight of the institution's ACU program components and facilities, as well as oversight of the ethical use of animals ensuring the minimum number of animals are used; pain and distress is minimized; and, non-animal models are used where possible.[4]

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[2] Refers to tissue acquired from an animal euthanized specifically to acquire that tissue for research or educational purposes, meaning the animal was killed solely to harvest its tissues, not as a byproduct of another study or natural death.

[3] Biomedical research is any research not related to farm production of livestock species

[4] Also known as the "3Rs": replacement, reduction and refinement: https://awionline.org/content/the-3rs#replacementhttp://awionline.org/content/reductiohttp://awionline.org/content/refinement

D. Office for Animal Care and Use (OACU) – The group that administratively and operationally supports the ACUC and the Institutional Official (IO) in the execution of their duties related to animal care and use at UC Berkeley.

E. Office of Laboratory Animal Care (OLAC) – The academic service unit responsible for veterinary care, husbandry of animals and maintenance of animal facilities at UC Berkeley.

F. Principal Investigator (PI) – Author and individual responsible for the protocol outlining the use of animals in the research or teaching. PI responsibilities are outlined in UCB's ACUC Policy on Principal Investigator Responsibilities.

G. Noncompliance – Activity that is not conducted in accordance with the applicable provisions of the Animal Welfare Act and Regulations (AWAR), the *Guide*, PHS Policy, UCB's Assurance; a PI's approved Animal Use Protocol/s; and/or UC Systemwide or campus guidelines and policies.

IV. Policy

A. Determination of Noncompliance

To determine whether a report and/or finding should be classified as a noncompliance, the Office of Animal Care and Use (OACU), in consultation with the ACUC Chair and/or Vice-Chair and the Office of Laboratory Animal Care (OLAC), will act on behalf of the ACUC in conducting an initial review of all reports of potential noncompliance. If the activity is noncompliant, it will be categorized based on its severity, a report will be presented to the ACUC, and necessary corrective actions will be determined.

Minor issues involving animals are not always initially deemed as noncompliant. When the OLAC and/or the OACU staff observe such incidents, the PI will be notified and given an opportunity to clarify what was observed and/or reported.

Self-reporting of potential noncompliance is encouraged. Self-reporting gives the OACU or OLAC the opportunity to recommend corrective action and the PI a chance to remedy the issue before it becomes noncompliant and allows the PI to inform the ACUC of self-corrective measures taken to prevent recurrence.

The ACUC *Policy on Principal Investigator Responsibilities* requires PIs to report noncompliances, as well as adverse events, unanticipated problems or complications, and animal welfare concerns to the ACUC Chair, Attending Veterinarian, or the OACU Director in a timely manner. More

details about reporting are described in the ACUC policy on *Reporting Adverse or Unexpected Events Affecting Animal Welfare*, and the guideline on *Reporting Suspected Deficiencies or Concerns in Animal Care or Treatment*.

Unanticipated outcomes that result in adverse effects on animal welfare are not necessarily noncompliances; however, they may result in the ACUC Chair and/or AV asking the PI to voluntarily cease the procedures/s that resulted in an unanticipated or severe AE.

B. Classification of Noncompliance

Following PHS Policy and the AWAR, the ACUC classifies noncompliance incidents as serious, continuing, or a deviation from The Guide. As situations vary, determinations are made based on the totality of the circumstances, including self-reporting, voluntary correction, and severity on animal welfare.

1. *Deviations or minor noncompliance:* Deviations or minor noncompliance may result from instances where a policy has been violated but the risk of harm to animals or researchers is minimal.

Consequences and Resolution of Minor of Noncompliance Incidents

Resolution of minor issues should be achieved through communication between OLAC personnel or OACU staff and the PI and lab personnel—without ACUC intervention. If a minor issue is not resolved or recurs, it will be reported to the ACUC. The following notification process may then be used to obtain compliance or escalate the noncompliance.

First notification: The PI will be required to provide a written response regarding why the incident occurred, how it was corrected, and how recurrence will be prevented. This response will be reviewed by the ACUC, which may require additional steps including retraining of laboratory staff member(s).

Second notification: Possible revocation of animal ordering or facility access privileges, depending upon the circumstances and the response of the PI. The PI may be required to appear before the ACUC or a subcommittee of the ACUC.

Third notification: The noncompliance may be reclassified as significant (see below). If reclassified, it may result in any of the potential consequences of significant noncompliance listed.

2. *Significant (serious and/or continuing) Noncompliance:* Significant noncompliance indicates a breach of regulations or university policy that puts animal welfare or researchers at risk for their health or safety.

Consequences and Resolution of Significant Noncompliance Incidents

The information gathered during the investigation will be presented at a convened ACUC meeting for discussion. After consideration of all information, the ACUC may choose one of more of the possible actions below, but is not limited to only these options:

- Determine that corrective actions proposed and/or taken by the PI are sufficient
- Impose conditions and/or restrictions on the PI and their laboratory regarding the use of animals
- Require additional corrective actions such as:
    - Protocol amendments
    - Increased continued monitoring of research
    - Retraining or mentoring of the PI or lab personnel
    - Periodic reporting to the ACUC
    - Restrictions of research activities or facility access
- Suspend the PI's animal research protocol(s)

If an occurrence of noncompliance directly results in a significant negative impact to animal welfare, PHS and UC Berkeley policy require the Attending Veterinarian or the ACUC Chair or their designee(s) to have the authority to immediately stop all procedures as necessary to protect the health and welfare of the animals. The PI will be contacted as soon as possible and the matter will be referred to the ACUC for further investigation.

If the ACUC votes for suspension, all activities of that protocol must cease during the period of suspension. The PI and their department chair will be contacted as soon as possible with a letter sent to the PI that requires a response regarding corrective action and future preventive measures. The PI may be required to meet with the ACUC, the ACUC Chair and/or the Institutional Official as a condition of reinstatement. Animals housed under suspended protocols will be transferred to the OLAC holding protocol;

however, recharges continue to be billed to the PI's account (though, animal related expenses cannot be charged to federal awards).

A suspension may be lifted by majority vote of the ACUC with a quorum present, after it has been determined that the protocol's activities can be accomplished in full compliance with relevant policies, regulations, and animal welfare; and, that adequate measures have been taken to prevent recurrence of the noncompliant activity.

In cases of significant noncompliance involving ongoing or willful misconduct, either the ACUC or the IO may permanently revoke animal research privileges or refer the case to the Academic Senate for further investigation.

C. Reporting Noncompliances

1. Office of Laboratory Animal Welfare (OLAW)
   - Reporting by the IO is required for PHS-funded animal activities. This includes animal activities funded through: NIH, NSF, NASA, DOD and VA.
   - Reporting is also required if the noncompliance involves functional, programmatic, or physical areas that could affect animal studies funded by these agencies.
   - Reporting to OLAW is required for these types of noncompliance:
     - Serious or Continuing Noncompliance with PHS Policy
     - Serious deviation from The Guide
     - Suspension of an activity by the ACUC
   - A prompt preliminary report may be made via phone, fax or email.

2. United States Department of Agriculture (USDA)
   - Reporting by the AV is only required if animal activities involve species covered by the Animal Welfare Act
   - Reporting to USDA is required for these types of noncompliance:
     - Suspension of a protocol by the ACUC
     - Noncompliance that involves the failure to adhere to a plan to correct a significant deficiency

Note: OLAW has an MOU with USDA. OLAW forwards reports involving regulated species to the USDA.

3. Association for the Assessment of Accreditation of Laboratory Animal Care (AAALAC)
   - Reporting to AAALAC is required for these types of noncompliance:
     - Noncompliance had the potential to compromise animal welfare

  - Noncompliance had an impact on human welfare (safety)
  - Animal use not approved by the ACUC
- Reports may be made using the online Adverse Event Report available through the Unit Login.

4. Department of Defense (DOD)
   - Reporting to DOD's Animal Care and Use Resource Office (ACURO) is required for DOD-funded animal activities.
   - All noncompliances must be reported to ACURO within 5 business days.

V. References

A. Public Health Service (PHS), 2015 Revision, Public Health Service Policy on Humane Care and Use of Laboratory Animals. Washington, D.C.: U.S. Department of Health and Human Services.
B. Animal Welfare Act of 1966 (P.L. 89-544) inclusive of amendments; 1970 (P.L. 91- 579; 1976 (P.L. 94-279); 1985 (P.L. 99-198).
C. Animal Welfare Act Regulations, (9 CFR. 2.31) Institutional Animal Care and Use Committee.
D. Office for Laboratory Animal Welfare, Reporting Noncompliance, https://olaw.nih.gov/guidance/reporting-noncompliance.htm.
E. Institute of Laboratory Animal Research (ILAR). National Research Council (2011). *Guide for the Care and Use of Laboratory Animals* (8th edition). Washington, D.C.: The National Academies Press.
F. ACUC Policy on Principal Investigator Responsibilities, https://acuc.berkeley.edu/policies/pi_responsibilities.pdf
G. ACUC Policy on Reporting Adverse of Unexpected Events Affecting Animal Welfare, https://acuc.berkeley.edu/policies/adverse_unexpected_events.pdf
H. ACUC Guideline on Reporting Suspected Deficiencies I Animal Care or Treatment, https://acuc.berkeley.edu/guidelines/reporting_suspected_deficiencies.pdf