

<p>Version: 1.6 Effective Date: 7/1/2020</p>	<p>ANIMAL CARE AND USE PROGRAM POLICY</p>	<p>Supersedes Document Dated: 3/15/2019</p>
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I. Background

The Laboratory Animal Welfare Act (AWA) of 1966, as implemented by the United States Department of Agriculture (USDA), initiated the need for regulation regarding the care and use of animals used in research and teaching. To oversee the institution’s animal care and use program after the AWA was approved, the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), National Research Council’s *Guide for Animal Care and Use of Laboratory Animals (Guide)*, and the USDA have required the use of an Institutional Animal Care and Use Committee (IACUC). Accordingly, the 8th edition of the *Guide* states that an animal care and use program encompasses “the activities conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions and animal facility design and management”.

II. Policy

- A. To comply with the PHS Policy, the AWA and the *Guide*, every institution that uses animals in research or teaching, including UC Berkeley (UCB), must have an animal care and use program (ACUP). The UCB ACUP must include 3 primary responsible individuals/entities – the Institutional Official (IO), the IACUC (Institutional Animal Care and Use Committee known at UCB as the Animal Care and Use Committee or ACUC), the Attending Veterinarian (AV) – as well as properly maintained facilities, and several related programs, including an occupational health and safety program for animal users, environmental health and safety program, a personnel training program, an adequate veterinary care program, and an environment, housing and management program.
- B. This document outlines UCB’s policy on the three individuals/entities, the facilities, and the above-mentioned related programs. In addition, this policy, in conjunction with UCB’s Animal Welfare Assurance (reviewed by the Office for Laboratory Animal Welfare, OLAW), establishes the framework for the institution to meet its ethical and regulatory obligations with an animal care and use program. However, access to and the use of animals in research or teaching is a privilege that is granted by the ACUC and said access and use of animals can be suspended and/or revoked by the ACUC.
- C. Specifically, access to animal care and use areas is a privilege governed by campus policies and federal regulations. As such, the ACUC and the IO require the Office of Laboratory Animal Care (OLAC) to refrain from granting individuals physical access to animal care and use areas until the Office for Animal Care and Use (OACU) confirms those individuals have: a)

completed the basic animal care and use training; b) completed enrollment in the animal occupational health and safety program; and c) are properly listed and approved as personnel on an approved animal use protocol. Similarly, in most cases in which individuals are no longer active on an animal use protocol, access to animal facilities is terminated.

III. Definitions

A. Animal –

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 dead¹ warm-blooded vertebrate used or intended for use in biomedical research², teaching, testing, experimentation, or exhibition. Some pet-related activities are also regulated. The AWA excludes 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. ^D
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. ^{A,B,C,G,I}
 - a) Any adult or neonate
 - b) Mouse, rat, and hamster fetuses ≥ 15 days gestation
 - c) Guinea pig fetuses ≥ 35 days gestation
 - d) Zebrafish at > 3 days post fertilization
 - e) Xenopus stage 44 (e.g. 3 days, 20 hour post fertilization @ 23°C for *x. laevis* ^L)
 - f) Avian or reptile embryos or eggs at ≥ 50% gestation

- B. Animal Occupational Health and Safety Program (AOHSP) – The program responsible for the development and implementation of programs for medical evaluation and preventative medicine for all individuals that use or come into contact with animals or their unfixed tissues. ^H
- C. Animal Use Protocol (AUP) – A cumulative description of all proposed animal species, numbers and procedures to be used or conducted over three years.
- D. Animal Welfare Assurance (Assurance) – The documentation from an institution assuring institutional compliance with the PHS Policy.

¹ Refers to tissue acquired from an animal euthanized solely for the purpose of research or teaching

² Biomedical research is any research not related to farm production of livestock species

- E. Animal Facility – Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment area outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours. ^D
- F. Attending Veterinarian (AV) –
1. The veterinarian responsible for the program of health and wellbeing of all laboratory animals used at the institution. ^H
 2. The AV must have graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education or have a certificate of equivalence issued by the American Veterinary Medical Association, have received training and/or experience in the care and management of the species being attended, and have direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary of Agriculture of the United States or his representative who shall be an employee of the Department. ^D
- G. Field Study
Research or teaching that is conducted in natural settings at locations that are not part of UC Berkeley's campus facilities (as designated in the Assurance) or a designated satellite facility overseen by OLAC are considered to be field studies.

For purposes of IACUC review and reporting, field studies include use of free-living animals as well as animals housed in captivity at locations other than those described above.
- H. Institutional Animal Care and Use Committee (IACUC) – The group responsible for assessment and oversight of the institution's ACUP and animal facilities. ^{D, H} This committee consists of at least five members, including an Attending Veterinarian (or his/her designee if more than one veterinarian is employed by the institution), Chair, nonaffiliated member, scientist and nonscientist. At UCB, this committee is identified as the Animal Care and Use Committee (ACUC).
- I. Institution – Any public or private organization, business, or agency (including components of Federal, state, and local government ^J).
- J. Institutional Official (IO) –
1. The individual who, as a representative of senior administration, bears ultimate responsibility for the ACUP and is responsible for resource planning and ensuring alignment of ACUP's goals with the institution's mission. ^H
 2. An individual who signs, and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of the PHS Policy will be met. ^J

- K. Office for Animal Care and Use (OACU) – The group that administratively and operationally supports the ACUC and the IO in the execution of his/her duties related to animal care and use at UCB.
 - L. Office for Environment, Health & Safety (EH&S) - The group that provides guidance and support to the institution on hazardous materials and the processes associated with the safe handling and use of the hazards in animal research or teaching. They also advise investigators on the development of field safety plans as appropriate.^H
 - M. Office of Laboratory Animal Care (OLAC) – The academic service unit responsible for veterinary care and maintenance of animals and animal facilities at UCB.
 - N. Research Units – Specialized, interdisciplinary groups that conduct research outside of a single, academic department.
 - 1. *Research Centers and Institutes* (or Organized Research Units) are organized around broad substantive research topics (e.g., Cancer Research Laboratory, Transgenic Core Facility).
 - 2. *Museums* are important research sites on the campus that have large collections in a variety of fields, including anthropology, paleontology and vertebrate biology (e.g., Museum of Vertebrate Zoology).
 - 3. *Field Stations* are remote locations that are ideal for studying reproduction, behavior and ecology.
 - O. Principal Investigator (PI) – Author and individual responsible for the protocol outlining the use of animals in research or teaching.
- IV. Responsibilities
- A. The Institution (UCB)

UCB accepts responsibility for the care and use of animals involved in activities conducted on campus, at campus managed locations, or at other, remote field study locations and for compliance with all applicable provisions of the Animal Welfare Act, PHS Policy, UCB's Animal Welfare Assurance, other federal statutes and regulations, state laws, and institutional policies relating to animals. Furthermore, the Institution has established and will maintain a program for activities involving animals in accordance with the *Guide*. UCB ensures that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with all applicable laws and regulations pertaining to animal care and use.
 - B. Institutional Official (IO)

At UCB, the Chancellor is the Chief Executive Officer and has delegated (in writing) the Vice Chancellor of Research (VCR) to be the IO. The Assistant Vice Chancellor for Research Administration and Compliance (AVC-RAC) is designated (in writing) as Acting IO if the IO is not available. The IO has the authority to appoint ACUC members including the Chair and Vice Chair.

The IO allocates resources that are required for the ACUP to function effectively based on recommendations from the ACUC, OACU, and OLAC. In addition, the IO files reports, communicates with federal oversight agencies, and appoints the Chair, Vice Chair and members of the ACUC.

C. Animal Care and Use Committee (ACUC)

1. The ACUC is appointed in accordance with the PHS Policy and reports directly to the IO through the ACUC Chair. Based on the experience and expertise of its members, this committee is qualified to oversee the institution's ACUP and facilities. The ACUC consists of at least five members, including a veterinarian, Chair, nonaffiliated member, scientist and nonscientist.

2. Program Review

Using the *Guide* as a basis for evaluation, the ACUC semi-annually reviews all aspects of the ACUP to ensure the humane care and use of animals and the safety of the individuals using or coming into contact with animals. More specifically, the ACUP review entails an evaluation of IACUC functions, facility inspections, training program for all individuals who use or care for animals in research, teaching and/or education, occupational health and safety program, veterinary care program, protocol review, recordkeeping, and reporting animal concerns. Based on the ACUP review, a report outlining UCB's compliance status, deficiencies, plans to correct said deficiencies, and written recommendations for the ACUP, facilities, and/or personnel training are presented to the IO on a semi-annual basis.

3. Reviewing Animal Concerns

The ACUC thoroughly reviews reported animal welfare concerns or non-compliances that are brought to the attention of the Attending Veterinarian (AV), AVC-RAC, ACUC Chair and/or OACU Director (see Reporting Suspected Animal Deficiencies policy for additional details). If deemed necessary, a subcommittee may be appointed by the Chair to investigate further the allegation on behalf of the committee. Following discussion of the findings, the ACUC notifies the IO and any other appropriate governing compliance groups or agencies of the outcome.

4. Protocol Review

All proposed uses of live vertebrate animals in research and teaching that are outlined in the Principal Investigator (PI)'s Animal Use Protocol (AUP) are reviewed by the ACUC. Protocol review is done in accordance with procedures described in the Assurance and the annual report to OLAW.

In addition, reviewers also decide whether justifications for animal numbers are reasonable and determine if any request for an exception to the *Guide* is appropriate and adequately documented in the protocol. The ACUC will also evaluate the qualifications of personnel

engaged in the animal activities described and may require additional training or supervision as deemed necessary before approving each individual's participation on the protocol. Based on the outcome of the review, the ACUC will approve, require modifications to, or withhold approval of the protocol. If necessary, the ACUC also has the authority to suspend a protocol if the activities and procedures involving animals do not comply with the PI's protocol, Animal Welfare Act, PHS Policy, the *Guide*, UC policies, and/or UCB's PHS Assurance or policies.

A. Field Study

1. All research or teaching done in the field (i.e. as a field study) requires that an AUP be reviewed and approved by the ACUC unless the activity undertaken is strictly and exclusively observational in nature, such that it will not substantially alter the animals' normal activities or environments.

2. If, during the course of field work for which there is an AUP, the accidental death of an animal occurs, it does not need to be reported to the ACUC. However, the AUP must include a plan that describes how the PI will perform humane euthanasia should a situation arise in which euthanasia is required (i.e. injury).

3. Field studies for which the express, approved purpose is to euthanize animals (e.g., preparation of museum specimens) do not need to report mortalities to the ACUC.

4. Annual reporting of animal use to the USDA/APHIS under the Animal Welfare Act and Regulations **excludes** field studies on free-living wild animals in their natural habitat with the exception of any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study. As such, the ACUC considers the following to be a non-exhaustive list of procedures exempt from annual reporting to USDA/APHIS:

- Humane euthanasia, administered directly or after trapping, for study collection or to address injury as described above.
- Capture for noninvasive measurement, sampling and/or identification followed by release.
- Sedation for safe restraint of an animal undergoing a non-invasive procedure
- Changes to an animal's natural environment (e.g., short-term removal of vegetation) that do not result in lasting behavior alterations.

5. Site Inspections

ACUC is mandated to conduct semi-annual site inspections of all institutional animal facilities, including housing locations (animals held over 12 hours), holding and satellite facilities, laboratories, surgical

suites, procedure rooms and storage space. The *Guide* and the inspection checklist provided by OLAW are used as guidelines for these inspections. Following the inspection, the OACU prepares a report of the evaluations on behalf of the ACUC, which is then submitted to the IO by the ACUC. In addition to semi-annual site inspections, the ACUC in coordination with OACU and OLAC may conduct inspections of any institutional animal facility space at any time.

6. Policies and Guidelines

To ensure compliance with federal regulations, state laws, institutional policies, and best practices, the ACUC may review, approve, or endorse policies and guidelines to manage and facilitate the ACUP.

7. Animal Occupational Health and Safety Program

With the assistance of the OACU and Occupational Health Clinic, the ACUC ensures that individuals coming into contact with or using animals in research or teaching are, at a minimum, enrolled in the Animal Occupational Health and Safety Program (AOHSP).

D. Office for Animal Care and Use (OACU)

1. The OACU participates in, supports, and/or assists the ACUC in the administration of the duties listed above.

2. Reports

The OACU prepares reports to federal agencies (e.g., OLAW, USDA) and accreditation organizations (e.g., Association for Assessment and Accreditation of Laboratory Animal Care International - AAALAC) on behalf of the ACUC and UCB.

3. Training

The OACU facilitates new member orientation for the ACUC as well as general compliance training for animal users. In addition, the OACU conducts continuing education sessions for ACUC members, notifies ACUC members of pertinent continuing education opportunities (e.g., webinars presented by professional associations, workshops, and compliance conferences that are sponsored by external entities), and may conduct outreach training to Investigators as needed.

4. Developing Contingency Plan

In conjunction with the veterinarians in the Office of Laboratory Animal Care (OLAC), and the Office of Emergency Preparedness, the OACU, alongside the ACUC, is charged with developing a contingency plan for natural disasters and criminal activity (e.g., personnel harassment, facility trespassing). Implementation of said plan is the shared responsibility of the AV, the ACUC, the OACU, and the campus Emergency Operations Center.

5. Communication

To update PIs on topics relevant to animal care and use on campus, the OACU disseminates information through newsletters, the ACUC website, and/or emails to various groups.

The OACU is the front line of contact with the public, investigators, and ACUC members, and does all administrative work in support of and on behalf of the ACUC.

E. Office of Laboratory Animal Care (OLAC)

1. OLAC is an academic service unit consisting of veterinary staff (including the Attending Veterinarian) and husbandry staff. The functions of OLAC include daily animal husbandry, veterinary care, the provision of research services, surgical assistance and monitoring, purchase of all live vertebrates, purchase and disbursement of controlled substances, and training of research technical personnel who use vertebrate animals in research or teaching.
2. Attending Veterinarian (AV)
 - a) The Director of OLAC is the AV and is responsible for the day-to-day management of the ACUP. The AV is a voting member of the ACUC and reports directly to the IO, who has overall responsibility for the ACUP. The AV has authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use, including access to all institutional animals and their records at all times as well as management the resources that maintain the health and wellbeing of animals used in or at the institution.
 - b) The AV is responsible for the management and assignment of animal space to investigators.
 - c) The AV ensures compliance with applicable federal regulations and policies, including overseeing the following:
 - (1) Availability of appropriate facilities, personnel, equipment and services to ensure animal welfare;
 - (2) Appropriate methods are available to prevent, control, diagnose, and treat diseases and injuries;
 - (3) Availability of emergency, weekend, and holiday care; all animals are observed daily to assess their health, behavior, and well-being and information regarding these issues is conveyed to AV in a timely manner;
 - (4) Guidance to principal investigators regarding procedures, appropriate animal models, and therapeutics for handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and,
 - (5) Adequate pre-procedural and post-procedural care complies with current established veterinary medical procedures.

3. Veterinary Staff

a) Veterinary Care

Under the authority of the AV, the veterinary and husbandry staff ensure the health and wellbeing of animals housed and/or used by UCB researchers by providing daily observation, veterinary care and oversight of all animals. Research support services and procedure-specific training are offered to ensure that all personnel using or coming into contact with animals is appropriately qualified. The ACUC may require that veterinary and husbandry staff certify individuals' competency to perform specific procedures or tasks.

b) Protocol Advice and Review

Veterinarians advise and participate in protocol reviews to ensure the ethical use of animals while minimizing pain/distress as well as the numbers of animals used.

c) Site Inspections

As stated above, the veterinarians may, as members of the ACUC, participate in semi-annual inspections of institutional animal facilities, including housing, holding and satellite facilities, laboratories, surgical suites, and procedure rooms.

d) Drafting Guidelines and Standard Operating Procedures (SOPs)

The veterinarians are responsible for the development and distribution of explicit instructions (i.e., SOPs) as well as a more general framework of principles (i.e., guidelines) for routine animal-related procedures conducted on campus.

F. Animal Occupational Health and Safety Program (AOHSP)

1. The AOHSP is managed by the Occupational Health Clinic, which consists of trained Occupational Health Specialists and physicians who are knowledgeable about the health and safety risks associated with the use of hazardous agents and animals.
2. Following review of completed Occupational Health Surveillance System (OHSS) risk assessment forms, this office may recommend or require (depending on the species and/or hazards used) additional safeguards (e.g., medical surveillance programs) for animal users. After this initial evaluation, all individuals using or coming into contact with animals or animal products will undergo an annual medical assessment (see Animal Occupational Health and Safety Program Policy for details).

G. Office of Environment, Health and Safety (EH&S)

1. Within the ACUP, EH&S provides guidance on the safe handling and use of hazardous materials or operations, such as biological agents (e.g., recombinant DNA, infectious agents, human specimens or cell

lines), chemical agents (e.g., carcinogens, toxins and mutagens), controlled substances, radioisotopes or radiation-producing machines (e.g., X-rays), and physical hazards (e.g., lasers, noise, needles), as well as exposure monitoring (e.g., isoflurane) in animal research or teaching.

2. Document Review

- a) EH&S reviews protocols to assess the use of hazardous agents, chemicals, operations, or compounds indicated for use *in vitro* and *in vivo*, ensures that appropriate SOPs for handling such items are in place, and determines if approved Biological Use Authorizations (BUAs) or Radiation Use Authorizations (RUAs) are in place prior to AUP approval when appropriate.
- b) EH&S assists with the development of field safety plans for AUPs that include field research.
- c) EH&S identifies PIs that need to be enrolled in the Campus Controlled Substance Program prior to being allowed to procure and work with Drug Enforcement Administration (DEA) - regulated controlled substances.

3. Site Inspections

A representative from this office may also participate in site inspections of all institutional animal facilities. In particular, these representative ensure that controlled drugs are documented and stored as required.

4. Equipment

Through the appropriate campus department or contractor, this office provides testing of fume hoods, biosafety cabinets, fire extinguishers, eyewashes and safety showers for verification of proper maintenance. In addition, guidance on proper personal protective equipment (PPE) and respiratory fit testing is available as indicated.

5. Training

EH&S, in conjunction with OLAC, provides facility orientations and training for individuals working with hazardous materials, as applicable (e.g., bloodborne pathogens, biosafety level 3 training; see Training and Education Policy for details).

H. Research Units

Research Units report to the Vice Chancellor of Research and may use animals as part of the research programs that they promote.

I. Principal Investigators (PI)

1. Overall responsibility

- a) As the individual with ultimate responsibility for the use of animals covered by their protocol, the PI must abide by all

- applicable laws, policies and regulations, including the Animal Welfare Act, the *Guide*, the PHS Policy, as well as all relevant UC and UCB policies and procedures regarding the humane use of vertebrate animals in instruction and research.
- b) The PI must ensure that their research receives appropriate review and approval from all applicable oversight committees (e.g., ACUC, radiation safety, biosafety, stem cell research oversight committee).
 - c) The PI is responsible for knowing when his/her protocol(s) expires and ceasing all animal work immediately if a protocol expires.
 - d) The PI must abide by all regulations governing the importation, collection and/or maintenance of wild species, including obtaining permits from all applicable regulatory agencies prior to the acquisition of animals. Likewise, the PI must ensure that biological material (e.g. antibodies or specialty strains of rodents) received for research under a Material Transfer Agreement must be duly processed through the Industry Alliances Office.
 - e) The PI is accountable for ensuring the safety and training of all personnel on his/her protocol, including training in all procedures listed in their AUP. All procedures involving live animals are performed under his/her authority.
 - f) The PI is responsible for reporting incidents of non-compliance, adverse events, unanticipated problems or complications, and animal welfare concerns. Such events must be reported to the ACUC Chair, Attending Veterinarian, or the OACU Director in a timely manner.
 - g) The PI is responsible for monitoring and for initiating corrective action related to the condition and maintenance of the facilities identified in their AUP as sites for research or teaching involving animals unless that space is designated as being the responsibility of the OLAC (see Principal Investigator Responsibilities policy for more detail).

2. Protocol Submission, Content, and Compliance

- a) The AUP must be submitted, reviewed and approved before any work with animals begins. Changes to an AUP must be submitted, reviewed and approved before implementation. The approved AUP should accurately describe current and proposed activities during a given three-year (de novo) approval period (see Policy and Procedures on Protocol Review for details).
- b) AUPs submitted online via eProtocol on behalf of a PI must document on the Certification Page the PI's acceptance of his/her responsibilities.

- c) In eProtocol, only the PI of a grant can identify and add the sources of funding that support the research, teaching and/or experimentation described in a protocol. Such funding or support must be accurate to enable ACUC/OACU to certify to funding agencies the congruence between said protocol and associated grants. There does not need to be a one-to-one match between a protocol and a funding source.

3. Personnel

- a) The PI must ensure that all individuals listed on the personnel sheet for their protocol and that come into contact with animals have read and understood the AUP.
- b) All individuals having direct contact with live vertebrate animals, including the PI, must be trained in humane and scientifically acceptable procedures for animal handling, administration of therapeutic drugs and euthanasia, as required by the procedures described in the protocol.
- c) The PI or other designated individual must provide and document hands-on training in relevant procedures as well as assess competency prior to allowing individuals to work independently.
- d) Prior to using live vertebrate animals, all personnel, including the PI, must complete the required training outlined in the ACUC's Training and Education policy as well as any procedure-specific training required by the ACUC.
- e) The PI will ensure that all individuals with animal or animal product contact are enrolled in the AOHSP and that all persons working with animals under his/her supervision are made aware of and enroll in this program.

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