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| Version: 1.2 Effective Date: 4/10/2019 | PRINCIPAL INVESTIGATOR RESPONSIBILITIES | Supercedes Document Dated: 6/1/2017 |
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I. Background

A Principal Investigator (PI) must have the experience, professional qualifications, and access to the research facilities and resources necessary to ensure the proper care and use of vertebrate animals in research and/or education. This individual must accept the responsibility as PI to conduct research or to teach using vertebrate animals at UC Berkeley.

It is a privilege, not a right, to use animals in research. All parts of the animal use community - PIs, research staff, students, the Animal Care and Use Committee (ACUC) and the Institutional Official (IO) – share a responsibility to protect UC Berkeley's ability to use animals in research and teaching.

II. Policy

Individuals who have been granted PI status (either on the basis of their employment status or because they have been granted such privileges by exception) or who are Instructors of Record accept responsibility for the ethical use of animals in research and/or teaching including appropriate design, execution, and management.

III. Definitions

- A. Animal Use Protocol (AUP) – A cumulative description of all proposed uses of animals as well as all species and the number of animals per species to be used over a maximum of three years.
- B. Principal Investigator (PI) –
 - 1. An individual who holds a qualified Berkeley campus appointment and is eligible under University policy to submit proposals for extramural support of a research, training, or public service project, and/or to teach or perform research involving animals. This individual has primary responsibility for the design, execution, and management of a research project or is the instructor of record for a course.
 - 2. Students may not act as PIs even if they are PIs on grant applications. The student's mentor or another individual must meet the above-mentioned requirements for eligibility and must be named as the PI on the associated AUP.
- C. Exceptional Principal Investigator (PI) – An individual who is a UC Berkeley employee and who is eligible under University policy to submit proposals for extramural support of a research, training, or public service and to teach or perform research involving animals. Requests for Exceptional PI status are granted by the Chancellor or his/her delegated representatives to individuals who do not have PI status but will have primary responsibility

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over the design, execution, and management of a research project and who will be involved in the project in a significant manner.

- D. Instructor of Record – An individual who is designated as the Instructor of Record for an academic course involving the use of live vertebrate animals, including courses that involve field studies or field trips.

IV. Applicability

- A. This policy applies to all individuals listed on an AUP as PI. To be considered a PI, UC Berkeley acknowledges the appointments and exceptions outlined in the University of California, Berkeley's policy, entitled "Policy on Eligibility for the Submission of Extramural Support Proposals and Procedures for Obtaining Exceptions".
- B. Only the Course Instructor of Record can serve as PI on a teaching AUP.

V. Responsibilities

A. Overall PI responsibilities

1. Abide by and personally ensure that all individuals named on their AUP abide by the applicable laws, policies and regulations including, but not limited to:
 - a) The US Department of Agriculture (USDA)'s Animal Welfare Act and Regulations (AWA/AWR);
 - b) The current *Guide for the Care and Use of Laboratory Animals (Guide)*;
 - c) The Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy);
 - d) UC Berkeley's Animal Welfare Assurance;
 - e) All UC System and UC Berkeley policies and guidelines regulating the humane use of live vertebrate animals in instruction and research, including occupational health and training requirements; and,
 - f) The Regents of the University of California Standards of Ethical Conduct.
2. Ensure that the transportation, care and use of animals is in accordance with the appropriate regulations, policies and guidelines.
3. Abide by all regulations governing the importation, collection and/or maintenance of wild species, and obtain permits from all applicable regulatory agencies prior to the use of animals (if necessary).

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4. Acknowledge that the failure to comply with federal, state, or local regulations on animal use or with university and IACUC policies and procedures may result in suspension of the approved protocol and notification sent to the regulatory agencies and PI funding agencies.
 5. Ensure that all procedures are conducted in accordance with UC Berkeley safety procedures, including those pertaining to personal protective equipment and health.
 6. Ensure that all personnel on protocol are appropriately trained and said training is documented, particularly if said training not provided by the OLAC Trainer or veterinary staff.
- B. Protocol Submission, Content, and Compliance
1. Submit an AUP that accurately describes proposed activities during a given three-year (*de novo*) approval period (see Policy and Procedures on Protocol Review for details). The AUP must be reviewed and approved by the ACUC before any work with animals begins.
 2. AUPs submitted online via eProtocol on behalf of a PI must document on the Certification Page the PI's acceptance of his/her responsibilities as PI.
 3. In eProtocol, the PI will identify and add information regarding sources of funding that support the research, teaching and/or experimentation as described in the protocol. If the PI of the protocol is not the PI on the award, then the PI of the protocol must add the PI of the award to the protocol in a role to enable the award PI to add the funding to the protocol. Such funding or support must be kept current and accurate to enable UCB/ACUC to certify congruence between said protocol and an award to funding agencies. There does not need to be a one-to-one match between a protocol and a funding source.
 4. Ensure that all changes in animal care and use - including any change in the personnel listed on the protocol - are submitted promptly to the ACUC/OACU for review and approval as an amendment prior to beginning the work or allowing new researchers to begin working.
 5. Design and perform procedures that:
 - a) Are relevant to human or animal health, advancement of knowledge, or the good of society;
 - b) Use the appropriate species, quality, and number of animals to obtain valid results;
 - c) Avoid or minimize discomfort, distress, and pain in concert with sound science;
 - d) Use appropriate sedation, analgesia, or anesthesia; and,
 - e) Use established experimental end points.

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6. Demonstrate that all proposed uses of animals are not unnecessarily duplicative of work done by yourself or others.
 7. Review pertinent scientific literature and/or databases to determine if valid alternatives to any procedures described in the AUP causing more than momentary or slight pain, distress, or generalized discomfort to animals (whether it is relieved or not) do not exist and are not appropriate
 8. Document that the number of animals requested is the minimum number required to address the scientific questions. This justification of numbers should be based on statistical analysis if possible. Pilot studies or initial study design based on published data may not require statistical justification.
 9. Conduct only the procedures and projects outlined in the most recent version of the ACUC-approved protocol.
 10. Complete (if applicable) the appropriate documentation for annual review in eProtocol (see policy on Protocol Review) to remain compliant.
 11. Respond in a timely manner to questions and comments from the ACUC or Office for Animal Care and Use (OACU).
 12. Report non-compliances, 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 as per the ACUC guideline, "Reporting Suspected Deficiencies or Concerns in Animal Care or Treatment".
- C. Use of Animals
1. Treat all animals—alive or dead—with respect.
 2. Acknowledge the definition of a vertebrate animal as outlined in the ACUC "Animal Care and Use Program Policy", Public Health Service (PHS) Policy and the Animal Welfare Act and Regulations.
 - a) Animals at or beyond the life stages identified in those documents must be included and approved in the PI's AUP prior to use.
 - b) If the PI uses animals that do not meet those criteria, a contingency plan must be established in case the animals develop beyond those stages.
 3. Abide by the procedures outlined in the approved AUP, ensuring that animals are obtained from approved sources and that the procedures detailed in the protocol are followed with precision.

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4. Conduct experiments on living animals only under the close supervision of qualified and experienced persons or ensure that only trained, qualified and experienced personnel conduct the experiments.
5. If PI care is approved by the ACUC, provide appropriate animal husbandry or ensure that qualified lab personnel provides such appropriate animal husbandry.
6. Ensure appropriate monitoring of all animals.
7. Notify the veterinary staff immediately if any animal health concerns arise, including unanticipated pain, distress, morbidity or mortality.
8. Maintain complete records and documentation appropriate to the type of research, including up-to-date and accessible animal health records.
9. Designated animal areas
 - a) Abide by the ACUC "Admission of Visitors to Animal Facilities" policy when receiving visitors and, if necessary, obtain permission from appropriate parties.
 - b) Monitor and initiate corrective action related to the condition and maintenance of the rooms designated on their AUP (unless the space is otherwise designated as OLAC's responsibility).
 - c) Ensure that sound generators (e.g., radios, alarms, cell phone ring tones) are not used in animal facilities unless approved as part of an enrichment program or are approved by ACUC as an exception to the Guide in the PI's AUP. Portable media devices with in ear headphones (buds) may be used. For safety reasons, only one ear bud may be used and volume must be low enough that the device does not disturb the animals and is not audible to people from either the used or unused ear bud.
 - d) Ensure that the use of media in animal facilities or labs adheres to the ACUC policy on such media recording and use.

D. Personnel and training

1. Cooperate with OLAC, ACUC and other investigators to ensure that only individuals with appropriate authorization have access to UCB animals and animal facilities.
2. Ensure and document that all individuals named in the personnel sheet have completed the basic and/or refresher training outlined in the ACUC "Training & Education" policy as well as procedure-specific training as needed and/or required by the ACUC
3. Certify and document that all individuals having direct contact with live vertebrate animals, including the PI, are trained in humane and scientifically acceptable procedures for: animal handling, surgical

techniques; administration of anesthetics, analgesics and/or therapeutic drugs; and, euthanasia.

4. Unless otherwise assigned (e.g., OLAC), provide adequate hands-on training and assess competency prior to allowing individuals to work independently.
5. Maintain training documentation (e.g., procedures, euthanasia, husbandry) for all personnel.
6. Ensure that a paper copy or online access of the approved protocol and any subsequent modifications is available to all laboratory personnel.
7. Animal Occupational Health and Safety Program (AOHSP)
 - a) Create a Risk Assessment for each lab member on an AUP using the Occupational Health Surveillance System (OHSS).
 - b) Confirm that any individual who fits the criteria below is enrolled and participates in the medical surveillance program through the Occupational Health Clinic:
 - (1) At potentially higher risk due to their specific animal work (e.g., exposure to certain viruses) and/or pre-existing medical conditions (e.g., asthma)
 - (2) Work with non-human primates (NHPs) and/or bats.
 - (3) Work with animals and specific biohazardous agents (e.g., tuberculosis) in a Biosafety Level 3 facility.
 - c) Enrollment in the AOHSP is mandatory and further participation may be based on an individual's health status and animal exposure(s) as well as any changes that might occur in these two aspects during the course of a year that would determine the frequency of follow-up in this program. (See AOHSP Policy for more detail).

E. Hazardous agents

1. Submit Biological Use Authorizations (BUAs), Radiation Use Authorizations (RUAs), Laser User Registration (LUR), and any other forms/applications required for the use hazardous agents. These documents must be reviewed and approved before any work with animals begins. Amendments must be approved before implementation. The approved documents must describe the proposed activities during a given three-year (de novo) approval period.
2. Cal/OSHA ([Title 8 CCR Sec. 5191](#)) requires that all laboratories have a written Chemical Hygiene Plan as a fundamental chemical safety

plan for the laboratory. For more details see:
<https://ehs.berkeley.edu/chemical-safety>

3. PIs and everyone who handles controlled substances in the course of research or instruction at the University of California, Berkeley must follow the procedures outlined in the Controlled Substances Policy to ensure compliance with the terms and conditions of the campus institutional Drug Enforcement Administration (DEA) registration. See <https://ehs.berkeley.edu/controlled-substances> for more details.

F. Miscellaneous

1. Ensure that research receives appropriate review and approval from all applicable oversight committees (e.g., radiation safety, biosafety, stem cell research oversight committee).
2. Biological material (e.g. antibodies or specialty strains of rodents) received for research under a Material Transfer Agreement as well as research agreements with company sponsors that will use animals must be duly processed through the Industry Alliances Office.

VI. References

- A. University of California Office of the President, Office of Ethics, Compliance & Audit Services. "Statement of Ethical Values & Standards of Ethical Conduct". Retrieved 15 November 2012, from <http://www.ucop.edu/ethics-compliance-audit-services/files/stmt-stds-ethics.pdf>
- B. National Institutes of Health, Office of Laboratory Animal Welfare. [What Investigators Need to Know about the Use of Animals](#)
- C. [United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.](#)