

## Use of Vertebrate Animals in Research and Teaching

### Research Policy

#### *Section IV.B. - Research Responsibilities: Animal Subjects*

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#### Background

All research activities performed by, or under the direction of, UCI personnel in the course and scope of University duties, or which use University resources, must comply with applicable UCI policies and procedures, regardless of funding and whether performed in UCI facilities or at offsite locations. The approval requirements for offsite research activities are delineated in the UCI *Offsite Research Activities* policy.

#### References

- A. Animal Welfare Act, 1966 [USC Title 7, Sections 2131 to 2156] as amended in 1970, 1976, 1985 and 1990.
- B. Animal Welfare Regulations [Title 9 CFR, Subchapter A, Animal Welfare, Parts 1, 2 and 3]
- C. Health Research Extension Act, 1985 [Public Law 99-158, November 20, 1985, Section 495]
- D. US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, 1985
- E. PHS Policy on Humane Care and Use of Laboratory Animals, 1986

- F. 2000 Report of the AVMA Panel on Euthanasia [JAVMA, Vol 218, No. 5, March 1, 2001]
- G. Guide for the Care and Use of Laboratory Animals (*Guide*) [NRC, 5<sup>th</sup> Ed., 1996]
- H. NIH Grants Policy Statement (03/01), Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General -- Part 2 of 7
- I. University of California Policy on the Use of Animals in Research and Teaching, October 15, 1984
- J. University of California, Irvine Animal Welfare Assurance of Compliance (A3416.01), March 1, 1998
- K. University of California, Irvine Academic Personnel Manual (APM 240)
- L. University of California, Irvine Sponsored Projects Administration Manual, (III-E) Deans, Chairs and Directors

### **Purpose**

It is the purpose of this policy to enumerate the specific requirements, roles and responsibilities for the use of live vertebrate animals in research, experimentation, biological testing, teaching, or for related purposes, hereinafter referred to as "Activities", in order to assure that any use of animals conforms to the ethical and humane standards for animal care and use, federal statutes and regulations, policies and guidelines; and applicable University policies and procedures.

### **Definitions**

- A. Offsite: Occurring outside of UCI owned, operated, or leased facilities (including international sites). For purposes of research oversight, private facilities located on UCI land are considered offsite locations.
- B. UCI facilities: Facilities owned, operated, or leased by UCI including UCI campus, UCIMC, and any space rented to the University.
- C. UCI personnel: UCI students, staff, and faculty (including part-time, emeritus, and volunteer faculty), or any other agents of UCI.
- D. UCI resources: Funds, facilities, employee time, equipment, supplies, services, and non-public information.
- E. University duties: Responsibilities assigned by the University or tasks performed to meet expectations of one's employment, affiliation, appointment, or academic program.

## **Applicability**

Any activity involving the use live vertebrate animals performed by or for UCI are covered under this policy if it satisfies any of the following criteria.

- A. It is conducted by or under the direction of UCI personnel in connection with his or her UCI responsibilities;
- B. it uses UCI property, facilities or resources to support or carry out the research;
- C. the name of the University of California, Irvine is used in applying for funds (intra or extramural);
- D. the investigator plans to use his/her University of California, Irvine association in any publication or public presentation resulting from the research.

## **Policy**

In order to demonstrate appropriate oversight of animal care and use activities and to comply with federal regulatory agency requirements, no animal care or use activities shall be initiated by UCI personnel prior to obtaining IACUC review and approval or offsite registration.

The UCI IACUC has the authority to approve animal care and use activities that are proposed to occur in UCI facilities, use UCI resources, or are performed at or in collaboration with offsite locations.

Any other applicable regulatory committee approvals (e.g., IRB, IBC, COIOC) and completion and/or receipt of all other necessary documentation is required prior to the initiation of any animal activity.

Animals for research, teaching or testing shall be purchased through ULAR or otherwise acquired with ULAR approval. Non-standard purchasing or acquisition of animals shall be described in the protocol and approved by the IACUC. All animals are subject to health assessment and quarantine by ULAR staff upon arrival at UCI.

Studies funded by outside entities, such as drug or device companies, require an agreement between the University and the company. If UCI will receive compensation for conducting or directing a research activity, a contract must be established through UCI Sponsored Projects Administration. When contracts or other agreements are required, the language is to be developed and negotiated by UCI Sponsored Projects Administration staff to document UCI's responsibilities for the conduct of the specific project.

## **Organizational Structure and Responsibilities**

## **A. Institutional Official**

The UCI Chancellor has delegated responsibility for compliance with applicable federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal care and use activities to the Vice Chancellor for Research.

The Vice Chancellor for Research is the designated Institutional Official (IO) and is assisted in the discharge of this responsibility by the Institutional Animal Care and Use Committee (IACUC), the Attending Veterinarian, and staff in the Office of Research Administration (ORA). The IO supports, facilitates, and promotes ethical and humane use of animals by demonstrating institutional commitment to uphold the standards set forth in the federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal activities.

The IO has the authority to establish campus policy for the use of animals and to disapprove, suspend or terminate Institutional Animal Care and Use (IACUC) protocols.

The IACUC reports, through its Chair, directly to the Vice Chancellor for Research. Nominations for membership on the IACUC are submitted to the Vice Chancellor for Research who reviews the qualifications of the nominees and makes the appointments. The Vice Chancellor also appoints the Chair and Vice Chair.

The Attending Veterinarian reports directly to the Vice Chancellor for Research regarding animal program issues.

The Vice Chancellor for Research designates the ORA as the office of record for the UCI animal care and use program. All records maintained by ORA are stored for least three years following the end of the study.

## **B. Institutional Animal Care and Use Committee (IACUC)**

The IACUC is the institutional body with responsibility for review and oversight of UCI's program for the humane care and use of animals. The IACUC supports, facilitates, and promotes ethical and humane use of animals by upholding the standards set forth in the federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal activities.

The IACUC is authorized to resolve concerns involving the care and use of animals brought to the attention of the committee by ULAR veterinarians, researchers, animal caretakers or others.

In accordance with PHS Policy, the Committee must consist of no fewer than five members, including a Veterinarian with direct or delegated program responsibility for activities involving animals, one practicing scientist experienced in research involving animals, one member whose primary vocation is in a non-scientific area, and one member

unaffiliated with the institution. In accordance with animal welfare regulations, not more than three members of the Committee shall be from the same administrative unit.

The IACUC oversees UCI's animal program, facilities, and procedures, and provides comprehensive reviews of research activities involving animals. The IACUC's specific responsibilities are to:

1. Review at least once every six months UCI's animal care and use program.
2. Inspect at least once every six months UCI's animal facilities, laboratories, and other areas where animals are used.
3. Prepare and submit reports of IACUC program evaluations and facility inspections to the Vice Chancellor for Research.
4. Review and approve, require modifications in (to secure approval) or withhold approval of proposed and continuing animal activities described in animal use protocols.
5. Review and approve, require modifications in (to secure approval) or withhold approval of all proposed changes (modifications) to approved animal activities.
6. Notify investigators in writing of its decision to approve, require modifications in (to secure approval) or withhold approval of proposed animal activities.
7. Review, and, if warranted, investigate concerns involving the care and use of animals in accordance with UCI's *Policy and Procedures for Resolving Regulatory Noncompliance*.
8. Suspend animal activities that are not being conducted in accordance with applicable federal statutes and regulations, policies and guidelines, and applicable University policies and procedures.
9. Make written recommendations to the Vice Chancellor for Research regarding any aspect of the UCI animal care and use program.

### **C. IACUC Chair**

The IACUC Chair is appointed by the Vice Chancellor for Research and is responsible for ensuring the IACUC performs its functions as outlined in the Animal Welfare Act, PHS Policy, and the University's Animal Welfare Assurance. The Chair also acts as liaison with the IO on behalf of the IACUC.

The Chair has the authority, on behalf of the IACUC, to halt any animal activity if the safety or welfare of an animal appears to be at risk, or if the work being performed on a project is not in accordance with the approved protocol. The Chair also has the

responsibility to address, in a timely fashion, any serious or repeated problems, concerns, complaints or allegations regarding the care and use of animals.

#### **D. Attending Veterinarian**

The Attending Veterinarian serves as a voting member of the IACUC. The Attending Veterinarian is the Director of University Laboratory Animal Resources (ULAR) and is responsible for UCI animal facility management.

The primary responsibility of the Attending Veterinarian is to assure that adequate veterinary care and husbandry is provided to all animals housed and used in UCI facilities. Adequate veterinary care includes programs of disease detection and surveillance, prevention, diagnosis, treatment, and resolution.

The Attending Veterinarian (or designee) is authorized to enter any UCI facility to conduct inspections of animal facilities and animals to ensure that animal husbandry, sanitation practices, and animal health and research techniques are in compliance with federal statutes and regulations, policies and guidelines; and applicable University policies and procedures.

The Attending Veterinarian's (or designee's) specific responsibilities are to:

1. Monitor the care and use of animals in UCI facilities.
2. Provide technical assistance and training to all UCI personnel involved in animal activities, including selection and procurement of animals, husbandry and care, handling and restraint, identification and records, animal health and welfare, employee safety and health concerns, specific experimental and surgical techniques and euthanasia.
3. Assist investigators with protocol preparation pertaining to animal housing, requirements for surgery, proper use of anesthetics, analgesics, and tranquilizer drugs, methods of euthanasia and other animal health and welfare issues.
4. Halt any animal activity if the safety or welfare of an animal is at risk or if the work being performed is not in accordance with an IACUC approved UCI animal use protocol.
5. Report animal welfare concerns and/or possible non-compliance to the IACUC.

#### **E. Office of Research Administration (ORA)**

The ORA staff support and coordinate all of the activities of the IACUC and serve as the liaison between the IACUC, ULAR and the UCI research community. The ORA's specific responsibilities are to:

1. Facilitate the protocol review process.

2. Communicate to investigators in writing, on the behalf of the IACUC, all committee decisions and actions.
3. Provide training, education, and consultation services on regulatory requirements.
4. Communicate to the IO any study-related issues that are likely to present risks or other concerns for the institution.
5. Communicate with other UCI administrative units and regulatory committees.
6. Conduct administrative audits (reviews) of alleged occurrences of regulatory noncompliance in collaboration with the IACUC in accordance with campus policy.
7. Assist the IACUC in the conduct of regulatory committee reviews in accordance with campus policy.
8. Report to the IO and governmental agencies any significant problems or violations of federal regulations, IBC requirements, or suspension or termination of IACUC approval.

**F. Lead Researcher**

1. Eligibility

Individuals who meet the criteria for Principal Investigator by virtue of their University appointment status may also serve as Lead Researcher on a research protocol. Individuals who do not meet the criteria for Principal Investigator may serve as Lead Researcher if they obtain a Faculty Sponsor for the activity. The Faculty Sponsor must be eligible to be a Principal Investigator. Refer to the UCI *Responsibilities for Conduct and Administration of Research* policy for further information concerning Lead Researcher eligibility.

2. Responsibilities

The Lead Researcher (and Faculty Sponsor, when required) is responsible for full compliance with all federal statutes and regulations, policies and guidelines, and applicable University policies and procedures concerning animal activities. This responsibility extends to all aspects of animal care and use and all co-investigators and research personnel who participate in the animal activity. Although the Lead Researcher may choose to delegate aspects of animal care and use to other laboratory personnel or faculty in his/her laboratory, the Lead Researcher retains ultimate responsibility and is accountable for all animal activities performed under their protocol(s).

All IACUC approvals will be granted for periods not to exceed one year. Annual renewal of IACUC approval is the responsibility of the Lead Researcher.

The Lead Researcher's specific responsibilities are to:

- a. Apply for IACUC approval or offsite registration prior to the commencement of any live vertebrate animal care or use activity and initiate animal care or use activities only after written IACUC approval is provided.
- b. Recognize that IACUC approval, in and of itself, does not necessarily constitute permission for implementation of animal use projects. Accordingly, the project should not begin until all required approvals have been obtained.
- c. Purchase any animals to be used at UCI through ULAR or arrange with ULAR for non-standard acquisition of animals.
- d. Make no changes to the approved protocol without first having submitted those changes for review and approval by the UCI Institutional Animal Care and Use Committee.
- e. Provide the IACUC with any information requested relative to the care and use of animals.
- f. Comply with an IACUC decision to suspend or withdraw its approval for an animal activity.
- g. Obtain continuing approval prior to the expiration date approval of the study and recognize animal activities must cease until current IACUC approval is obtained.
- h. File a closing report with the UCI IACUC at the conclusion of the study.
- i. Ensure all personnel having direct live animal contact have been or will be trained in applicable humane and scientifically acceptable procedures for animal handling, administration of therapeutic drugs and euthanasia prior to beginning any procedures with live animals.
- j. Maintain and make available for inspection by the IACUC, Attending Veterinarian and federal agency inspectors all IACUC protocol and animal care and use records in accordance with federal regulations.

**G. Deans, Directors, Department Chairs, Division Chiefs, Section Heads**

College or school deans, department chairs, and program or ORU directors are accountable for the performance of animal activities performed by investigators under their supervision, including the scientific and financial management of sponsored projects. Specific responsibilities related to this accountability vary in accordance with various academic

organizational arrangements. No distinction is made between these roles unless specified. The basic responsibilities include:

## 1. Research-Related Academic Administration Responsibilities

- a. **Deans, Directors, and Chairs:** Report any failure of a faculty or staff member to carry out their animal care and use responsibilities and recommend appropriate disciplinary action.
- b. **Deans:** Responsible for ensuring Chairs assume their responsibilities.
- c. **Directors:** Responsible for oversight of all animal care and use activities performed within their research unit.
- d. **Medical Center Director:** Shares the following responsibilities related to research:
  - (1) costs are appropriately projected and covered by available resources,
  - (2) records management is in accordance with federal, state and University requirements,
  - (3) assumption of responsibility for research by those with non-faculty appointments.
- e. **Chairs:** Have the following responsibilities related to research:
  - (1) departmental observance of proper health and safety regulations,
  - (2) maintenance of records and preparation of reports in accord with University procedures,
  - (3) review of annual disclosure of outside activities of academic appointees as required.

## 2. Responsibilities to Regulatory Committees

- a. **Chairs:** Responsible for review of animal protocols prior to submission to the IACUC to determine that the investigator is eligible and competent to perform the activity or supervise it.
- b. **Chairs:** Maintain a current inventory of the department's animal use activities, including protocol number, and submit this information the Office of Research Administration upon request.
- c. **Chairs:** Require that the Lead Researcher or Principal Investigator provide information on any personal financial interest in the animal protocol before signing the application form.
- d. **Chairs:** Advise the Office of Research Administration within five working days of the reduction to less than 50% appointment of the Lead Researcher.

- e. **Deans and Chairs:** Recommend and encourage faculty members from the department, unit, school, or college to serve on the IACUC.

### 3. Fiscal and Institutional Responsibilities

- a. **Deans:** Administrative responsibilities for a division, college, school or other unit including fiscal responsibility for ensuring systemwide and local policies are observed.
  - (1) Sponsored Projects - Proposals and Awards: Specific responsibilities related to this accountability vary in accordance with various academic organizational arrangements, and are affirmed by the signature in the administrative approval and other project-related forms. Basic responsibilities include:
    - (a) Determining eligibility for Principal Investigator status and requesting approval for exceptions to policy from the VCR when appropriate.
    - (b) Determining consistency of proposed project and subsequent award with the educational, research, and/or public service objectives of the unit.
    - (c) Determining the appropriateness and acceptability of proposed faculty time, space, equipment, and University financial commitments, e.g., released teaching time, cost sharing or matching, equipment screening.
    - (d) Reviewing project costs to ensure appropriateness, realistic projections, and that the source of funding is identified.
    - (e) Ensuring that project performance complies with University policies and sponsor terms.
    - (f) Consulting with the Principal Investigator to resolve quickly a deficit or disallowance incurred under a grant or contract.
  - (2) Internally Funded Research: Accountable for the performance of investigators under their supervision, including scientific and financial management. Specific responsibilities related to this accountability vary in accordance with various academic organizational arrangements. Basic responsibilities include:
    - (a) Determining the investigator is competent to perform the research or supervise it.
    - (b) Determining the appropriateness and acceptability of faculty or staff time, space, equipment, and University financial commitments, e.g., released teaching time, departmental funds.
    - (c) Reviewing research costs to ensure appropriateness, realistic projections and that the source of funds is identified.
    - (d) Ensuring project performance complies University policies.
    - (e) Consulting with the investigator to resolve quickly a projected or actual deficit in an account/fund assigned to the investigator.

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