

**ANIMAL RESEARCH PROCEDURES
IN PATIENT CARE ENVIRONMENTS****RESEARCH**

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I. PURPOSE

To delineate guidelines, policies and practices that safeguard patient and staff health while promoting the humane care of animals used in teaching and testing. To provide information that will enhance animal well-being, the quality of biomedical research, and the advancement of biologic knowledge relevant to humans or animals. To delineate guidelines for the safe use of patient care environments and equipment used to perform for animal research procedures in accordance with federal guidelines, state statutes, university guidelines, Joint Commission on Accreditation of HealthCare Organization standards and medical center safe practices.

II. BACKGROUND

All animal research protocols at UCI are under the auspices of the UCI Animal Care and Use Program under the direct guidance of the federal Animal Welfare Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals, as well as state, local laws and regulations and University policy. Under direction of a UCI campus veterinarian, the University Laboratory Animal Resources (ULAR) establishes methods and procedures for the housing, feeding, care and use of all research animals housed at UCI facilities. The animal program is overseen by the UCI Institutional Animal Care and Use Committee (IACUC).

Additional oversight is afforded through the Occupational Health and Safety Program that focuses on maintaining a safe and healthy workplace by ensuring risks associated with the experimental use of animals are reduced to acceptable levels. The Occupational Health and Safety Program identifies and evaluates potential hazards such as animal bites, chemical cleaning agents, allergens, and zoonoses that are inherent in or intrinsic to animal use. The program is administered by UCI Environmental Health and Safety Office that is responsible for oversight for work performed on the UCI campus and the animal vivarium located in Building 55 at UCIMC. The program includes oversight and safety recommendations for use of animals [zoonoses, allergens, bites and scratches], chemicals, infectious agents, waste disposal and other occupational health hazards.

III. DEFINITIONS

Vivarium: Approved animal housing facility managed by University Laboratory Animal Resources [ULAR]

- Zoonoses: Infectious disease agents shared between animals and humans
- Non-invasive procedure: Any procedure that does not penetrate the body cavity

IV. **POLICY**

- A. The use of any patient care environment to perform research procedures on animals follows specific Medical Center guidelines approved by the Governing Body. *On a case by case basis*, the Medical Center Chief Executive Officer (CEO) grants final approval for use of any patient care clinical environment to perform research procedures on animals approved by the Institutional Animal Care and Use Committee. When the Medical Center CEO is away from the facility, final approval is given by the Chief Medical Officer or a designee named by the CEO. The Infection Control Officer is responsible for providing guidance on decontamination procedures.

NOTE: This policy applies to non-invasive procedures performed on live animals and animal cadaver parts. Invasive procedures shall not be performed on live animals in patient care environments due to risk of zoonoses transmission.

- B. Scheduled animal research procedures will be cancelled by the department should a need for patient use arise.

- C. Additional requirements include the following criteria:

1. Animals shall be obtained from a ULAR-approved vendor;
2. Animals shall be recently examined by a veterinarian [or designee] prior to the procedure and found to be free from apparent signs of clinical infection.
3. Data required for the study shall not be available through any other modality.
4. After approval by the Medical Center CEO, a written request for use of the clinical equipment shall be sent by the investigator to the Chief of the Division providing the service.

- E. This policy pertains to the following sites:

UCI Medical Center*
UCIMC Department of Radiology*
UCIMC Building 55, excluding the ULAR Animal Vivarium*
Gottschalk Medical Plaza*
Beckman Laser Institute*

PET Imaging Center [Irvine campus]
Research Imaging Center [Irvine campus]
UCI/Toshiba CT Education and Research Center [Irvine campus]
MRI Center [Irvine campus]

F. Animal Transport Guidelines

1. An IACUC-approved protocol must accompany animals during transportation and research procedures.
2. All procedures performed on animals, including a description of animal transportation and procedures performed in patient areas, must be described in the approved IACUC protocol.
3. Only animals from the UCI vivarium and IACUC-approved investigator maintained housing areas can be transported to patient care environments.
4. The Director of ULAR, must be notified when animals will be transported to patient care environments for a procedure. Information includes: date of visit, time departing animal housing area and time returning to housing area, approximate time and duration in the patient care environment.
5. When required by study design for animal and human safety, animals shall be sedated and/or anesthetized prior to transport to patient care areas. When required, each animal to be transported must be adequately sedated or, anesthetized with a patent, and unobstructed, airway during the time it is outside of its housing area. The animal duration time within the clinic area is to be pre-approved and the time duration is not to be exceeded.

NOTE: In the event of a clinical emergency or, clinical urgency [clinic area needed for patient use before animal use is completed], with expediency, the sedated/anesthetized animal must be safely removed from the clinic area so as not to compromise clinic use or animal safety.

6. Animal/s transported to the clinic area must be accompanied by the Lead Researcher and/or her/his designee.
7. Any untoward events are to be reported to the IACUC, ULAR, Campus Veterinarian and UCIMC Clinical Research Compliance Officer.
8. Animal transport from the Main Campus [Irvine] must be approved by the Campus Veterinarian and coordinated by ULAR.

NOTE: Species carrying agents that are either highly infectious [e.g., sheep and Q-fever] and/or cause serious disease [non-human

primates and hepatitis B virus] to humans, are not to be transported to, and/or in, the clinic areas.

9. Animal transportation should be planned to:
 - Prevent the risk of zoonoses
 - Minimize the exposure to animal allergens
 - Protect the animals against physical trauma
 - Avoid the visibility of animals to the public
 - Minimize transit time
 - Use service elevators when available. This includes transportation of empty carriers, transport cages, shoebox cages, *etc.*
10. The following guidelines are applicable to animal transportation through public areas:

Requirements for Live Animal Transport Equipment

Animal	Transport Equipment
Cats, dogs, pigs	Covered large animal transport cage with pan for feces and urine collection
non-human primates, sheep	HEPA-filtered, self-contained transport carrier
Rabbits	Covered transport cage
Rodents	Covered transport cage ¹
Dead animals	Shall not be used in patient care environments

¹Isolation gowns and red biohazard bags are ***not acceptable*** for covering rodent cages. Rodents must be transported within a filter-top micro-isolator cage covered from view with a breathable material, such as an opaque cloth drape.

9. Transport Vehicles for Animal Transfer

Contact the ULAR for details concerning animal transport in University vehicles or to arrange shipment by a commercial transport company.

NOTE: *Animal Welfare regulations specify that animal transport vehicles must meet minimal standards. To adequately address these federal guidelines, IACUC and ULAR guidelines require research staff to transfer animals through either ULAR or a commercial company. The use of personal cars to transfer animals is prohibited.*
10. When UCIMC equipment is utilized to perform an animal research procedure, a Medical Center trained technician must operate the equipment. Neither the investigator nor other research staff members will be permitted to operate the equipment.

V. **PROCEDURE**

**RESPONSIBLE
PERSON(S)/DEPT**

PROCEDURE

Principal
Investigator/Co-
Investigator

A. Permitted Use

1. Obtains approval of the Institutional Animal Care and Use Committee [IACUC] for animal research.

NOTE: Only procedures identified in IACUC-approved protocols are to be performed.

2. Determines that research procedure/s is/are non-invasive.
3. Identifies patient care areas to be used when it is not feasible to conduct the procedures outside of a patient care area [*e.g.*, the equipment is not portable and/or the cost to purchase the equipment specifically for animal use is prohibitive].
4. Verifies activities are in compliance with the UCIMC policy and procedure “*Animal Research in Patient Care Environments.*”

Infection Control

- C. Provides guidance, on a case by case basis, for the decontamination of the patient care environment after any clinical equipment or space has been utilized to perform a research procedure on an animal.

Principal Investigator or
Designee

D Room Scheduling and Preparation

1. Notifies the clinic manager at least 2 weeks in advance of the procedure, if possible, of the request to use the equipment and room.

Principal Investigator or
Designee

2. Obtains approval of the area manager for the procedure and staffing allocation for use of the equipment.

Principal Investigator or
Research Assistant

3. Drapes and/or covers all equipment surfaces and undersurfaces of the equipment to be used during the procedure.
4. Covers all unused equipment and surfaces in the room.

UCIMC Clinic

5. Requests a written employee notification by the manager in clinical areas where research is taking place when the procedure is conducted M-F between 8-5 or if research is conducted when staff/patients are present. If possible, research should be scheduled after hours or on weekends.

Principal Investigator

E. Procedure Guidelines

1. Ensures animals are covered to reduce the introduction of potential allergens, dander and hair into the patient care environment.
2. Ensures exposed animal parts are moistened, if possible, to reduce the introduction of allergens into the environment.
3. Ensures safety precautions are consistent with OSHA Bloodborne Pathogen precautions for staff and environment.
4. Ensures all staff members demonstrate competency with the procedure, equipment and policies & procedures governing the welfare of animals during their transportation and research procedures.

Research Staff

5. Ensures recommended practices are implemented for the safe care of the animals while minimizing the opportunity for transmission of disease through identification of potential hazards in the research environment.

Principal Investigator

F. Post Procedure Guidelines

1. Assures cleaning of the room in coordination with the area manager prior to use on humans.

NOTE: The room cleaning includes wiping down the equipment used during the procedure, floors and walls, and/or other exposed surfaces, e.g. door and light handles, light switches, *etc.* with a UCIMC approved disinfectant.

Principal Investigator
and UCIMC Clinic
Manager

2. Ensure at least 1-2 hours of downtime occurs in the room between animal and human use to permit the complete exchange of air from the room and to

Principal Investigator or
Research Assistant

- minimize any potential for transmission of zoonotic illnesses.
3. Provides for immediate disposal of any hazardous waste generated during the research, according to the California Waste Management Act.

VI: **REFERENCES:**

Animal Welfare Act, 7 U.S.C. §§ 2131 – 59

Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, Amended August, 2002

Health Research Extension Act (HREA) of 1985, Public Law 99-158

Authors: Marilyn Coffelt, Research Compliance Officer
Guy Mulder, Director, University Laboratory Animal Resources

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