POLICY

It is recognized that cutting edge biomedical research to further the goals of translational and relevant clinical research can be optimized by the use of sophisticated patient care equipment that cannot be purchased solely for use on animals and only exists in patient care areas. To ensure public and animal safety/well-being, the use of animals in a public or patient care environment requires adherence to procedures to minimize the potential for interaction between animals and the public (including patients, staff, volunteers, students and visitors).

The UNMC/UNO IACUC maintains oversight for all procedures conducted on research animals in public and patient care areas and ensuring compliance with all applicable regulations. Failure to solicit the involvement, approval, and assistance of appropriate organizational units may result in suspension of the privileges for the use of patient care equipment for research/clinical purposes.

REQUIREMENTS

The Guide, 8th Edition, Pg. 17 – Occupational Health and Safety of Personnel; “The OHSP must be consistent with federal, state, and local regulations and should focus on maintaining a safe and healthy workplace (Gonder 2002; Newcomer 2002; OSHA 1998a).”

PROCEDURE

1.0 Study/Procedure Approval for UNMC Investigators:

1.1 Animal research and teaching procedures/studies performed within TNMC and UNMC must have prior approval from the UNMC/UNO IACUC.

1.2 Procedures/ studies that involve the use of radioisotopes must be approved by the UNMC or UNO Radiation Safety Office. Procedures/ studies that involve the use of biohazardous agents must be approved by the UNMC/ UNO Institutional Biosafety Committee (IBC).

1.3 Following approval from the IACUC and Radiation Safety or IBC, as applicable, the Form for Proposal to Use Animals in Patient Care Areas at UNMC/TNMC must be submitted to the CM Safety/ Compliance Coordinator to initiate planning and approval of the proposed procedure.

Contact: Miriam McCann, Safety/ Compliance Coordinator
Comparative Medicine
402-559-8395
Durham Research Center I, A022

2.0 Scheduling of Animal Use in Patient Care Areas:

2.1 After the Proposal has been approved, it is the UNMC investigator’s responsibility to schedule procedures with the applicable Department Chair or their designee. In order to minimize overlap with patient care, all procedures will be scheduled outside of normal working hours, i.e., between 5:00 p.m. and 8:00 a.m. Monday through Friday, or on weekends or holidays and at a time when facilities and equipment are not being utilized for patient care. The PI should remain sensitive to patient care issues. At times, clinical situations arise that may preclude the use of the equipment for research purposes even though such use has been scheduled.

2.2 When there is an option of which unit of equipment is to be used, the alternative that is least likely to provide an opportunity for contact between animals and patients will be chosen.
3.0 Record Keeping:

3.1 For large animal species, the PI must record all procedures and administration of drugs and other substances to the animals. A copy of this record must be included in the animal’s clinical record file. If radionuclides or biohazardous agents are used during procedures with any animal species, the appropriate radioactive / biohazardous waste handling methods previously approved by Radiation Safety/ the IBC must be employed.

4.0 Animal Transportation:

4.1 Animal transport to and from the hospital/ patient care areas must be approved in the Form for Proposal to Use Animals in Patient Care Areas at UNMC/TNMC. Animals must be transported in an enclosed, escape-proof cage or transport box that is concealed from external view either by an enclosed transport cart or by an opaque material. The transportation cart, including the casters, must be sanitized with an approved disinfectant after leaving the vivarium or transport vehicle.

4.2 Only routes that minimize the potential for patient/public contact with animals will be utilized for transporting animals to and through public/patient care areas. CM will provide these approved transport routes when the Proposal is approved. Service elevators will be used when possible. Service elevators will not be used to transport animals or animal care items and patients or patient care items at the same time.

4.3 Research staff must contact the clinical department personnel before leaving the animal housing area to alert technical staff that he/she is on the way. If the procedure is delayed because of equipment failure or patient emergency, department personnel will notify the research personnel immediately so that the animal is not transported. Research personnel will notify the department if it is not possible to bring the animal at the scheduled time.

5.0 Procedures for Animal Use in TNMC/UNMC Patient Care, Imaging or Therapy Areas:

5.1 Animals must be prepared for procedures prior to transport to TNMC/UNMC patient areas. This may include hair removal, initial skin scrub/preparation, bladder catheterization/expression, intravenous access, and/or endotracheal intubation. In most cases, large animals must be anesthetized prior to transport through public/patient care areas.

5.2 To minimize the potential for contamination of equipment in the procedure room, mobile equipment that is not required for the study must be removed from the study area prior to the arrival of the animal. The PI will make arrangements for the removal and replacement of this equipment.

5.3 The PI’s technical staff or department personnel will drape the examination table or area with moisture-proof plastic sheeting that is lined with absorbent material. If contamination occurs, the procedure for cleaning blood/body fluid spills should be followed, i.e., the spill should be cleaned immediately followed by the use of a sodium hypochlorite 5.25% solution (diluted 1:10) or a phenolic disinfectant.

5.4 Doors to the study area will remain closed at all times. A sign stating, "Special Study in Progress: Do Not Enter" will be placed outside the room. No one other than personnel actively involved in the procedure will be allowed in the room.

5.5 Personal protective clothing and mucous membrane protection, e.g., fluid retardant gowns/aprons, hair covers, shoe covers, gloves, respiratory masks, and eye splash protection, must be worn by all personnel during procedures that involve macaque nonhuman primates. In addition, a bite and scratch kit and a copy of the current CDC guidelines on treatment for Macacine Herpesvirus 1 (Herpes B virus) exposure must accompany macaque nonhuman primates to the patient care area. Appropriate personal protective equipment must be utilized during procedures on all animals to protect against exposure to blood and other body fluids. Special personnel protective equipment may be required for animals that have been exposed to biohazards and/ or radioisotopes. These requirements are outlined in the IACUC and/or IBC protocols.
5.6 At the completion of the study, the room must be cleaned and disinfected following the procedures used for "contact isolation" patients as determined by TNMC Infection Control and Epidemiology. These terminal cleaning procedures include the following: (1) Attire indicated for the type of isolation should be worn when cleaning the room, (2) all horizontal surfaces of furniture, including tables and mattresses, should be cleaned with an approved disinfectant, and (3) equipment that is not returned to Material Support Services (MSS) or discarded is to be cleaned thoroughly with a detergent solution followed by the use of an approved disinfectant. Patients will not be allowed to enter the area until it has been cleaned and sanitized/disinfected. Post-study clean-up will be arranged by the departmental technical staff and research staff and will be performed immediately after the study. Linens and protective covering, contaminated medical waste, radioactive material, and all other items that were used in the study must be removed from the area.

5.7 A portable High Efficiency Particulate Air (HEPA) filtration system must be placed in the room and allowed to operate until the next workday to reduce airborne particulate allergens from animal's fur and dander. This unit will be available from CM. CM will also arrange for annual testing and change the filters on a regular basis.

5.8 Appropriate euthanasia may be performed, but carcass dissection is not permitted within TNMC/UNMC patient care areas.

5.9 Patient care equipment (probes, transducers, restraint devices, etc.) and surgical instruments that come into direct contact with the animals must be sterilized/disinfected before re-use per TNMC Policy IC14 - Disinfection/Sterilization.

5.10 In the event of a suspect prion disease or Creutzfeldt - Jakob disease (CJD), all animals, tissue, waste and instruments that could potentially be contaminated, will be handled in accordance with TNMC Policy IC-25: The Nebraska Medical Center Policy for Suspected or Confirmed CJD. This includes the use of the Algorithm for Activation of CJD Protocols in the Operating Room. If CJD is confirmed in an animal anytime post procedure, CM will notify ICE to determine if further action(s) may be warranted.

5.11 No food or drink is permitted in the study area during the study.

5.12 Personnel must refrain from discussing the project in patient or other public areas.

6.0 Waste Disposal:

6.1 All waste material generated during the animal study will be considered contaminated medical waste, and/or radioactive, and disposed of according to current guidelines from the UNMC Safety Manager, the ICE, UNMC Director, Chemical and Radiation Safety, IBC and IACUC.

6.2 When radioactive material is administered to an animal, the PI is responsible for proper handling, monitoring and disposal of all radioactive/biohazard waste generated in the study area, cage, transport vehicle and subsequently, in the animal housing area.

7.0 Management and Approval for Use of Animals in Patient Care Areas at UNMC/TNMC:

7.1 Director of Comparative Medicine, UNMC
7.2 Safety and Compliance Coordinator Comparative Medicine, UNMC
7.3 Medical Director, Infection Control and Epidemiology
7.4 Director Chemical Safety and Radiation, UNMC
7.5 Manager, Infection Control and Epidemiology
7.6 Manager, Diagnostic Radiology
7.7 Manager, Operating Room
7.8 Manager, Safety & Risk Management
7.9 Infection Preventionists, Infection Control and Epidemiology

LINKS TO RELATED FORMS, RECORD LOGS, AND SOPS

Form for Proposal to Use Animals in Patient Care Areas at UNMC/TNMC