

Guidelines for Animal Use in Human Subject Study Environments
The University of Texas at Austin Institutional Animal Care and Use Committee

These guidelines have been written to assist faculty, staff, and students in performing vertebrate animal procedures in a humane manner and complying with pertinent regulatory requirements. Under some circumstances deviations from these procedures may be indicated but such variances must be approved in advance by the IACUC.

This document provides information to be used when planning and performing vertebrate studies to take advantage of unique equipment and devices that are available on campus in areas primarily utilized for human studies at The University of Texas at Austin. It is organized into four parts:

- Section A – Purpose
- Section B – Background
- Section C – Principles
- Section D – Approval Process
- Appendix 1 – Template for Written Description

Section A – Purpose

To provide guidelines, policies and practices that allow IACUC-approved animal studies to take advantage of unique equipment and devices that are available on campus in areas primarily utilized for human studies. The intent is to

- 1) Provide for safe transport, appropriate handling and adequate monitoring of the animals during the research procedure,
- 2) Protect the health of humans who have exposure to the area but are not affiliated with the animal studies, and
- 3) Avoid concerns about the animal use and potential exposure on the part of human research subjects, facility staff, and the general public.

NOTE: Although many of the concepts would be the same, this guideline does not apply to use of animals in clinical areas where human patients would be exposed. That type of study may require additional precautionary steps and approval from an appropriate infection control officer. Likewise, studies involving off-campus non-UT facilities have specific considerations that must be addressed. Such projects must be dealt with on a case-by-case basis.

Section B – Background

Nearly all university animal research is conducted within defined animal research laboratories or centrally managed vivarium (animal facility) spaces. Procedure-related equipment in those areas is dedicated to animal use, people in the area are acclimated to animal exposure, and animal transport is simple and short. However, there are times when specialized equipment that is located outside of animal research areas, such as a magnetic resonance imaging (MRI) scanner, would allow faculty to perform critical experiments that cannot be done without access to areas generally dedicated to human subject use.

Successful projects at many universities have shown that human and animal studies can safely co-exist, but carefully considered written policies and procedures must be put in place. A clearly defined approval process should be provided, and it should involve the IRB, the IACUC, the Attending Veterinarian, Office of Environmental Health and Safety and the director of the research unit responsible for the device or equipment being used for dual purposes.

Section C – Principles

1) Animal Safety

- a. Transport and holding plans must prevent animal escape.
- b. Transport and holding plans must provide appropriate climate control and ventilation.
- c. Animals must be monitored at all times by trained staff members that have the experience and the means to deal with potential complications.
- d. Use of dedicated equipment and thorough disinfection procedures (see below) are needed to protect animals from exposure to infectious agents from humans.

2) Research staff safety

- a. Transport and holding plans must prevent animal escape.
- b. Staff should have appropriate training for the species involved (e.g., primate exposure training if macaques are involved).
- c. A first aid kit and any special materials needed for the species involved (e.g., a primate bite kit) must be available during transport and at the study location.

3) Security/Privacy for the research study

- a. Transport plans must provide means to shield animals from public view.
- b. Transport must be routed to minimize use of primarily public spaces, locations with high personnel traffic, and areas such as cafeterias or break rooms.

4) Safety to human subjects and others at the research site that are not affiliated with the animal studies

- a. Transport and holding plans should minimize exposure of nonaffiliated persons.
- b. Access to the area when animals are present must be limited to those that are actively engaged in the procedure.
- c. Feces, urine and other potentially contaminated wastes must be captured, contained, and properly disposed of.
- d. Whenever possible, duplicate items should be procured so that animal studies utilize dedicated equipment (e.g., providing a small imaging table for animal use).
- e. Thorough cleaning and sanitization with an approved hospital-grade disinfectant of all surfaces potentially coming in direct contact with animals is performed before the study.
- f. Thorough cleaning and sanitization with an approved hospital-grade disinfectant of all surfaces that came in direct contact with animals or potentially become secondarily contaminated is performed after all animal studies.
- g. Animals selected for use in human subject areas should have been obtained from approved vendors and documented to have tested negative for agents with significant human risks (e.g., macaques must have current negative testing for B Virus and tuberculosis).
- h. If the species used is known to be a source of potential airborne allergens, consideration should

be given to the ventilation rates and relative air pressure balances within the room(s) utilized for animal studies.

5) Other considerations

- a. Whenever it is compatible with the principles listed above and the aims of the study, animal sedation during transport is preferred.
- b. In busy locations, off-hour or weekend use of human subject areas may be preferred, as long as trained staff members are available and the other principles listed above can be satisfied.

Section D – Approval Process

The following stepwise process will be used to approve animal use of animals in human subject study areas.

1) Preliminary Administrative Consideration

The Principal Investigator, the Attending Veterinarian, and the manager or director of the human subject study area who is responsible for the equipment to be used will meet to discuss the general plan for the proposed animal experiment. If they are all in agreement that the project is a) feasible using available resources, b) consistent with current policies, and c) can be done safely if appropriate precaution are put in place, then they will notify the Vice President for Research (or designee), who will also serve as a means for appeal if a consensus is not reached at this stage.

2) IACUC Approval

Once it has been determined that there are no administrative concerns regarding the project, the Principal Investigator will submit an Animal Utilization Proposal Form (AUP, or protocol) (or a modification to an existing and related protocol) to the IACUC. Information must be provided to show how the principles from Section III will be fulfilled. A template for providing this information is found in the Appendix of this document. As part of their deliberations, the IACUC will confer with safety specialists from Environmental Health & Safety to assure that the plan for cleaning and disinfection is appropriate. As a member of the IACUC, the Attending Veterinarian will also be able to participate in the decision.

3) Notification of the IRB

To promote the sharing of relevant information between the compliance committees, the IACUC will provide notice to the IRB when animal use has been approved for equipment or devices that are also used for human subject studies under an approved IRB protocol. This would allow the IRB (if they so choose) to verify that the disinfection plans were sufficient and/or to determine if human subjects should be informed of animal use in the area.

4) Notification of other entities

If the equipment involved is also utilized for human subject work that is under the oversight of another entity (such as a non-UT institution using equipment on a contract basis), the Principal Investigator or the manager/director of the human subject study area who is responsible for the equipment to be used will be asked by the IACUC for verification that they have notified the other entity of the approved work.