



GUIDELINES FOR AN ANIMAL PROCEDURAL SPACE EXCEPTION

The Institutional Animal Care and Use Committee (IACUC) will consider, on a case by case basis, an Animal Procedural Space Exception (APSE) for an investigator-maintained facility in which animals will be maintained and tested for periods greater than 12 hours. During this testing phase, required facility maintenance and animal care is provided by the investigator. Federal regulations state that the authority and oversight of these facilities lies with the institution through the Institutional Animal Care and Use Committee (IACUC).

Approval of an Animal Care Application (ACAP) and approval of an APSE are two separate issues. Approval of an APSE will only occur where there is appropriate justification and provided the requested procedural space meets IACUC standards. Justification must be based on experimental needs and/or the inability of the Division of Laboratory Animal Medicine (DLAM) to provide the necessary procedural space, and must be reviewed at a convened meeting of the IACUC. NO ANIMALS ARE ALLOWED TO BE HOUSED FOR A PERIOD LONGER THAN 12 HOURS IN THE ANIMAL PROCEDURAL SPACE FACILITY UNTIL RECEIPT OF WRITTEN IACUC APPROVAL OF THE EXCEPTION.

It is the responsibility of the Principal Investigator (PI) to ensure that all institutional regulations are implemented [as defined by Standard Operating Procedures (SOPs)]. The PI is responsible for enrolling all personnel exposed to the animals in the University Employee Occupational Health Clinic Program (UEOHC). The PI must ensure that all personnel involved in animal handling are properly trained in animal care and use. Veterinary and IACUC Compliance oversight will continue as if the animals were in a DLAM facility. Semi-annual IACUC inspections will be performed of each APSE. Failure to meet all required expectations may result in the loss of APSE status.

Prior to occupancy, the following are required steps for approval of an APSE Facility at UNC-Chapel Hill:

1. Written justification for the Animal Procedural Space Exception (the concept requires approval at a fully convened IACUC meeting)
2. Initial inspection of proposed Animal Procedural Space Facility by IACUC, DLAM, and Environment, Health and Safety (EHS) representatives
3. Written response outlining resolution of any deficiencies noted during the initial inspection
4. Written notification from the IACUC approving the housing space

SOP: ANIMAL PROCEDURAL SPACE EXCEPTION

The PI should design an individual Animal Procedural Space SOP based on the topics listed below. The Animal Procedural Space SOP must be approved by the IACUC, and must be maintained in an accessible location in the Animal Procedural Space Facility (as described in Section 8 below)

1. Physical Plant

Where possible, the facility should meet the species-specific recommendations for animal housing units as set forth in the *Guide for the Care and Use of Laboratory Animals*. However, it is understood that an Animal Procedural Space may be created in rooms originally designed for human occupancy, and therefore unable to meet all recommendations of the Guide. Since the Animal Procedural Space is an experimental area, not a designated animal housing facility, deviations from the Guide are permissible so long as the animal is tested in conditions (ventilation, temperature control, etc.) suitable to the health and well-being of its species.

2. Security

The PI is responsible for maintaining and ensuring that the Animal Procedural Space is locked at all times when unoccupied by research personnel. Housekeeping is not allowed to enter the Animal Procedural Space when animals are present.

3. Biosecurity

A plan to prevent potential animal escape is required. An agreement must be made with the DLAM facility supervisor on handling of caging materials borrowed from a DLAM facility.

4. Animal Identification

All animals must be identified by a current IACUC approved protocol (eg: with DLAM bar-coded animal identification cage cards or individual acceptable method), along with any physical markings/identifications, and the date the animal was brought to the Animal Procedural Space.

5. Training

It is the responsibility of the PI to ensure that everyone working with the animals in the Animal Procedural Space is adequately trained in all animal-handling aspects. Training includes knowledge of the requirements for the Animal Bio Safety Level of that facility.

6. Occupational Health

The PI is responsible for complying with all UNC-Chapel Hill Occupational Health requirements stipulated by the University Employee Occupational Health Clinic (UEOHC). This includes enrolling in the UEOHC program all persons who are exposed to animals being tested in the Animal Procedural Space.

7. Sanitation

The PI is responsible for complying with species-specific sanitation requirements as per DLAM SOP's. The housing area must be easily cleaned and sanitized. Cages must be clean when brought to the Animal Procedural Space. An extensive cleaning routine should be outlined by the PI and may be performed when animals are not present.

8. Required Documentation

Current IACUC ACAP ID #s, Animal Procedural Space SOP and all required safety signage (EHS) must be present in the facility. It is permissible to maintain these documents within a notebook which is accessible to site visitors. The UNC-Chapel Hill notice "Reporting Concerns Regarding Animal Welfare" and contact information for animal health (veterinary) concerns must be visibly posted within the Animal Procedural Space facility.

9. Hazards

The PI is responsible for complying with EHS and all other applicable rules and regulations regarding any physical, radiation, biological and chemical hazards. The PI is responsible for notifying all personnel (including IACUC) of any hazards present, and assuring that all personnel are aware of potential hazards, and properly trained to avoid any hazard present.

10. Exceptions

Any modifications to the Animal Procedural Space exception and its SOP must be presented in writing to, and be approved by, the IACUC. Exceptions and modifications must be clearly outlined in item 8.0 of the ACAP as well as in the individual Animal Procedural Space SOP.

Required information to be submitted ANNUALLY for each approved Animal Procedural Space Exception Facility

Name of Facility

Principal Investigator:

Laboratory animal coordinator:

Location (building, room):

Species undergoing testing:

Animal Enclosure (Please describe the typical length, interval and frequency of testing and any testing enclosures or apparatus):

List all personnel that work with the animals:

Physical plant

Floor plan of the facility including layout of testing enclosures or apparatus

How is access to the facility restricted / secured?