UNIVERSITY STANDARD

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
STANDARD ON ANIMAL PROCEDURAL SPACE EXCEPTION (APSE)

Introduction

PURPOSE
The standards and procedures described below provide guidance to all researchers and animal handlers for the responsibility of the Principal Investigator (PI) to ensure that all institutional regulations are implemented within the PI maintained areas, for animals maintained and tested for limited periods greater than 12 hours for USDA-regulated species and 24 hour for non-USDA regulated species.

SCOPE OF APPLICABILITY
All personnel engaged in the care and testing of animals in an investigator maintained facility for periods greater than 12 hours for USDA-regulated species and 24 hour for non-USDA regulated species.

The UNC-CH IACUC expects that anyone involved in animal work at the University will comply with this Standard. Requests for exceptions to this Standard must be reviewed and approved by the IACUC.

Standard

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 limited periods greater than 12 hours for USDA-regulated species and 24 hours for non-USDA regulated species.

During this testing phase, required facility maintenance and animal care are 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, Environment,
Health and Safety (EHS), and Division of Comparative Medicine (DCM) standards. Justification must be based on experimental needs and/or the inability of the DCM 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 (USDA covered species) or 24 (non-USDA covered species) HOURS IN THE ANIMAL PROCEDURAL SPACE FACILITY UNTIL RECEIPT OF WRITTEN IACUC APPROVAL OF THE EXCEPTION.**

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, DCM, and EHS representatives
3. Collection of and IACUC review of temperature and humidity data (high/low) over a 5 day period prior to facility approval in APSEs. Recording does not apply to spaces used only for prolonged non-survival surgery, incubator housing or continuous testing in which animals are maintained in specialized equipment (e.g., behavioral conditioning apparatus). For APSEs consisting only of an incubator, the PI should provide IACUC/OACU with manufacturer specifications. The OACU may have temperature/humidity devices available for loan to investigators.
4. Written notification from the IACUC approving the time-limited housing space

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 DCM/EHS, and must be maintained in an accessible location in the Animal Procedural Space Facility (as described in Section 8 below)

**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 (8th edition). 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 maintained in conditions (ventilation, temperature control, etc.) suitable to the health and well-being of its species.

**Security:** The PI is responsible for 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.

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

**Animal Identification:** All animals must be identified by a current IACUC approved protocol (e.g. with DCM RFID cage cards or an approved, acceptable method), and the date the animal was brought to the Animal Procedural Space.

**Training:** It is the responsibility of the PI to ensure that everyone working with the animals in the approved APSE space is adequately trained in all animal-handling aspects. Training includes knowledge of the requirements for the Animal Biological Safety Level (ABSL) of that facility.

**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 held in the Animal Procedural Space. The Research Profile and Animal Handler Form can be found [here](#).

**Sanitation:** The PI is responsible for complying with species-specific sanitation requirements as per DCM 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.

**Required Documentation:** Current IACUC ACAP ID #s, Animal Procedural Space SOP and all required safety signage (EHS) must be present in the space. It is permissible to maintain ACAP and SOP 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.

**Hazards:** The PI is responsible for complying with EHS regulations and all other applicable local, state and federal rules and regulations regarding physical, radiological, 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.

**Disaster Plan:** The PI is responsible for ensuring that a disaster plan is in place in the event of an emergency which endangers the health and welfare of the animals maintained in the APSE. Indicate how animals will be cared for in the event that the University is operating under conditions when only ‘Mandatory’ employees are allowed access to campus. (Described in the [UNC Adverse Weather and Emergency Events Policy](#) and [Pandemic and Communicable Disease Emergency Policy](#).) Advance coordination and training with DCM personnel is required to ensure emergency backup husbandry. (Include DCM contact information to be used in the case of emergency, and describe training provided to DCM.) Alternately, indicate the key employees who are considered ‘Mandatory’ personnel (list employees’ names with Mandatory status).

**Contact Information:** Current 24-hour contact information should be posted within the Animal Procedural Space area so that the PI/LAC can be contacted in the event of an emergency.

**EXCEPTIONS:**
Any modifications to the APSE and its SOP must be presented in writing to, and be approved, by the IACUC. Exceptions and modifications must be clearly outlined in section 8.0 of the ACAP as well as in the individual Animal Procedural Space SOP. Additionally, requests for exceptions to this Standard must be reviewed and approved by the IACUC.

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**Definitions**

**IACUC:** Institutional Animal Care and Use Committee  
**DCM:** Division of Comparative Medicine  
**University Standard:** The minimum acceptable limits or rules used to achieve Policy implementation, enforceable by the IACUC.  
**APSE:** Animal Procedural Space Exception
ACAP: Animal Care Application  
OACU: Office of Animal Care and Use  
PI: Principal Investigator  
UEOHC: University Employee Occupational Health Clinic  
SOP: Standard Operating Procedure  
EHS: Environment, Health and Safety  

Related Requirements

EXTERNAL REGULATIONS AND CONSEQUENCES

UNIVERSITY POLICIES, STANDARDS, AND PROCEDURES

For more detailed guidance, please refer to the University Policy on the Care and Use of Vertebrate Animals for Research, Training and Teaching Purposes.

Contact Information

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<thead>
<tr>
<th>Subject</th>
<th>Contact</th>
<th>Telephone</th>
<th>Email</th>
</tr>
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<tbody>
<tr>
<td>IACUC Protocol</td>
<td>OACU</td>
<td>919-966-5569</td>
<td><a href="mailto:iacuc@med.unc.edu">iacuc@med.unc.edu</a></td>
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<tr>
<td>Animal Health</td>
<td>DCM</td>
<td>919-962-5335</td>
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<td>EHS Concerns</td>
<td>EHS</td>
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Important Dates

- Effective Date and title of Approver: 10/2009; UNC IACUC
- Revision and Review Dates, Change notes, title of Reviewer or Approver: Revised 08/2012; Revised 08/2012; Revised 04/2016; Revised 11/2018, Placed on University Standard Template; UNC IACUC

Approved by: UNC IACUC

Dr. Roland Tisch  
UNC IACUC Chair

Policy Title: UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL STANDARD ON ANIMAL PROCEDURAL SPACE EXCEPTION (APSE)  
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