PI-MANAGED (HOUSING/HOLDING) FACILITIES

**PERFORMANCE STANDARD:** Animal care, irrespective of location, will be performed to the same level of consistent standards as defined by the Guide, IACUC Policies, and DLAR care standards.

**BACKGROUND:** Federal regulation, PHS Policy, and standards of AAALAC accreditation require each research institution to establish a process for animal care that meets referenced standards and veterinary care expectations. This policy applies to all areas where animals are maintained for longer than 12 hours outside of a DLAR-managed animal care facility. Potential exceptions to this policy are addressed on a case-by-case basis.

**ROLES:** The Principal Investigator (PI) has a number of duties and responsibilities that include responsibility for all animal care and use activities performed under their IACUC-approved animal protocol.

**DEFINITION:**
- DLAR: Division of Laboratory Animal Resources
- DLC: Duke Lemur Center
- DML: Duke Marine Laboratory
- DMR: Designated Member Review
- E&O: Engineering and Operations
- FCR: Full Committee Review
- FM: Facilities Management
- FMD: Facilities Management Department
- HVAC: Heating, Ventilation, and Air Conditioning (HVAC)
- IACUC: Institutional Animal Care and Use Committee
- OESO: Occupational and Environmental Safety Office
- OAWA: Office of Animal Welfare Assurance
- PI: Principal Investigator
- PI-MANAGED FACILITY: Includes any non-DLAR animal space managed by an individual, a group of individuals, or a department
- RH: Relative Humidity
- SCSC: Significant Change Subcommittee
- SOP: Standard Operating Procedure(s)

**POLICY:** Housing or holding un-anesthetized animals outside of a DLAR-managed facility for periods longer than 12 hours is defined as use of a PI-Managed Facility and requires IACUC approval.
1. PROCEDURES FOR NEW PROPOSALS FOR PI-MANAGED HOUSING: The IACUC uses a three step process for consideration and approval of PI-managed space.

Stage 1:

a. The PI completes the IACUC application for a PI-Managed Housing Facility (Section T found at: http://vetmed.duhs.duke.edu/FormsReports.html)

1. The PI must provide compelling scientific justification for a PI-managed housing space including why DLAR or a Specialized Use Facilities (Appendix I) cannot meet their housing needs. Physical inspection of the proposed room is performed separately as outlined in Stage 2.

2. Processing of protocols will be in accordance with established policies.
   a. Protocol Management (New Protocols, De Novo Protocols, and Annual Progress Reports)
   b. IACUC Review and Approval Practices (Amendments to Approved Protocols)

Stage 2:

a. A Subcommittee consisting of representatives from OESO, IACUC, and DLAR will visit the proposed housing location. This Subcommittee will review the proposed site for appropriate infrastructure, adequate safety and husbandry provisions, effective security, and proper disease prevention and surveillance techniques.

b. In addition to the work of this Subcommittee, the following actions will also be performed:

1. Engineering and Operations (E&O) or Facilities Management Department (FMD) will perform a Heating, Ventilation, and Air Conditioning (HVAC) assessment for appropriate air flow measurements; and

2. DLAR will assist the PI in establishing appropriate operational processes, including training in husbandry, health reporting, or management as necessary to assure that individuals providing care to the animals held at the PI-Managed facility are properly trained.

3. DLAR will provide veterinary care for all animals housed in PI-managed areas.
Stage 3:

a. The IACUC SCSC or Full Committee will consider each of the above reports (as described in sections a. and b.), and either approve, require additional clarification, or disapprove the request for PI-Managed Housing. NOTE: Disapproval requires a vote of the Full Committee.

2. ANNUAL RE-APPROVAL OF PI-MANAGED HOUSING: An annual re-approval will be required for all PI-Managed Housing. The IACUC will consider the following for the annual re-approval:

   a. IACUC Review Procedures:
      1. Full Committee Review is required if there is a change in scientific justification from that of the prior year.
      2. DMR by the IACUC Chair or their designee may be used if the scientific justification has not changed from the prior year to the present annual report.

   b. Review & Clearance of the facility by the IACUC Subcommittee (e.g., DLAR, OESO, & IACUC) during the previous year.

   c. HVAC update assessment during the previous year.

   d. Adequate scientific justification for continued use of the PI-Managed Housing.

   e. The IACUC will review and either approve, require additional clarification, or disapprove the request for continuation of the PI-managed housing space (DMR cannot disapprove, but may elevate consideration of the justification to FCR).

   f. If disapproved, the animals held in those facilities will be transferred to DLAR ‘Holding Protocol’ immediately.

3. SPECIFIC REQUIREMENTS FOR PI-MANAGED HOUSING

   a. A responsible individual (the PI or a Designee) must be assigned for each facility and approved as personnel on the protocol.

   b. The responsible individual must ensure that animal care is provided daily, including weekends and holidays.

   c. If graduate or undergraduate students are used to maintain the facility and/or care for the animals, a plan for facility operations during student vacations must be included in the request for PI-managed housing.
d. Quarterly validation procedures (e.g., RODAC plates, Firefly, etc.) must be performed to validate the effectiveness of sanitation of primary contact areas (e.g., cages). Quarterly validation is not required when the caging materials are sanitized by a DLAR mechanical cage washing system. Formal arrangements must be made with DLAR. Contact the operations manager of the cage wash location.

e. Temperature: At a minimum, room temperature must be monitored and documented once a day. Twenty-four hour (automated) monitoring is preferred. Ranges of temperature defined for the species in The Guide should be used, unless deviation is approved by the IACUC. For aquatic species, daily room temperature monitoring is not required; however, water temperature monitoring must be performed in accordance with the SOP for that species. For animals housed outdoors, monitoring must be performed in accordance with the SOP for that species.

f. Humidity: Twenty-four hour humidity should be maintained within the range of 30% to 70% relative humidity (RH) for terrestrial species. When daily monitoring records indicate humidity has fallen below the 30% or greater than 70% for more than 72 continuous hours, E&O/FMD should be contacted. Contact DLAR if there are animal welfare concerns. For aquatic species, daily room RH monitoring is not required; however it must not impact occupational health or promote excessive condensation or evaporation. For animals housed outdoors monitoring must be performed in accordance with the SOP for that species.

g. General Husbandry: Husbandry practices, including but not limited to provision of food and water, sanitation (primary enclosure, receptacles, etc.), and environmental enrichment, must be performed as outlined by the Guide, Duke Policies, and DLAR SOPs. If these standards cannot be met for scientific reasons, an IACUC exception to policy waiver must be applied for, scientifically justified, and approved by the IACUC. Species for which there is not a standard outline of care, husbandry must be performed in accordance with the SOP for that species.

h. Environmental and census recordkeeping should be standardized by using a PI-managed lab recording sheet that includes temperature, humidity, feeding, providing water, sanitation, and animal census, as appropriate. Records should be available for review.

1. When animals are not being housed in the facility, the records must indicate the date the animals were removed (no animals were held). Daily monitoring records are not required when animals are not being housed for 12 hours or longer.
2. When animals are returned to the holding room, the monitoring records must indicate the date the animals were returned, after which daily monitoring is required.

3. Monitoring forms are available at the animal program website or appropriate sheets can be obtained from DLAR.

i. Live Traps for Rodent Animal Facilities:
   1. Facilities holding rodents must have a live capture trap within the facility. If the holding area is enclosed within a suite, then a trap within the suite, between the holding spaces and the exterior door, is appropriate.
   2. The live trap must be a commercial product designed for the purpose of live trapping, with a viewing window.
   3. The live trap must be assessed daily when transgenic animals are housed in the facility and this daily check must be documented on daily records. Traps should be removed if no animals are in the facility.

j. Any animal captured in the live trap will be reported to DLAR immediately for disposition. To ensure that situations that endanger animal welfare are recognized, all personnel involved in PI-managed Housing are required to take a DLAR-directed training course on recognizing animal illness.
   1. *Husbandry and Veterinary Care for Investigator-Managed Non-rodent Animal Colonies*
   2. *Husbandry and Veterinary Care for Investigator-Managed Rodent Colonies*

k. Veterinary care should be sought as outlined in the policy “Clinical Conditions Warranting Additional Veterinary Support.”

l. Each facility will have a determined maximum housing density. Density is defined as the number of cages (rodents) or number of animals (larger species) that can thrive in the space allotted under the conditions provided. Aquatic species density is defined by appropriate water quality and general minimal volume per animal for the species being housed. All deviations from published standards must be IACUC-approved. For mice refer to the Cage Space Requirements for Mice policy ([http://vetmed.duhs.duke.edu/ProgramPolicies.html](http://vetmed.duhs.duke.edu/ProgramPolicies.html)).

m. HVAC reassessment is required every three years when attached to a central environmental monitoring system; annually when not attached to a central environmental monitoring system. See 3.e., 3.f., and 3.h. above.
4. DISASTER PREPARATION / PREVENTION / MITIGATION:

a. LEVELS OF DISASTER ARE IDENTIFIED AS:

   Level 3, Significant Adverse Event - The animal facility is not usable. Primary consideration is given to the safety of the personnel. Disposition of affected animals will be governed by DLAR/DLC/DML SOPs for Disaster Management. Prevention of animal suffering and public health hazards are the primary concern. If necessary, live traps can be implemented for the capture of animals that have escaped.

   Level 2, Moderate Adverse Event – The animal facility is usable, but not operating normally. Water and electrical power may be unavailable, but the building is intact enough to provide shelter for the animals without danger of collapse. If water and electrical power are unavailable, begin coordinating plans to obtain appropriate water for the animals in this space. For cages that require power to operate (e.g. ventilated cages), coordinate plans to remove cage lids or transfer animals to other locations. Contact DLAR management (919.970.7272) to coordinate movement of animals to housing if necessary.

   Level 1, Temporary Disablement – Water and power are unavailable for a brief period, but the building is essentially intact. If the disaster is judged to be of a lesser magnitude than described above, animal facility staff will attempt to keep the animals alive until a complete assessment of the situation can be made. If it becomes clear that utilities cannot be restored within a reasonable period, the disaster level will be upgraded to level 2. Meanwhile, the Animal Facility Coordinator can request qualified individuals to participate in the care of animals. If help is not available, the animals will be euthanized.

b. PROCEDURE:

   i. Daily observation, care and provision of an adequate environment are mandated by federal animal care laws and regulations. Assurance must be given that all animals maintained in PI-managed facilities receive this care during adverse events.

   ii. The responsible individual is responsible for ensuring that appropriate staff is available to respond to an emergency/disaster, including weekends and holidays.

   iii. Refer to your disaster plan for details.
c. PREPARATION RECOMMENDATIONS (may vary based on species and housing location):

   i. Maintain adequate food, water, bedding, water bottles/source, etc. for animals for a short interruption of supplies.

   ii. Have supplies available for people who may need to stay with the animals.

   iii. Obtain ice if required (e.g., to cool animal rooms). Have portable fans and heaters to adjust environmental conditions (if possible).

   iv. Stock flashlights and batteries and store them where they can be easily accessed.

   v. Maintain inventories of animals and know which are most important to save in case euthanasia must occur.

   vi. Store emergency supplies in a cart that can be moved to other locations. Heavy duty work gloves, electric cords, tool kit, utility knife, first-aid kit, blankets, light sticks, zip ties, etc. may be useful.

   vii. Have an escape plan in case of an emergency.

   viii. Have contact information and emergency plan available at work and home.

   ix. Maintain an up-to-date hard copy of the facility disaster plan in an easy-to-access location, for reference in the event that on-line versions are not accessible.

x. SPECIAL CONSIDERATIONS:

   A. Feed and water: To support life, it is acceptable to use other than the prescribed nourishment (e.g., dog food for rodents, or city (tap) water instead of RO or filtered). Gel Packs may also be available from DLAR.

   B. Loss of power for the HVAC system/Ventilated racks: Prop open doors to provide air circulation, unless doing so would release a biohazard. Run fans or put ice on floors to cool animals. Run heaters or provide additional bedding to warm animals. Have available battery-operated fans and flashlights. Remove cages from ventilated racks and maintain as static cages. Emergency generators are available from Facilities Management (FM) or Engineering & Operations (E&O). Emergency Contact numbers are listed below.
C. **Personnel Absences:** Maintain a call list of lab staff that can be implemented in the event that unanticipated personnel shortages are experienced. When staff shortages are critical and may impact animal care, contact DLAR or OAWA for guidance and support.

D. **Evacuating animals:** Depending upon the extent of damage to an animal holding area, animals may be relocated, cared for at a DLAR-managed location, or euthanized. The extent is to be evaluated by public safety personnel. Animals which have escaped may need to be trapped. Consider whether the animals are harmful (zoonotic, venomous, have claws, etc.) when moving them and whether they will be put in greater jeopardy if moved.

E. **Relocation and Transportation:** When a PI-Managed housing area is unable to provide an environment suitable for maintaining life of the research models, animals will be relocated to other campus facilities, or if required, to regional animal facilities or contract organizations. For rodents, cryopreservation of critical lines in DLAR or at a contract research facility should be considered well ahead of the disaster event. In the event animals must be transported, contact the DLAR Incident Team Leader (see list below) for assistance in securing approved transportation. If you have an IACUC-approved privately owned vehicle, it may be used to transport the species it has been approved for to an alternate location.

F. **Euthanasia:** Maintain a kit with syringes, needles, euthanasia agent, and other materials for large animals. Gravely injured animals should be euthanized. Euthanasia can be performed in the absence of the PI if in the opinion of animal care provider it is best in the interest of the animal. Contact DLAR Vet on call (919.970.9410) or DLAR Manager on call (919.970.7272) for assistance with euthanasia and/or carcass disposal.

G. **Unsafe conditions:** Examples of hazards include natural gas leaks, live and sparking wires, standing or flowing water, broken and sharp materials, and chemical spills. Do not enter the animal facility if such hazards are initially present, until it has been approved for the safe entry of humans by knowledgeable authorities. Use caution and protective gear when accessing and handling animals.
H. **Fires:** Contact emergency services first (911), as valuable time can be lost while fighting the fire. Know where fire extinguishers are located. Safety to yourself and others must be the main consideration. Don’t fight large fires yourself. Fires are unpredictable; don’t assume that you can control them.

d. **REPORTING:** Any level of disaster in a PI-Managed area must be reported to DLAR and OAWA. The incident should be reported during (preferred) or within 72 hours after resolution.
e. **EMERGENCY CONTACT NUMBERS:**

- Engineering & Operations (Medical Center), 24 hour: 919-684-3232

- Facility Maintenance Division (University)
  - Phone: 919-684-2122
  - Pager: 919-970-9880

- Duke Fire Department: Phone: 919-560-4242

- Duke Police: Phone: 919-684-2444

- DLAR:
  - Vet on Call Pager: 919-970-9410
  - Manager on Call Pager: 919-970-7272

- OAWA: Phone: 919-668-6720

- Animal Welfare Hotline: Phone 919-684-3535

- **DLAR Incident Team Leader Master Call List:**
  - Peg Hogan:
    - Office: 919-684-3885
    - Pager: 919-970-7129
    - Cell: 919-812-5837
  - John Norton
    - Office: 919.684-4204
    - Cell: 919-812-1807
  - Randall Reynolds:
    - Office: 919-684-4933
    - Cell: 919-812-1240
  - Francis Sun:
    - Office: 919-684-2341
    - Pager: 919-970-7317
    - Cell: 919-358-9114
ADVERSE EVENT PREVENTION, RECOGNITION, & MITIGATION PLAN FOR PI MANAGED AREAS
(Disaster Plan)

Authorizations Page

PI MANAGED LOCATION:
BDLG._______________
ROOM #_______________

By signature below we confirm that all staff members have reviewed and understand this plan and agree to implement when determined necessary. Any updates or changes will be reviewed with all staff members prior to implementation.

PI Name & Signature ________________________ Alternate Name & Signature ________________________
Contact #:_________________________ Contact #:_________________________

2nd Alternate Name and Contact
#:_________________________________________

3rd Alternate Name & Contact
#:_________________________________________

Endorsed By Duke Animal Program Reviewers:

DLAR: ______________________________ Date: ___________

OESO: ______________________________ Date: ___________

OAWA: ______________________________ Date: ___________

IACUC: ______________________________ Date: ___________

* Endorsement by Duke Animal Program reviewers is only required at the time of initial review. Any changes to the plan may require further review.
Appendix I: Current Specialized Use Facilities

These operations remain under Duke animal program oversight and Attending Veterinary authority, but provide their own independent veterinary care and operate under a Memo of Understanding (MOU). Two of these activities are Duke activities and the third is a privately-owned veterinary care corporation using client-owned animals.

**Duke Lemur Center (DLC):** The Lemur Center is located within the Duke Forest, approximately 5 miles from the core campus. The DLC has two veterinarians on the DLC staff for DLC-specific animal care, diagnosis, and treatment. The DLC has an American Zoological Association (AZA)-accredited breeding program. The DLC is included in the university’s AAALAC-accredited program. An MOU between the DLC and DLAR places institutional veterinary responsibility with the Attending Veterinarian while maintaining local veterinary authority for the DLC-assigned veterinary staff. Animal care and use oversight at the DLC is maintained via a multi-level process. The DLC is considered a part of the Animal Care and Use program, thus is subject to all requirements of the program. Specific management items unique to the DLC are:

- All animals at the DLC (all lemurs and loris species) are maintained by DLC specific SOPs on animal care and use and cared for by dedicated DLC staff and veterinarians (Responsible individuals). These SOPs are reviewed by the IACUC on a routine basis, generally every 2 years.
- Experimental use of animals requires approval by the DLC Research Committee and Duke IACUC. Animals used are captured under and counted against the experimental protocol throughout the duration of the study.
- The DLC is responsible for assuring that all animal care staff is appropriately trained.
- The DLC is responsible for all items outlined in Section 3 and 4 of this policy.
  - A separate inspection by the PI-managed housing subcommittee is not required (Stage 1). NOTE: The DLC is inspected by the IACUC on a semiannual basis to meet regulatory requirements.
  - IACUC approval is required for all proposed activities (above and beyond routine care which is captured by SOP) on animals housed at the DLC. The DLC must be indicated as the animal housing and use location in the protocol; however, a Section T (PI managed animal holding facility) is not required (Stage 2).
  - Documents described in the policy will be maintained by the DLC and are available upon request.

**Duke Marine Laboratory (DML):** The DML is located at Beaufort, N.C., approximately 250 miles distant from the main campus. The DML is a unit within the Nicholas School of the Environment. Modern laboratory, field, and shipboard facilities are available for use by researchers. An MOU exists between a veterinarian local to the DML with skills in marine animal veterinary care and the Duke Attending Veterinarian. The MOU delegates provision of veterinary care for animals at the DML to the local veterinarian, for emergencies.
- All animals at the DML are maintained by DML specific SOPs on animal care and use and cared for by dedicated DML and/or research staff. These SOPs are reviewed by the IACUC on a routine basis but at least every 2 years.
- Housing of animals at the DML requires approval by the DML Responsible Individual. All animals housed at the DML are maintained under an IACUC approved protocol.
- The DML is responsible for assuring that all animal care staff is appropriately trained on animal care. All animal care personnel are required to have an animal handler role on the IACUC approved protocol under which the animals are maintained or be defined as the DML Responsible Individual.
- The DML is responsible for all items outlined in section 3 and 4 of this policy.
  o The DML must be indicated as the animal housing and use location in the protocol; however, a Section T (PI managed animal holding facility) is not required (Stage 1).
  o The DML Responsible Individual will perform an annual self-audit of their local program and send the completed audit to the OAWA office (IACUC@Duke.edu) in lieu of an inspection by the PI-managed Subcommittee (Stage 2). NOTE: The DML is inspected by the IACUC on a semiannual basis to meet regulatory requirements.
  o Documents described in the policy will be maintained by the DML and are available upon request.