Standard Operating Procedure (SOP):
Approving Investigator-Managed Use Sites and Housing Areas

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Definitions
Investigator-managed Housing Area: Any investigator managed building, room, area, enclosure, or other containment site in which animals are housed for periods longer than 12 hours.

Investigator-managed Study Area/Use Site: Any investigator managed building, room, area, enclosure, or other containment site to which animals are taken for use (i.e. surgery, euthanasia, behavioral testing, or acute procedures) under an IACUC approved protocol for periods less than 12 hours.

AWRs: USDA Animal Welfare Act Regulations

PHS Policy: Public Health Service Policy on Humane Care and Use of Laboratory Animals


IACUC: Institutional Animal Care and Use Committee of the University of Pittsburgh

DLAR: Division of Laboratory Animal Resources at the University of Pittsburgh

DLAR Housing Area: Any DLAR managed building, room, area, enclosure, or other containment site in which animals are housed for periods longer than 12 hours.

DLAR Study Area/Use Site: Any DLAR managed building, room, area, enclosure, or other containment site to which animals are taken for use under an IACUC approved protocol.

Scope
The US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, Principle VII states that “the living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.” In accordance with this principle, the USDA AWRs and the Guide set standards that are mandatory for the environment, housing, and management of laboratory animals. This document forms the basis for the IACUC’s approval and evaluation of investigator managed animal use sites and housing areas.
Procedures
Establishing Investigator-Managed Use Sites and Housing Areas
In accordance with the AWRs and the PHS Policy, the IACUC is required to conduct inspections of all animal facilities at least once every six months, including but not limited to, animal study areas and areas where animals are maintained for periods longer than 12 hours. This includes the DLAR managed and investigator managed housing areas and use sites. The DLAR manages and maintains a listing of DLAR housing areas and use sites. The DLAR listing is provided to the IACUC to direct semi-annual inspections. The investigator managed housing areas and use sites are specified in IACUC protocols and a current listing is maintained by the IACUC.

I. Establishing an investigator-managed use site
Animals may be taken to investigator-managed study areas/use sites provided that:

A. Scientific justification for this arrangement is reviewed and approved by the IACUC. The IACUC’s “APPLICATION FOR APPROVAL TO USE VERTEBRATE ANIMALS IN RESEARCH and TEACHING, NEW SUBMISSION” is completed by the investigator and submitted for IACUC review. The application requires the investigator to answer:

1. “Are animals transported from the holding room through approved animal facility space to another location/lab?”

2. “If yes, indicate building(s) and room(s) of destination”, and

3. “Provide rationale for the need to remove animals from dedicated facilities and justify why such work cannot be performed in dedicated, approved animal facility space.”

The IACUC will review this information as part of the protocol review process and approve, ask for further clarification, or disapprove the request.

B. When removing animals from dedicated housing and procedure areas is deemed necessary by the IACUC protocol reviewers, an IACUC staff member will determine whether the use site in question is present on the roster of currently inspected and approved sites. If the site is not currently approved, the RCCO will be notified so that an inspection of the site can be arranged.

C. If approved, the study area is inspected and certified by the IACUC prior to initial use and thereafter at least once every six months. IACUC certification of a study area is valid for a 6 month period with the condition that acceptable standards are maintained. The RCCO must be notified when a study area is actively being used in order to facilitate the identification of active areas requiring oversight by the IACUC and DLAR.
II. Establishing an investigator-managed Housing Area

Animals may be taken to an investigator managed housing area provided that:

A. Scientific justification for this housing is reviewed and approved by the IACUC. The IACUC’s “APPLICATION FOR APPROVAL TO USE VERTEBRATE ANIMALS IN RESEARCH and TEACHING, NEW SUBMISSION” provides for the investigator to apply for IACUC review of an investigator managed housing area. The application requires the investigator to answer:

1. “Are animals transported from the holding room through approved animal facility space to another location/lab?”

2. “If yes, indicate building(s) and room(s) of destination,”

3. “Provide rationale for the need to remove animals from dedicated facilities and justify why such work cannot be performed in dedicated, approved animal facility space”, and

4. “Will vertebrate animals be housed in these alternate locations for greater than 12 hours?”

The IACUC will review this information as part of the protocol review process and approve, ask for further clarification, or disapprove the request.

B. The housing area must be inspected and certified by the IACUC prior to initial use and thereafter at least once every six months. IACUC certification of a housing area is valid for a 6-month period after the date of inspection with the condition that acceptable standards are maintained.

C. Copies of housing site logs must be maintained at the housing site for inspection (see Guidelines – Management of Housing Areas III.A).

D. Ventilation in the housing site must be adequate as measured by Facilities Management or Environmental Health and Safety (see Guidelines – Management of Housing Areas I.D and III.C).

E. The Attending Veterinarian or designate must be provided access (i.e., a key or combination) to the housing site for evaluation of animal health and well-being (see Guidelines – Management of Housing Areas IV).

F. The investigator-managed housing site must comply with the Guidelines for Management of Housing Areas specified in that section.

G. A DLAR Animal Transfer and Movement Approval Form available on the DLAR website (www.dlar.pitt.edu) must be completed and approved prior to relocating animals to the investigator managed area.
Guidelines
Management of Use Sites

I. All animal use sites must have a regular sanitization maintenance schedule and must be kept clean, neat, and uncluttered.

II. No food or drink for human consumption is permissible in the animal use area.

III. Any surgical procedures conducted in an animal use site must fully comply with the IACUC Surgical Guidelines.

IV. If chemical or biological hazardous agents are being used in the facility, the Department of Environmental Health and Safety must certify the facility for this use.

Management of Housing Areas

I. Animal Facility

A. Sanitation
   The housing site must have a regular sanitization maintenance schedule and must be kept clean, neat, and uncluttered.

B. Food and Bedding Storage
   Food and bedding materials must be stored in closed containers to avoid contamination and the potential spread of disease. Containers must seal so that vermin are excluded from the food and bedding being stored and must be made of a material such that the container can be sanitized on a regular basis.

   If food is not stored in its original bag, the milling date printed on the bag must be indicated clearly on the food container. If no milling date is listed on the food bag, label the bag with the date received. With proper storage, food can generally be used up to 6 months after the milling or receipt date. However, the shelf life of food can be shortened by several factors, including temperatures above 21 °C (70 °F), humidity extremes, unsanitary conditions, light, oxygen, and pests. Furthermore, food with vitamin C has a shelf life of only 3 months unless a stabilized form of vitamin C has been utilized in the manufacturing process and verified by the manufacturer.

C. Temperature and Humidity
   Temperature and humidity must be monitored and recorded on a daily basis to ensure that adequate levels of these environmental factors are maintained in the housing area. Daily room temperature and humidity monitoring must evaluate the range of fluctuations experienced over the 24-hour period. The minimum and maximum temperature and humidity of the previous 24 hours must be recorded in addition to the current temperature and humidity observed. Relative humidity should be maintained between 30 to 70%. Unless
special environmental conditions are approved by the IACUC, the area temperature must be appropriate to the species (see table below). Temperature extremes can affect research results, alter an animal’s performance, or lead to clinical effects and death. Any deviations from the humidity range of 30 to 70% or beyond the temperature ranges for species sited below should be reported to the DLAR immediately so a veterinarian can evaluate the impact on animal health and well-being.

| Recommended Dry-Bulb Temperatures for Common Laboratory Animals |
|-----------------|-----|-----|
| Species                    | °C  | °F  |
| mouse, rat, hamster, gerbil, guinea pig | 20-26 | 68-79 |
| rabbit                    | 16-22 | 61-72 |
| cat, dog, nonhuman primate | 18-29 | 64-84 |
| farm animals and poultry  | 16-27 | 61-81 |

D. Ventilation
Although factors such as species, animal size, number of animals, type of bedding, and frequency of cage changing can affect the minimum ventilation rate required, an acceptable general standard for a vivarium room containing the maximum animal density permitted by other constraints is 10-15 fresh air changes per hour. Investigators’ laboratories are frequently set up in space not designed to permit 10 – 15 fresh air changes per hour. An acceptable general standard in such cases is that the maximum number of animals in a housing area be reduced proportionately. Although lower or higher ventilation rates may be required in certain instances, provisions must be made to ensure that harmful or unacceptable concentrations of toxic gases, odors, or particles do not accumulate in an animal’s primary enclosure.

E. Illumination
Several factors should be considered when determining adequate illumination, such as light intensity and wavelength, duration and time of light exposure during the circadian cycle, animal pigmentation and light history, body temperature, hormonal status, age, species, sex, and animal stock/strain.

F. Noise
Unnecessary noise in the housing area should be minimized. Radios and other audiovisual entertainment devices should be not utilized in the animal housing or use areas unless they are part of an IACUC approved animal protocol.

G. Hazardous Agents
Hazardous biological, chemical, or physical agents must not be stored where animals are housed.

H. Doors
Doors must fit tightly within the frame to prevent escape of or injury to animals.
I. Monitoring Animal Biosecurity (Colony Health Status)

The IACUC may require the placement of sentinel animals in rodent housing areas to monitor for the presence or introduction of rodent pathogens. These animals would be included in the DLAR’s disease surveillance program, and the placement, care and removal of the sentinel animals would be in accordance with this program. The IACUC will determine the necessity of placement of sentinel animals in a housing area on the basis of the number of animals at the site, the duration for which animals remain at the site, and the trafficking of investigators between the site and other animal use and housing sites. The PI will be charged for this service.

J. Reporting Problems

Any problems with maintaining the conditions specified in this SOP should be brought to the immediate attention of a DLAR veterinarian.

II. Animal Husbandry and Care

A. Daily Observation of Animals

In order to comply with federal Guidelines AWR’s §2.33(b)(3) and the Guide, animals must be observed daily, including weekends and holidays, by qualified personnel to assess animal health and well-being. Daily observation of animals must be recorded on the housing site log (see Guidelines – Management of Housing Areas III.A). Additionally, AWRs §2.33(b)(3) requires that a mechanism of direct and frequent communication with the attending veterinarian or his/her designate exists so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed. Contact a Division of Laboratory Animal Resources (DLAR) veterinarian for animal health concerns.

B. Food and Water

Adequate provisions for feeding and watering of animals must be made at all times unless otherwise outlined and justified in an IACUC approved protocol. To avoid contamination, food must be stored properly and provided in feeders that are so placed to prevent contact of food with feces and urine. Additionally, animals must have access to potable drinking water appropriate for the species. Watering devices should be checked daily to ensure proper operation and must be washed and sanitized at least weekly.

C. Cages and Bedding

Bedding changes can vary from daily to weekly depending on factors such as animal number and size, cage size, urinary and fecal output, and experimental conditions. Cages must be cleaned and sanitized on a regular basis. The frequency of cage sanitation may vary depending on specific husbandry practices, such as bedding type, cage type and size, animal density, and frequency of bedding changes. Rodent cages should be sanitized at least once a week.
III. Record Keeping

A. Housing Area Log
Records of animal care, room maintenance, and environmental conditions must be posted in the housing site and be kept up to date by responsible personnel. Attached is a sample housing area log (attachment 1) that can be modified as appropriate to the specific protocol and animal species. The format of the modified log should be kept on file and should accurately reflect the tasks performed and the frequency of each task as described in the Standard Operating Procedures (SOP) for the housing area (see Guidelines – Management of Housing Areas III.B). Copies of housing site logs must be maintained at the housing site by the investigator’s personnel, for the duration of the housing period, and be available for inspection by DLAR, RCCO, and IACUC personnel.

B. Standard Operating Procedures (SOP) for Animal Husbandry and Study Area Maintenance
A description of procedures for animal husbandry and housing site maintenance must be provided to the DLAR. Attached is a sample SOP template (attachment 2). The area specific SOP must be kept on file and made available to representatives of the IACUC, the Attending Veterinarian or his/her designate, and regulatory agencies.

C. Room Ventilation
A copy of Facilities Management’s or Environmental Health and Safety’s report regarding room ventilation (exhaust and air exchange rate) must be submitted to the IACUC. This document must be kept on file and available to representatives of the IACUC, the Attending Veterinarian or his/her designate, and regulatory agencies.

IV. Veterinary Access
The Attending Veterinarian or his/her designate must be provided access (i.e., a key or combination) to the housing site in order to ensure the provision of adequate veterinary care in accordance with federal Guidelines (AWRs) and the Guide.
Attachment 1

Housing Site Daily Log

<table>
<thead>
<tr>
<th>Date</th>
<th>Daily Procedures</th>
<th>Weekly</th>
<th>Monthly</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temp: current</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Temp: min, max</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Humidity: current</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Humidity: min, max</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Feed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Water</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Animal health</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ &amp; empty trash</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>¥ Cages/Boxes*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>¥ Water bottles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Clean/sanitize area</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Sanitize feed container</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓Expiration dates</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Care taker initials
Attachment 2 – SOP Template

STANDARD OPERATING PROCEDURE (SOP)
FOR ANIMAL HUSBANDRY AND HOUSING SITE MAINTENANCE

I. Purpose
The purpose of this document is to describe the procedures for animal husbandry and housing site maintenance utilized in an investigator managed housing site.

II. Scope
This SOP will apply to all research animals housed in LIST building room number(s) under the care of LIST investigator’s name.

III. Responsibilities
A. LIST the principal investigator’s name is responsible for reviewing and updating this document annually or as needed to keep the information current.
B. All research personnel involved with the maintenance and care of the animals housed in this area will be responsible for reading and complying with this SOP.

IV. General
A. LIST the species housed
B. Husbandry Guidelines
   1. LIST the environmental parameters including temperature, humidity, light cycle, air change, and room pressure.
C. Special needs
   1. LIST applicable items such as a special diet or feeding schedule, special bedding/litter changing schedule, use of sterile or deionized water, etc.

V. Procedures
A. Daily monitoring and care of animals.
   1. IDENTIFY by whom, method of communication with the DLAR veterinarian regarding animal health or welfare concerns, weekend, emergency, and holiday care, etc.
B. Feeding
   1. IDENTIFY the type and quantity of diet fed, how feed is provided, frequency of feeding, food storage and monitoring mechanism, etc.
C. Watering
   1. IDENTIFY how potable water is provided, frequency of monitoring, water container/device changes, etc.
D. Bedding and cage changes
   1. IDENTIFY the frequency of bedding/cage changing, type of bedding used, storage and monitoring of bedding, etc.
E. Sanitation of housing area, cages or tanks, feeders, water bottles, food and bedding storage containers, racks or shelves
   1. IDENTIFY the frequency of process for sanitation, the chemicals used, etc. Please note that sanitation “as often as needed” is not acceptable.
F. Record keeping
   1. IDENTIFY record keeping procedures for room/area maintenance (see sample housing area log).