PURDUE
UNIVERSITY

Institutional Animal Care and Use Committee (IACUC)

Standard Operating Procedures (SOPs)

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1. PURPOSE:

An important part of Purdue University's program for the care and use of animals used in research, teaching, or testing, is the meaningful monitoring of procedures approved by IACUC and the monitoring of the health of the animals used under an approved protocol. In this regard, IACUC requires that a copy of approved protocols and amendments be available at or near the site where the animals are housed. This will ensure that the inspection teams, (e.g. IACUC, USDA, AAALAC-I) and laboratory animal veterinarians/veterinary technicians have easy and ready access should a question arise while they are visiting the facility where animals are being housed. This will also ensure that all animal care stave have sound knowledge of the procedures being performed on the animals so they may anticipate what health problems might occur as part of the study/course. This will allow them to distinguish such problems from naturally-occurring ones and to also alert investigators to any problem.

All animal study areas must be approved by the Purdue University Institutional Animal Care and Use Committee (IACUC) prior to use and are subject to inspections by the IACUC. For additional information regarding proper animal care and use, please contact the Purdue University LAP office at 494-9163. All animal housing must conform to the standards in the Guide for the Care and Use of Laboratory Animals. To acquire a copy of the Guide for the Care and Use of Laboratory Animals contact the LAP office at 494-9163.

By housing animals in a study area, the investigative / research staff assumes certain responsibilities associated with such use to include those outlined and described in this SOP. It is recommended this SOP be posted in the animal study area.

2. DEFINITIONS

2.1 *Animal Study Area.* A study area is an area outside an approved university animal housing facility where animals are housed for a period of 12 or more hours.

3. PROCEDURES

3.1 General Responsibilities

3.1.1 Training:

(a) All individuals working with animals must be properly trained in order to provide adequate care to the animals.

(b) Information regarding training can be acquired via the Laboratory Animal Program (LAP).

3.1.2 Daily Animal Care

(a) Daily animal care must be documented. A Daily Animal Care sheet or log book, maintained in the area with the animals, is suitable to document the provision of daily care.

3.1.3 Veterinary Care

(a) If any animal is noted as being abnormal, sick, injured or is found dead, the researchers or staff must notify the laboratory animal veterinary staff as soon as possible (494-9163).

3.1.4 Water Feeding and Storage of Feed

(a) Animals will be fed a palatable, noncomtaminated, and nutritionally adequate food daily or according to their particular species requirements.

(b) Feeding instructions should be documented in order to ensure investigative staff is feeding the proper amount.

(c) Open bags of feed must be stored in enclosed, vermin-proof containers. Feed containers must be labeled with type of feed and milling date (if feed is not milled, the date the feed was labeled with type of feed and milling date purchased/acquired should be on the container).

(d) Animals should have access to potable, noncontaminated drinking water according to their particular species requirements

3.1.5 Animal Identification

(a) Animals need to be clearly identified through the use of cage cards that include name of responsible investigator(s), source, species/strain/breed, number of animals in cage/enclosure, approved IACUC protocol number, and information such as birth/age, sex, arrival, and surgery dates (where applicable).

3.1.6 Sanitation, Housekeeping and Cage Placement

(a) Cages/enclosures must be sanitized regularly in order to provide a healthy environment for the animal.

(b) The sanitation and cleaning schedule should be documented. This can be accomplished by documenting the cleaning duties performed each day on the Daily Animal Care Sheet.

(c) A specific location in the laboratory used for the animal study area should be designated solely for animal housing and be free of clutter. The animal study area must be kept neat and clean.

(d) The area/facility should have surfaces that are easily sanitized. These surfaces should be wiped clean daily and sanitized at least weekly.

3.1.7 Environmental Monitoring

(a) The area where the animals are housed should be suitable for that particular species and must be monitored on a daily basis to ensure proper environmental parameters (e.g. temperature, humidity) are being maintained.

(b) A minimum/maximum thermometer and hygrometer needs to be placed in each animal room. These units can be purchased from common vendors (e.g. Fisher Scientific (or VWR Scientific Products) The temperature and humidity readings should be recorded on the Daily Animal Care Sheet.

(c) A 24-hour monitoring system must be in place that will send notice of failures to responsible parties. For species specific recommendations on environmental parameters, please contact the LAP office at 494-9163.

3.1.8 Illumination

(a) Traditionally, laboratory animal housing areas are equipped with controlled lighting systems that provide regular diurnal cycles. If it is not possible to control the lighting in the animal study area, the researcher must be certain that variable light cycles will not affect the research objectives and data.

(b) Where it is not possible to control the lighting in the animal study area, as a minimum, lights should be turned off at night / on in the morning.

3.1.9 Emergency Information and Security

(a) Emergency contact information must be posted in order to instruct emergency and maintenance personnel who to contact if there is a concern with the animal housing.

(b) This should include office and after-hours phone numbers. The animal study area should be kept locked and access should be restricted to authorized personnel only.

3.2 Maintaining security of, and supplying a copy of, protocols and amendments in Animal Study Areas.

3.2.1 At the time of the housing request or animal order from the Principal Investigator or supporting staff, the Animal Facility Supervisor should request a copy of the approved protocol. A Principal Investigator may also choose to give access to his/her protocol via the IACUC electronic system to animal facility personnel.

3.2.2 It is the responsibility of the Principal Investigator to supply a copy of the approved protocol(s) and amendment(s) to the Animal Facility Supervisor or to give access to their protocol(s) via the electronic system.

3.2.3 If a Principal Investigator does not wish for a copy of their protocols and amendments to be available in the animal housing area or to provide access via the electronic system, a request for exemption to this policy must be made to the IACUC Administrator, in writing. The exemption request will be forwarded to the full membership of IACUC for review.

3.2.4 If provided a paper copy, all protocols and amendments must be kept in a secure, locked area. At no time are these documents to be left unsecured in the animal areas. These documents are confidential and are available only to animal care staff (not students), IACUC, and the LAP.

3.2.5 When disposing of paper copies of protocols and/or amendments when the project is completed, they must either be shredded or placed in a secure recycling container. These containers are locked and only opened by recycling personnel where the shredding will take place. These documents are not to be placed in the trashcan or in a regular recycling container.

4. APPLICABLE REGULATIONS AND GUIDELINES

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition.

1. PURPOSE:

This SOP establishes the training requirements and documentation for animal care and use protocols. Five sources guide Purdue's training programs:

(1) Animal Welfare Act

(2) Animal Welfare Regulations

(3) The Guide for the Care and Use of Laboratory Animals

(4) The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching

(5) The PHS Policy on Humane Care and Use of Laboratory Animals

2. PROCEDURES

2.1 Required Elements for Training

2.1.1 The Principal Investigator or Supervisor is responsible for ensuring that everyone under his or her direction who works with animals is adequately trained and fulfills the following requirements.

2.1.2 Those who must be properly trained include:

(a) Principal Investigators and supervisors;

(b) Research staff;

(c) Animal care staff;

(d) Graduate Students;

(e) Undergraduate employees;

(f) Students working with animals under the auspices of a course or research protocol with IACUC approval (including independent research courses.)

2.2 Personnel Requirements

2.2.1 Personnel must be certified as Qualified on an IACUC Animal Use Qualification Form.

(a) An individual must have species-specific expertise for the animal being handled.

(b) For protocols involving wild organisms, training can be done with the same species as listed in the protocol or with a closely related species.

(c) The individual must also be able to perform, independently, the procedures that are necessary to fulfill their role as outlined in the approved IACUC protocol.

(d) Among the procedures that require the submission of an Animal Use Qualification Form are:

(i) Husbandry;

(ii) Handling/Restraint;

(iii) Breeding;

(iv) Nutrition;

(v) Blood Collection;

(vi) Injections;

(vii) Oral gavage;

(viii) Surgery, including

(1) Aseptic Technique

(2) Anesthesia and Analgesia

(3) Suture Techniques

(ix) Pre- and Post- Procedural Care;

(x) Euthanasia

2.2.2 Qualified individuals must either be trained or have antecedent expertise.

(a) Hands-on training

(i) Training may be provided by the LAP office or by another individual who has a completed IACUC Animal Use

Qualification Form on file for that specific species and technique, or by an off-campus individual who has the necessary qualifications to provide the training.

(ii) If someone other than a LAP staff member trains the person, individual training documentation must be completed and filed with the employee's supervisor for each item submitted on the IACUC Animal Use Qualification form.

(iii) Training should be hands-on with the relevant species as listed in the approved IACUC protocol.

(iv) An example of a Hands-On Training Form that may be used for training documentation is available on the IACUC/LAP website. This form may be modified as needed by the PI/Supervisor to suit individual training needs.

(b) Antecedent expertise

(i) Prior expertise should be documented by an abbreviated CV that describes relevant professional degrees, licenses, certification, and experience in protocol related procedures. Publications may be listed if appropriate to the protocol related procedures.

(ii) Visiting Researchers and Research Staff who will be working on procedures for which Purdue normally requires an Animal Use Qualification Form must submit a Training Exemption Request at least one week in advance of arrival. This form is available on the IACUC website or through the electronic system. This request may be sent to the IACUC office by email to the IACUC office.

2.2.3 Examine Website Materials on the Animal Exposure Occupational Health and Safety Program.

(a) Personnel must review material on the IACUC Occupational Safety website and must complete a Risk Assessment Form that is returned to the IACUC office. This is mandatory, not optional.

(b) Once the Risk Assessment Form is received, a Risk Summary will be prepared for the individual and returned to him/her along with a Participation/Declination Form.

(c) After the individual has been informed of the occupational health program, the person can decide whether to participate or decline participation in the program.

2.2.4 Personnel must satisfy the Radiological and Environmental Management (REM) Requirements for the Handling of Controlled Substances, if applicable.

2.2.5 All personnel must be informed (where applicable) about the provision of veterinary care, keeping health records, handling of expired medical materials, or handling of pharmaceutical-grade compounds by reviewing applicable SOPs and guidelines found on the IACUC/LAP website.

2.2.6 Complete on-line CITI Program training modules: Complete on-line CITI Program training modules.

(a) The mandatory modules are: Working with the IACUC, Biosafety, and any species-specific module(s) needed for the animals that they will work with at Purdue.

(b) Personnel will be instructed to complete these modules once the IACUC office receives their Animal Use Qualification Form.

2.3 Instructor Responsibilities

2.3.1 Instructors must notify all students attending courses in which they may be exposed to animals of all risks associated with that species.

2.3.2 Some, though not all, information about such risks can be found on the Purdue Occupational Health link

2.4 Training Programs

2.4.1 Training programs are available through LAP and may be used by anyone using or caring for animals used in research or teaching.

(a) IACUC Newsletter – quarterly informational training provided to all personnel who use animals on campus.

(b) AALAS Training Courses – provided by Laboratory Animal Program on a rotating basis for all levels (i.e. ALAT, LAT, LATG, and CMAR)

(c) Hands-on sessions – These courses cover handling, restraint, behaviors, injection and blood collection techniques. These sessions will be documented using the Hands-On training form.

Species covered may include mice, rats, rabbits, and other species depending on availability of transfer from another approved protocol.

2.4.2 Specialized training in farm techniques, wildlife training, particular research procedures, etc. is available through LAP as needed.

3. APPLICABLE REGULATIONS AND GUIDELINES

Animal Welfare Act, 9 CFR § 2.31

PHS Policy on Humane Care and Use of Laboratory Animals

FASS, Federation of Animal Science Societies. (2010). Guide for the care and use of agricultural animals in research and teaching.

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition. Washington (DC): National Academies Press (US); 2011. Available from: https://www.ncbi.nlm.nih.gov/books/NBK54050/ doi: 10.17226/12910

1. PURPOSE:

The Purdue University Laboratory Animal Program strives to maintain animal facilities that are safe for both humans and animals. This policy serves as a basis for the biosafety and biosecurity within Purdue animal rooms and facilities.

2. DEFINITIONS

2.1 *Biosafety*. Practices that reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents.

2.2 *Biosecurity.* Practices that protect an animal colony from microbial contamination, and that prevent the loss, misuse, or theft of microorganisms, biological materials, and research-related information.

2.3 *Personal Protective Equipment (PPE).* Equipment designed to protect one from exposure to elements of the field; PPE can be used to protect humans from allergens and microorganisms harbored by the animals, or to protect immunocompromised animals from microorganisms harbored by humans. PPE can also be used to prevent the transmission of microorganisms, allergens, and pheromones from one animal room to another.

3. PROCEDURES

3.1 Biosafety Cabinet and Animal Transfer Station Use

3.1.1 Biosafety cabinets or animal transfer stations are provided in most animal rooms that have ventilated caging. The use of ventilated caging combined with the cabinet/station provides superior allergen protection for humans, as well as protection of the humans, animals, and environment from contamination. Biosafety cabinets also provide protection from infectious agents.

3.1.2 Proper Cage Handling Technique in the Biosafety Cabinet/Transfer Station

(a) Turn on cabinet for ~5 minutes prior to use.

(b) The sash must be down while in use for both biosafety cabinets and animal transfer stations; if the sash is up on a biosafety cabinet the unit will alarm, the alarm must not be turned off or silenced.

(c) Spray down the entire cabinet with disinfectant (Rescue/Peroxiguard, Defender, or Virkon).

(d) Place cage and any other items to be used in the cabinet.

(e) Spray cage and other items with disinfectant.

(f) Open cage and flip the lid so the inside of the lid is facing upward.

(g) Spray gloves prior to touching the wire bar or anything inside the cage.

(h) Place the wire bar inside of the lid (if removing the wire bar).

(i) Each time an item outside of the cabinet is touched, spray gloves prior to touching the inside of the cabinet, or inside of cage again

(j) When finished, spray the inside of the cabinet with disinfectant and wipe clean with paper towels

(k) Turn off the cabinet and lights

3.2 Facility Biosecurity

3.2.1 Facility Access

(a) Facility access is provided after facility orientation has been performed by animal care management. Do not allow those without orientation training to enter animal facilities unattended.

(b) Do not allow people without known facility access to follow you into an animal facility.

(c) Do not prop open doors to animal facilities, or to animal rooms.

(d) Be sure to lock animal room/research equipment room doors when finished using the room.

3.2.2 Dirty and in-use caging that is brought out of an animal room must be covered with a lid or drape/gown to prevent spread of allergens and contaminants.

3.3 Personal Protective Equipment (PPE)

3.3.1 General Requirements

(a) In most cases, garb except gloves is to be donned prior to entering the room. Gloves may be put on once in the animal room.

(b) Coats and jackets are not to be brought into animal rooms. They should be hung in the appropriate place within the animal facility prior to entering the animal room.

(c) A gown, lab coat, or coverall and gloves are required in all rodent, chinchilla, and rabbit rooms. Please refer to door signage for appropriate garb in each room.

(d) Gloves are required for work with fish and amphibians.

(e) A gown or lab coat is recommended for work with all other species.

3.3.2 Shoes

(a) Closed-toed shoes are required in animal rooms and laboratories.

(b) Shoe covers or dedicated boots are recommended when entering large animal runs

3.3.3 Gowns and lab coats

(a) A gown, lab coat, or coverall and gloves are required in all rodent, chinchilla, and rabbit rooms. A gown or lab coat is recommended for all other species.

(b) Gowns and lab coats worn into animal rooms must be removed at the threshold upon exit and disposed of/laundered. Gowns and lab coats may be re-used for 7 days if stored in an individual container (i.e., Ziploc bag). Husbandry technicians should dispose of their gown on cage change or bottle fill days when handling large number of cages. In some areas (Bindley barrier; MJIS B063, B099-B107; VLAB, Hansen barrier, Biology 108 suite), gowns may be worn from room to room in the suite while following room order. Note: 7-day usage by PI staff may be extended to 1 month in cases of gown shortages.

(c) Rodent health levels 1 and 2 require the use of a gown or coverall, gloves, surgical loop mask, hair bonnet, +/- shoe covers.

(d) Rodent health level 7 requires the use of a gown or coverall, gloves, N95 respirator, hair bonnet, +/- shoe covers. Rodent health level 8 requires all of the above except for N95 respirator use.

3.3.4 N95 Respirators and Safety Glasses

(a) N95 respirators and safety glasses are REQUIRED while administering biohazards/chemicals and while handling open cages (even under the cabinet) contaminated with these agents.

(b) N95 respirators are REQUIRED in animal rooms housing rodents, rabbits, chinchillas, guinea pigs, and wild birds in open static caging.

(c) N95 respirators are NOT required when working in an IVC rodent room in which the animal cages are only opened under the biosafety cabinet/transfer station and have not been exposed to biological or chemical hazards.

(d) All personnel working in animal rooms that require N95s must have N95 fit testing performed annually.

(e) N95 respirators may be reused if stored in a sealed Ziploc bag labeled with the person's name. The mask must be inspected for damage or gross contamination at each use and disposed of when it occurs. N95 respirators may NOT be reused when used after actively administering biological or chemical hazards to animals, or in ABSL2 room with static housed animals.

(f) Exceptions for N95 use may be granted for occasional visitors of the animal rooms that will not be using animals, including but not limited to those performing maintenance or inspections.

3.4 PPE Compliance System

3.4.1 In order to encourage proper use of the animal facilities as listed above, the following compliance system is in place.

3.4.2 The first time a person is identified as not in compliance, a verbal warning will be given and the person will be required to be retrained by facility personnel.

3.4.3 A second offense will require a meeting with PACUC; this will result in revocation of facility access until PACUC reinstates access.

4. APPLICABLE REGULATIONS AND GUIDELINES

Biosafety in Microbiological and Biomedical Laboratories, 6th Edition

1. PURPOSE

The IACUC reviews all submitted protocols using vertebrate animals in teaching, exhibition, or research and may decide to approve or disapprove the proposed ~~research~~ activity, or to specify modifications required to secure IACUC approval of the activity. Standardized procedures are necessary to ensure proper communication of protocol status between the IACUC Members, Laboratory Animal Program (LAP), IACUC Office Staff, Principal Investigators, and research/teaching personnel, and others charged with the welfare of vertebrate animals.

2. PROCEDURES

2.1 Protocol Submission

2.1.1 Principal Investigator (PI) and Co-PI Eligibility

(a) All faculty (tenured, tenure-track, research and clinical) and senior research scientists are automatically eligible to be a Principal Investigator on a vertebrate animal research, teaching, or testing protocol. Being a principal investigator of an IACUC-approved protocol at Purdue University comes with a distinct set of responsibilities. The Pl accepts overall responsibility for directing the animal activity as well as for compliance with relevant University policies and federal regulations.

(b) If a principal investigator cannot oversee their project for a prolonged period of time because they are away from the activity site, it is required that they name another person listed on the protocol as a co-Pl. Co-Pl eligibility must also be faculty or senior research scientists. The co-Pl will be responsible for day-to-day oversight and ensuring that the protocol is followed. Adjunct faculty not based on a Purdue campus, faculty on prolonged or sabbatical leave must name a co-Pl before any animal use is allowed to continue on their approved protocol.

2.1.2 PIs must certify and submit complete applications through the electronic system including all training materials and criteria established in 9 CFR 2.31(d) and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. Applications lacking this information will be returned to the PI for edit prior to further review.

2.2 Protocol Review

2.2.1 Prior to IACUC review, each member of the Committee shall be provided with a list of proposed activities to be reviewed. Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full Committee review of those activities. If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities. If full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum;

(a) PHS Policy on IACUC member conflict of interest states that no IACUC member may participate in the IACUC review or approval of an animal protocol, non-compliance issue, or report of concern for which that member is personally involved. In this circumstance, the IACUC member will recuse themselves from the review and vote.

(b) To prevent the appearance of conflict of interest, other reasons for recusal during Full Committee Review include times when an IACUC Member:

(i) has a significant financial interest in the project;

(ii) has a spouse or dependent child who is on the study team;

(iii) currently serves as a mentor to any graduate students or post-doctoral scholars involved in the project;

(iv) has any other personal interest or role that leads the IACUC member, in his or her own best judgment, to believe that

he/she lacks impartiality (e.g., subordinate, supervisory, collaborative, or other relationship.)

(c) The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC

2.2.2 The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator.

2.2.3 When substantive information is lacking from a protocol (new or triennial), or amendment to a protocol, that has been sent to the full committee for review where the committee may have questions requiring a response from the PI before approval can be granted, the following action(s) may be taken if approved by the quorum present at the convened meeting:

(a) The IACUC may vote to require modifications to the protocol or amendment before it can be approved and have the revised document reviewed and approved by the designated member review process. The designated member review must be conducted by the chair of IACUC or designee (e.g. Associate Chair) and the veterinarian or designee who performed the pre-review of the protocol.

(b) If the IACUC uses the above process, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date must be reported to OLAW as a serious noncompliance with the PHS Policy.

2.3 Protocol Renewal

2.3.1 The IACUC shall conduct complete reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not

less than every 3 years. The complete review shall address all requirements related to the care and use of animals as stated in the Animal Welfare Act, 9 CFR § 2.31 and PHS Policy.

2.3.2 Ninety (90) days prior to the expiration date of a protocol, the IACUC Office staff will send out a notice via electronic communication to the Principal Investigator (PI) notifying them that a complete protocol rewrite is required.

2.3.3 Thirty (30) days prior to expiration, the IACUC Office staff will send a reminder to the PI if their protocol has not been completed through the electronic submission system.

2.3.4 The protocol must be received in the IACUC office not less than 30 business days prior to expiration so that IACUC has time to review it prior to the protocol expiring.

2.3.5 If the protocol renewal has not been received within 30 business days of the protocol's expiration date, the protocol approval may lapse if the IACUC cannot get the review process completed. Communication will be sent to the PI if this is the scenario.

2.4 Protocol Suspension or Expiration

2.4.1 The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

2.4.2 If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity; and

2.4.3 Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

2.4.4 The possibility exists that a protocol can become inactive (e.g., protocol approval expires due to lack of timely triennial renewal, or protocol is suspended), but animals remain in an animal facility. In order to avoid euthanasia of such animals, and to remain in compliance with regulatory requirements, the IACUC allows transfer of such animals to the LAP Animal Holding Protocol for a maximum of 60 days. During this time, the investigator of the expired or suspended protocol must take the necessary actions to gain approval for the use of the animals. Failure to gain approval will result in permanent forfeiture of the animals.

(i) When animals are assigned to the Animal Holding Protocol, the oversight of the animals will be the responsibility of the Attending Veterinarian or LAP veterinary staff designee. During the time animals are assigned to the Animal Holding Protocol, the animals will be provided routine care. Procedures necessary to maintain the health and well-being of the animals will continue. Examples might include ongoing post-operative care, chronic catheter maintenance, administration of insulin, etc. No experimental procedures, data collection, or teaching activities will be allowed.

(ii) The day a protocol expires or is suspended, notice from the IACUC office will be provided to the Principal Investigator informing the individual that their protocol has expired / been suspended. The PI will be informed that all per diem charges that may apply are the responsibility of the PI and/or their department.

(iii) If there are still animals on that protocol, the location, species, and number of animals will be determined and the information provided to the Attending Veterinarian or LAP veterinary staff designee.

(iv) If the three-year approval period has expired and the teaching or research associated with the expired protocol has continued or if the protocol has been suspended, the IACUC is required to report this fact to the Office of Laboratory Animal Welfare (OLAW) and the USDA (if applicable).

(v) Upon IACUC approval of the new protocol or lifting of a suspension, the animals will be transferred back to the Principal Investigator. If the protocol is not reinstated, the disposition of the animals will be at the discretion of the LAP veterinary staff as described in the LAP Animal Holding Protocol.

(vi) No protocol may continue past its expiration date if materials for renewal and continuation as described above have not been completed by the PI and approved by IACUC.

2.4.5 Protocol Deactivation by Principal Investigator

(i) If a PI wishes to deactivate a protocol prior to the expiration date, they may indicate this in writing to the Purdue IACUC Office.

(ii) The protocol will be deactivated only after it is verified that no animals are currently being used on the protocol. Verification may be done by direct contact with the PI or animal care staff. If no animals are connected with the protocol, it may be deactivated.

(iii) If animals are connected with the protocol, the PI must either keep the protocol active or transfer the animals onto another active protocol.

3. REFERENCES

Animal Welfare Act, 9 CFR § 2.31

PHS Policy on Humane Care and Use of Laboratory Animals

Purdue Policy, Research and Teaching Involving Animal Subjects (I.C.2)

Principal Investigator Eligibility, Sponsored Program Services

Prior Purdue IACUC documents combined and updated for this SOP:

Annual Continuation of Approved Protocols
Conflict of Interest with IACUC Issues

Designated Member Review Subsequent to Full Board Review
Expired/Suspended Protocols
Principal Investigator/ Co- PI Eligibility

1. PURPOSE:

This SOP outlines the various internal and external responsibilities of the Institutional Animal Care and Use Committee (IACUC) in collaboration with the Laboratory Animal Program (LAP). Both internal reporting to the Institutional Official and external reporting to appropriate agencies and accrediting bodies serve toward continuous knowledge and resolution of concerns. These agencies include: the United States Department of Agriculture (USDA), The Office of Laboratory Animal Welfare (OLAW) under Public Health Services, and the American Association for Accreditation of Laboratory Animal Care. Further, other reporting may be necessary as described in specific contractual arrangements or applicable regulations, as outlined in specific contracts or sponsor guidelines (e.g. Department of Defense, industry sponsors).

2. PROCEDURES

2.1 Process for Reporting

2.1.1 Items involving protocol deviation, noncompliance, animal welfare, or other concerns related to the treatment or use of vertebrate animals in research or teaching are to be reported to the IACUC office.

2.1.2 Through its administrative staff (e.g. IACUC Administrator) and the IACUC Chair (or their designee), the item will be reviewed for relevance and substantiation. Actions may include, but are not limited to:

(a) written or verbal inquiry to the Principal Investigator and/or their staff;

(b) request for Post Approval Monitoring (see IACUC SOP 203 – Post Approval Monitoring.)

(c) consultation with Laboratory Animal Program veterinarians or staff.

2.1.3 The IACUC Chair (or designee) will decide whether the matter is substantiated and able to be resolved. They may then choose whether the matter should be sent to the convened IACUC for review or notification. In general, all matters of noncompliance or animal welfare will be reported to the IACUC for comment, review, and/or resolution.

2.1.4 PIs will be notified in writing of the requirements and outcome of the review.

2.1.5 Should the matter require external reporting as outlined in this SOP these items will be referred directly to the Institutional Official (IO). Prompt external reporting of adverse events and incidents by the IO is of central importance. As stated in University policy, the IO "bears overall responsibility for the University's animal care and use program, including resource planning, alignment of the program's goals with the University's mission."

2.2 Whistleblowing

2.2.1 Processes to Report to IACUC

(a) Purdue University supports the humane use of animals in research, teaching, and testing. The Institutional Animal Care and Use Committee (IACUC) is responsible for ensuring that all animals used in research, teaching, and testing procedures are treated humanely and in accordance with the Federal Animal Welfare Regulations, the PHS "Policy on the Care and Use of Laboratory Animals," the Guide for the Care and Use of Laboratory Animals, the Guide for the Care and Use of Agricultural Animals in Research and Teaching, and all other applicable government regulations.

(b) Anyone who witnesses or suspects any violations of regulation or have any questions or concerns about the specific use of animals at or in association with Purdue University, is encouraged to contact the IACUC Office.

(c) To report anonymously via Purdue's Hotline see www.purdue.edu/hotline, or 1-866-818-2620. Please note that if contacting the Purdue Hotline, your concern may not be immediately addressed. For concerns requiring immediate/emergency attention, please contact 494-7206 directly.

(d) No employee or student of the University will be subject to reprisal for reporting suspected violations or animal welfare concerns. Purdue University Policy III.A.4., describes University Procedures for Protection Against Reprisal for Good Faith Disclosures. Please see https://www.purdue.edu/policies/ethics/iiia4.html for full policy.

2.3 Reporting and Registration Maintenance

2.3.1 USDA Reporting under the Animal Welfare Act (AWA)

(a) Internal Reporting

(i) At least once every six months the IACUC will supply a report to the IO (also known herein as "Semi-annual Report" or "semiannual evaluation") reports shall be reviewed and signed by a majority of the IACUC members and will include any minority views. The Semi-Annual Report will include:

(1) Review of the research facility's program for the humane care and use of animals

(2) Results of the inspections of animal facilities, including animal study areas.

(3) If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

(ii) When USDA Representatives perform an inspection of Purdue facilities, the IO will be notified promptly of the inspection, result, and any corrective measure(s) noted.

(b) External Reporting

(i) As of January 2022, research facility registration is no longer required every three years. Changes or cancellation to the registration of the facility will be made utilizing the appropriate APHIS Forms (e.g. The Notification of Change form (APHIS Form 7033) available at https://www.aphis.usda.gov These changes must be authorized by the IO.

(ii) As required in the AWA the Semi-Annual Report will be updated at least once every six months and will be maintained by the IACUC Office for at least three years, made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request.

(iii) The IACUC shall submit an annual report to the Deputy Administrator (USDA) on or before December 1 of each calendar year utilizing the appropriate forms (e.g. APHIS form 7023) or electronic systems. The report will include

items referenced in §2.36 The report will be reviewed and signed by the IO.

(iv) For animals covered under USDA regulations, the IACUC will report pursuant to the standards articulated in § 2.32 (7). If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity.

2.3.2 Reporting Requirements - OLAW

(a) Internal Reporting

(i) As described in Section 2.2.1(a)i of this SOP, the semiannual report will be provided to the IO.

(ii) The IACUC through its administrative staff, Chair, and/or Associate Chair will inform the IO of potential noncompliance with PHS Policy.

(iii) The Attending Veterinarian will keep the IO informed of veterinary, facility or other concerns related to health and welfare of animals covered under PHS Policy.

(b) External Reporting

(i) According to PHS Policy, the IO must maintain the Animal Welfare Assurance (AWA) that fully describes the institution's program for the care and use of animals in PHS-conducted or supported activities. No greater than every five years, the AWA documentation will be updated with OLAW via the IO.

(ii) The IACUC will submit an annual report through the IO no later than December 1 of each year. As detailed in PHS policy (https://olaw.nih.gov) the report will include:

(1) any changes to the program of animal care and use,

(2) AAALAC accreditation status,

(3) IO and IACUC membership,

(4) semiannual evaluations of the program and facilities and minority views expressed

(5) this report is required even if there are no changes. See PHS Policy, IV.F.2

(iii) Noncompliance

(1) Reporting Noncompliance, As stated in the PHS Policy, IV.F.3, The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

a. any serious or continuing noncompliance with PHS Policy;

b. any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals]; or

c. any suspension of an activity by the IACUC.

(2) The IO in cooperation with the IACUC is responsible for this reporting. Examples of each item are contained in referenced PHS Policy, IV.F.3. As required by PHS Policy, reports will contain:

a. The Animal Welfare Assurance Number (AWA)

b. relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS a full description of any potential or actual effect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (see examples in PHS policy).

c. Full explanation of the situation, including what happened, when and where, the species

of animals involved and the category of individuals involved (e.g. principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.)

d. description of actions taken by the institution to address the situation; and

e. description of short- or long-term corrective plans and implementation schedule(s).

2.3.3 Reporting Requirements - AAALAC

(a) Internal Reporting

(i) Although no specific internal requirements are outlined for AAALAC for internal reporting, the Semi-Annual Report via USDA and OLAW requirements previously referenced are general expectations.

(b) External Reporting

(i) Administrative Reporting As detailed in AAALAC reporting standards, annual reports will be made promptly in the event of the following.

(1) Significant Organizational Changes in:

a. institutional ownership (e.g., sale, merger, etc.)

b. unit contact (must include degree, title, address, phone and fax numbers, and email)

c. facility size, location, name if site visit is pending before Annual Report is to be submitted

(2) Withdraw from the AAALAC accreditation program.

(ii) Annual Reporting

(1) Annual Reports will provide required data for a period of time no greater than 12 months after the prior report.

(2) At a minimum, this report will provide AAALAC with updates on the following.

a. Key personnel contact changes;

b. Changes in physical areas of supporting your animal care and use;

c. Actions taken in response to Suggestions for Improvement (SFIs);

d. Organizational structure changes;

e. Animal usage;

f. Protocol violations which had the potential to compromise animal welfare;

g. Animal use not approved by the IACUC or comparable oversight body;

h. Significant adverse events not previously reported as required by the Rules of Accreditation.

(iii) Adverse Events.

(1) AAALAC Rules of Accreditation require prompt reporting in the following events.

a. Inadequate veterinary care

b. Conditions that resulted in unexpected animal harm or deaths

c. Accidents or errors

d. Equipment failure

e. Natural disaster

f. Significant animal rights activities (e.g., protests, break-ins, property damage, FOIA and other public records requests that include AAALAC International documents)

g. Inappropriate euthanasia techniques and/or failure to confirm euthanasia

h. Substantiated complaints or reports regarding animal welfare concerns

i. Internal or external reviews/inspections or other similar reports that document significant adverse events or noncompliance that resulted in animal harm or death; investigations by national oversight bodies; and other serious incidents or concerns that negatively impact animal well-being (e.g., failure to follow the approved protocol which resulted in compromised animal welfare; death during transport)

j. Significant human health issue directly related to the animal care and use program

(2) AAALAC guidance states that adverse events not meeting the criteria above may be added to the Annual report described in this section and in the AAALAC Rules of Accreditation.

2.3.4 In the case of a serious noncompliance or serious adverse event, as determined by the IACUC, reporting to other sponsors of vertebrate animal research will be conducted in the manner designated by the contractual arrangement.

3. RESPONSIBILITY

The IACUC and LAP are responsible for assessing the severity of adverse events or matters related to IACUC protocol noncompliance.

The IACUC and LAP Staff are responsible for maintaining institutional registrations and obtaining metrics and inspection reports to be added to the semiannual and referenced annual reports.

As stated in University policy, the Institutional Official (IO) "bears overall responsibility for the University's animal care and use program, including resource planning, alignment of the program's goals with the University's mission."

4. APPLICABLE REGULATIONS AND GUIDELINES

Animal Welfare Act, 9 CFR § 2.31 et seq.

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition

National Institutes of Health Office of Laboratory Animal Welfare (OLAW)

https://olaw.nih.gov/faqs#/guidance/faqs?anchor=questionreport_1

https://olaw.nih.gov/guidance/obtaining-an-assurance.htm

https://olaw.nih.gov/policies-laws/phs-policy.htm

NIH guidance https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html

AAALAC Rules of Accreditation, Available at www.aaalac.org

Purdue University Policy I.C.2, "Research and Teaching Involving Animal Subjects"

Purdue University Policy III.A.4., describes University Procedures for Protection Against Reprisal for Good Faith Disclosures.

REFERENCES TO OTHER APPLICABLE SOPs

IACUC SOP 201 – IACUC Protocol Processing and Closure

IACUC SOP 203 – Post Approval Monitoring

1. PURPOSE:

Post-Approval Monitoring (PAM) processes are an important part of the Purdue University Institutional Animal Care and Use Committee (IACUC) program for the care and use of animals in research, teaching, or testing. This process involves meaningful monitoring of the protocols that have been approved by the IACUC.

The PAM process may involve laboratory/site visits to observe animal procedures being performed, evaluation of record keeping, confirmation of proper personnel training, and discussions related to approved activities. The process is meant to facilitate dialogue and education between the IACUC and researchers.

This SOP applies to all Purdue University IACUC protocols approved or otherwise overseen by the Purdue University IACUC.

2. DEFINITIONS:

2.1 *Directed Monitoring* – Method of monitoring conducted at request of the IACUC or IACUC Administrator based on research aim, species, risk or pain category.

2.2 *For Cause Monitoring* – Method of monitoring conducted in response to reported complaints or potential anomalies related to an IACUC protocol. Expedited Review.

2.3 *Monitor* - An Office of Research and Partnerships Post-Approval Monitor or a team consisting of IACUC Members or IACUC staff, or Laboratory Animal Program (LAP) Veterinarians selected to conduct monitoring activities.

2.4 *Random Selection Procedure* - Manner of selection based on review type without investigator identifiers.

3. PROCEDURES

3.1 Selection Criteria

3.1.1 The Monitor will select approved protocols based on the following criteria:

(a) Active protocols with a USDA animal use category of D or E. These protocols may be subject to more frequent monitoring or at the request of the IACUC or a Laboratory Animal Veterinarian (LAV).

(b) Any active protocol may be selected for Directed monitoring based on record-keeping requirements (e.g. wildlife, client owned

animals, livestock) risk level, species, or funding source (e. g DoD, USDA). Though primary preference for monitoring will be given to those projects including active animal use within the past year, IACUC protocols do not need to have active animal use for the PAM process to occur.

(c) Any active protocol may be selected for post approval monitoring using a Random Selection Procedure. Though primary preference for monitoring will be given to those projects including active animal use within the past year, IACUC protocols do not need to have active animal use for the PAM process to occur.

(d) For Cause Monitoring may be conducted at any time, with or without notice to the PI, if requested by the IACUC or LAV.

3.2 Post Approval Monitoring Process

3.2.1 When a protocol is identified for PAM, the Monitor will send an initial notice to the Principal Investigator of the IACUC protocol. This message will notify the Principal Investigator of the PAM selection and explain preparations for the visit.

3.2.2 Prior to the visit, a pre-visit questionnaire will be sent to the PI via email and should be completed and returned to the Monitor within five business days. If the pre-visit questionnaire is not completed, the visit will still occur, but the Monitor will need to gather additional information from the PI during the monitoring visit.

3.2.3 The visit will be scheduled for a mutually agreeable time for the PI and the Monitor. The PI may ask for additional laboratory/teaching staff to assist with the visit, but during the visit, the PI will discuss the activities of the protocol. Whenever feasible, the Monitor will observe animals from the protocol and research/teaching activities.

3.2.4 The Monitor will complete the Protocol Post-Approval Monitoring Form during the visit. Problems or deficiencies noted on these visits will be corrected at the time the deficiency is noticed and further training/education provided, if needed. General observations will be discussed with the PI/personnel at the conclusion of the visit.

3.2.5 A summary of PAM visits, will be reported to the IACUC Administrator by the Monitor. The Monitor may attend any IACUC meetings in non-voting status to clarify any matters from the report. The final report will become part of the IACUC protocol record.

4. RESPONSIBILITIES

A Monitor is responsible for conducting monitoring activities including, but not limited to, Random Selection Procedures, notification, scheduling, and conducting a monitoring visit. A Monitor will also draft timely reports summarizing the observations and adherence to the IACUC protocol.

The Purdue IACUC is responsible for requesting Directed or For Cause Monitoring, reviewing Post-Approval Monitoring reports, maintaining documentation within the approved file, and making determinations associated with any findings or corrective actions related to the final report from the Monitor.

Principal Investigators and research personnel are responsible for upholding the requirements of the approved protocol, completing Post-Approval Monitoring documents, and completing the required PAM process.

5. APPLICABLE REGULATIONS AND GUIDELINES

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition.

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5. APPLICABLE REGULATIONS AND GUIDELINES

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition.

1. PURPOSE:

Animals and animal caging must be transported in a contained manner to protect the animals, minimize risk of escape, and to protect personnel along the transport route from potential exposure to animal allergens.

Reducing stressors by maintaining appropriate ventilation, avoiding temperature and humidity extremes as well as minimizing noise and odors play a significant role in reducing research variability. It is also important to maintain an animal's health status by avoiding exposure to potential pathogens.

2. PROCEDURES

2.1 Animal Transportation Safety

2.1.1 Animals must be transported safely and in a manner that minimizes stress.

(a) The cage, carrier or container must be escape proof, (e.g., there must be a latch or locking mechanism [band or bungee]) to prevent unintended cage top opening. Containers must not be needlessly jostled, tilted, or unsafely stacked.

(b) A secondary enclosure (e.g., disposable box or cloth tote) must be used in addition to the primary enclosure when transporting rodents between buildings. Examine the interior of any disposable transport box used before disposal to assure animals are not left in the container.

(c) Transportation of animals should avoid public areas. When it is necessary to transport animals through public areas, particularly outdoors, animals must be visually obscured using a shroud or opaque secondary enclosure. Personnel should be aware of the risk of possible reaction by those opposed to animal use.

2.1.2 To minimize release of bedding from rodent cages, animal dander, and airborne animal allergens into the environment, personnel must ensure that filter tops are used on rodent cages or that cages, carriers, or animals are covered with a drape or shroud during transport.

(a) Empty, soiled cages (with or without bedding) or carriers must be handled in the same fashion. Soiled cages / carriers must be covered during transport and should avoid personnel areas. Soiled cages may also be contained in bags as a means of minimizing allergen exposure during transport. They should be returned to an animal facility as soon as possible.

(b) Temperature extremes need to be avoided. Special precautions to protect animals from heat or cold stress or postponements are required when temperatures are below 45º or above 85º Fahrenheit. Inclement weather (e.g., rain) may also necessitate postponement dependent upon the planned mode (e.g., foot vs. controlled climate vehicle) and distance of transport.

(c) Reusable enclosures must be sanitized between use to prevent the spread of pathogenic micro-organisms, animal wastes and allergens.

(i) When any body fluids (blood, urine, saliva mucus), feces, or dirty bedding contacts any surface outside the carrier, it must immediately be removed and the area disinfected with an appropriate disinfectant.

2.2 Required Methods of Transport

2.2.1 EVPRP provides free transport services for rodents via a university owned climate-controlled vehicle. The vehicle cargo areas must be capable of being cleaned and decontaminated as necessary to prevent contamination of future transports. Principal investigators and their staff are strongly encouraged to use this service. To obtain transport through EVPRP complete the Mouse/Rat Movement Request Form (https://www.purdue.edu/research/regulatory-affairs/animal-research/guidelines-resources/index.php) and submit to animaltransport@groups.purdue.edu 2-3 business days prior to needed transport. Species other than rodents should be transported in appropriate university-owned, climate-controlled vehicles.

2.2.2 The use of private vehicles is strongly discouraged as a means to transport caged animals as it presents a risk of contamination due to exposure to allergens, zoonoses, and other hazards associated with animal exposure. he use of private vehicles to transport animals exposed to a hazard (radioisotope, bacterial, viral or chemical agent, etc.) is PROHIBITED by Purdue REM and EVPRP transport MUST be utilized. Animals may NOT be transported in private vehicles unless described in an approved IACUC protocol.

(a) Even under emergency circumstances, the IACUC encourages investigators to first contact EVPRP to make arrangements for transportation prior to using a private vehicle. If a personal vehicle must be used, the IACUC (pacuc@purdue.edu) must be contacted

for approval of such personal vehicle transport if not described in the approved protocol.

(b) During vehicle transport, adequate heating/cooling must be available to maintain general animal comfort (i.e., a truck bed or car trunk is not acceptable).

(c) In addition, protection from direct sun and protection from public view must be assured.

(d) A method to contain waste (e.g., plastic sheet under the cage, container around animal cage, etc.) as well as a method to discourage allergens from contaminating the vehicle (container around animal cage, etc.) must be provided as allergens may impact future human riders.

(e) The cage inside of the vehicle needs to be stable and/or anchored to prevent tipping

(f) The only exception to the above paragraphs in regards to the use of a private vehicle is for transport of commercially received rodent shipments at the Purdue University Fort Wayne (PFW) campus. As the transport from PFW Shipping and Receiving to PFW animal facilities would not be covered under any one protocol, and an animal facility owned vehicle is not available, the transportation guidelines allow the PFW facility manager to move the surface disinfected commercial crates from PFW Shipping and Receiving to the animal facility in a climate-controlled area of a personal vehicle. Shipments are received in commercial (primarily Jackson Labs) rigid and filtered containment crates that should prevent personnel and vehicle exposure to allergens and other hazards associated with animal exposure. In addition the number of shipments is few enough (approximately 6 or less per year) that coordinating ordering and delivery for when the facility manager is present should be feasible. This exception prevents the rodent shipment from potential climate extremes in the Shipping and Receiving vehicle.

(g) For transport of animals to locations outside Purdue, contact the facility supervisor for information pertaining to transfer. Individuals planning to transport live animals (or carcasses) exposed to hazardous materials (e.g. infectious materials, hazardous chemicals, radioisotopes) from one location to another

should contact Purdue University Radiological and Environmental Management (REM) for specific guidance.

1. PURPOSE:

This SOP has been created to standardize the minimum requirements in maintaining an aquatic animal facility. More frequent intervals for maintenance of the below items are encouraged.

This SOP excludes outdoor aquatic animal housing (i.e. ponds, mesocosms). The care and maintenance for these housing types should be described in the approved protocol for animal use.

Exceptions to this SOP must be approved by IACUC in the animal use protocol.

2. PROCEDURES

2.1 Housing and Husbandry

2.1.1 Housing Density

(a) The *Guide for the Care and Use of Laboratory Animals* recommends a housing density of 10 adult zebrafish per liter, and 2 liters per adult *Xenopus* frog. Younger animals may be housed at higher densities. For zebrafish, 20-200 eggs or embryos/100ml, 20 larva 3-30dpf/400ml, 5-10 fish >30dpf/L.

(b) Housing density should allow for adequate space between animals and promote well-being.

(c) Each tank must be individually identified.

2.1.2 Tank Sanitization and Frequency

(a) Tanks should be checked for algae accumulation daily and cleaned as necessary. Algae must not inhibit viewing of the animals.

(b) Reusable enclosures must be sanitized between use to prevent the spread of pathogenic micro-organisms, animal wastes and allergens.

(c) Tanks must be removed and sanitized at regular intervals, not to exceed 60 days for zebrafish. For other species, sanitization of tanks should occur at an appropriate interval for the species and research performed. As tanks or rows of tanks/shelves are sanitized this must be recorded. Care must be taken to thoroughly rinse any chemical residue prior to use.

(d) Tanks should be suctioned/spot cleaned as needed to remove debris.

(e) Recirculating and flow-through systems should have partial water changes daily to semi-weekly.

(f) Static tanks with animals over 30 dpf (fish) or stage 30 (amphibians) should have weekly water changes of at least 75%. Animals less than this age should have water changes as appropriate.

(g) Lids must be wiped off at least once weekly to remove excess food and debris.

2.1.3 System Maintenance

(a) System water level must be checked daily and refilled as needed.

(b) If a UV light is used, the indicator light must be checked daily.

(c) Baffles should be checked weekly and cleaned as necessary.

(d) Mechanical filters should be changed or cleaned as often as necessary or at least monthly.

(e) Carbon filters should be changed monthly.

2.1.4 Feeding

(a) Feeding frequency, amount, and type is to be determined at the discretion of the investigator. It must be recorded at each instance and animals should be fed on a regular schedule.

(b) Prepared foods must be discarded either 6 months after being received or opened or at the manufacturer's expiration or best-by date. All food containers must be sealed and labeled with the date of production, date of receipt, and/or date opened, as well as the expiration date. Freezing the food prior to the expiration date will extend the use-by date by 6 months. The date frozen must be labeled in addition to the updated expiration date.

(c) Live foods should be cultured on the premises and derived from pathogen-free environments.

2.1.5 Enrichment - The support of enrichment in aquatic animal enclosures is variable in the literature. If used, it should be safe for the animals.

(a) Zebrafish- current literature suggests that enrichment is beneficial to reduce aggression in low density housing scenarios. It also suggests plastic plants may enhance fecundity in breeding pairs. Classical music may also benefit zebrafish by reducing stress.

(b) Wild-caught animals should be provided plastic plants or a device to hide in to reduce stress associated with captivity. Eggs hatched in captivity are not considered wild-caught for this purpose.

(c) Frogs must be provided a shelter to hide in to reduce stress.

2.2 Water Quality

2.2.1 Monitoring

(a) Water quality monitoring must be performed for each system for recirculating and flow-through systems, or for each tank if static. For static tanks, if they are on the same water change schedule, one tank per shelf may be tested to represent the whole shelf. In these cases, the tank with the highest density should be tested.

(b) Water temperature must be monitored daily.

(c) Dissolved oxygen must be monitored daily for fully aquatic species or life stages.

(d) Water quality parameters should be based on species, type of aquatic system, animal density, and whether the system is established versus new. New systems require more frequent testing than those that are established.

(e) For static systems, if complete water change occurs at least weekly, no testing of pH, ammonia, nitrate, or nitrite is needed. Otherwise weekly testing is required.

(f) The following parameters must be tested at least monthly in established recirculating and flow-through systems, and at least weekly in static systems.

(i) Ammonia (NH3) should remain at 0mg/L

(1) For production fish (aquaculture), the following recommendations apply.

a. Salmonids – Unionized Ammonia less than 0.0125 mg/L

b. Cool-water fish – Total Ammonia Nitrogen less than 1.0 mg/L

c. Warm-water fish – total Ammonia Nitrogen less than 3.0 mg/L

(ii) Nitrite should remain under 0.1mg/L

(iii) Nitrate should remain under 200mg/L

(iv) pH

(v) Chlorine (for systems not supplied by RO water or well water) should remain at 0mg/L

(g) It is recommended to monitor other parameters such as hardness, alkalinity, conductivity, and total gas pressure monthly or more often as appropriate for the species.

2.3 Health Monitoring

2.3.1 Daily Health Observations

(a) Daily health observations of each tank must be performed to evaluate the health of the animals.

(b) Health should be evaluated by using body condition scoring (Appendix B) and the Health Evaluation Chart (Appendix A) below.

(c) Dead and euthanized animals must be recorded on a mortality log daily for animal of life stages large enough to individually count, for example zebrafish 30dpf and older. Some mortality is anticipated in large colonies and with developing fry. If within expected ranges, mortality data can be provided to LAP in a monthly summary.

2.3.2 Monthly Health Observations

(a) Within the first week of each month, health, mortality, and census logs from the previous month are to be sent to LAPvet@groups.purdue.edu.

2.3.3 Reporting Health Concerns

(a) If a sick/injured animal is observed, it must be reported on the health observation log of what concern was found, how many animals were affected, and the action taken (euthanasia, separation, approved treatment). Treatment must be approved by veterinary staff.

(b) If the animal is being monitored or treated, the tank should be clearly identified as such.

(c) If a colony-wide health concern is observed LAP vet staff must be contacted by phone or email. This includes unanticipated and higher than normal rates of mortality

2.3.4 Sentinel and Environmental Testing (Zebrafish)

(a) At least 5 fish should be maintained in a flow-through tank in the sump as pre-filter sentinels if the system allows.

(b) Sentinel fish will be collected every 6-12 months for testing. Colony animals may be submitted as necessary with investigator approval.

(c) Environmental swabs of filter sludge, sump, and live feed may be submitted for testing if necessary.

2.3.5 Animal Room Maintenance

(a) Daily Maintenance

(i) Room temperature and humidity must be recorded daily.

(b) Weekly Maintenance

(i) Room sinks and counters must be sanitized at least once weekly.

(ii) Room floor must be swept and mopped at least once weekly.

(iii) Room or tank light timers must be checked once weekly to ensure proper function if present. Lighting should be on a 14:10h light:dark cycle and 54-324 lux for zebrafish.

(iv) Trash cans must be emptied when full, or at least once weekly.

(c) Bi-Monthly Maintenance

(i) Net solution must be changed at least once every two weeks. Alternatively, nets may be autoclaved prior to each use.

2.3.6 Disaster and Emergency Response Plan

(a) While the Purdue campus disaster plan applies to all rooms on campus, aquatic animal rooms must have an emergency response plan in place and posted within the animal room. This plan must address actions taken in the event of an electrical outage or a water outage.

2.3.7 Quarantine Procedures (Zebrafish; production fish are required to follow the Aquacultural Research SOP)

(a) Importing Animals

(i) Health reports should be obtained and submitted to LAPvet@groups.purdue.edu prior to shipment.

(ii) Imported animals should not enter the main colony if possible.

(iii) Imported animals should be equilibrated by floating the bag in the new tank for a few hours and slowly introducing new tank water into the bag.

(iv) Fish should be in quarantine for 3-4 weeks prior to breeding to monitor for disease.

(b) Embryo cleaning

(i) Embryos from quarantined animals should be cleaned using appropriate agents for the microbes/parasites of concern.

(1) Iodine for *mycobacteria*

(2) Bleach for most other agents

(3) Washing for *P. tomentosa*

(4) *P. neurophila* and other microsporidians are unlikely to be killed with embryo treatment.

(ii) Once the new line has been established, adults in quarantine can be euthanized.

2.3.8 Zebrafish Larvae Maintenance

(a) Incubators housing zebrafish larvae must be labeled with "Live Zebrafish Larvae" and the protocol number(s) on the outside door.

(b) Petri dishes or other containers with larvae must be labeled with the spawn date.

(c) Incubator temperature must be recorded daily.

(d) Larvae and water levels must be observed daily and recorded.

(e) Incubators must be cleaned when visibly soiled. Chemical disinfection should be performed as necessary to control mold infection, with thorough rinsing of residues.

2.3.9 Record Keeping

(a) Paper log sheets must be maintained in each animal housing room. Digital records may be kept in lieu of paper records only if the digital records are emailed to lapvet@groups.purdue.edu along with census data each month.

(b) Records must be kept for all items mentioned in this SOP.

(c) A census of current individual animals that have hatched must also be recorded and reported to LAP monthly. For very small larva, an estimate may be appropriate.

(d) See Appendix C for examples of acceptable log sheets.

3. APPLICABLE REFERENCES

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Chapter 20 - The Biology and Management of the Zebrafish, Michael Y. Esmail, Keith M. Astrofsky, Christian Lawrence, Fabrizio C. Serluca, Pages 1015-1062,
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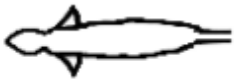
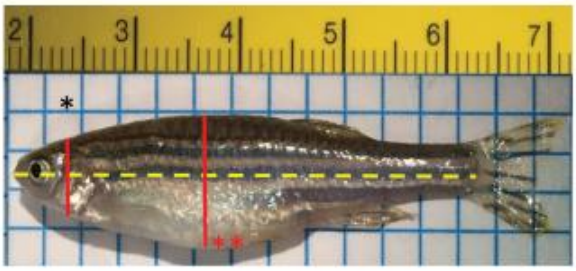
Appendix A. Health evaluation chart.

Indicator	Plan of Action	General Appearance	Behavior	Skin/Body Appearance	Conformation
Black 	Immediate disposal/Euthanize	Moribund/Dead	Little sign of life/movement	N/A	N/A
Red 	-priority to remove from system -possible signs of contagious disease or system failure -for critical research fish euthanize or contact LAP to start treatment -must euthanize non-critical fish	-severe emaciation (BCS 1/5) -severely distended abdomen and reddened -critical body deformities	-complete loss of equilibrium and complete cessation of movement -respiratory distress (excessive operculum movement or gasping) and no response to external stimuli (moribund)	-body ulcers, lesions, hemorrhaging -protruding eyes -raised scales -masses affecting natural development or behavior -erythema affecting >50% of body	-severely curved spine; unable to perform natural behaviors and abnormal development
Orange 	-Euthanize non-critical to research fish -Monitor critical research fish for decline- ID tank and notify LAP vet staff	-under-conditioned (BCS 2/5) -moderate abdominal distension and reddening	-Gasping -lethargic but responsive to stimuli and returns to normal activity -unable to maintain normal buoyancy	-discoloration of scales, reddening (not phenotypic) -fins deteriorating -multiple masses under skin/fins not affecting natural behavior -erythema affecting 25-50% of body	-curvature of spine is not phenotypic and is affecting development
Yellow	Monitor for change in clinical presentation	-non-critical -mild abdominal distension and no reddening/ "egg-bound" -minor deformities -abnormal healthy phenotype	-swimming reduced, but eating and responding to stimuli -intermittent buoyancy disruption	-missing operculum -partially deformed or missing fins -1 mass under skin not affecting behavior -erythema affecting <25% of body	-mild signs of spine curvature, not affecting natural behavior
Green 	Good health	-well-conditioned -sleek body conformation	-swimming normal, not erratic -no signs of distress	-consistent pattern/color	-no signs of bone malformation

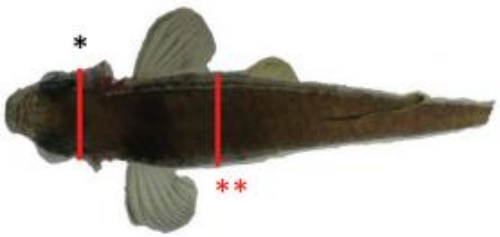
Approved by IACUC 2/16/22

Appendix B. Body Condition Scoring Chart.

Adult Zebrafish BCS		
	Lateral View	Dorsal View
BCS 1: • Head larger than body (big head) • Lateral- concave ventral surface between head and abdomen (narrow abdomen) • Dorsal- body is more narrow than head and linear • **Fish is thin (emaciated)**		
BCS 2: • Head and body equal size • Lateral- flat ventral surface between head and abdomen • Dorsal- head and width of abdomen are equal • **Fish is underconditioned**		
BCS 3: • Body larger than head • Lateral- slight convex ventral surface • Dorsal- head is slight smaller to a fusiform body • **Fish is well-conditioned**		
BCS 4: • Body significantly larger than head • Lateral- body moderately convex ventral surface • Lateral- Symmetrical ventral surface • Dorsal- head visually smaller to a moderately distended abdomen • **Fish is over-conditioned**		
BCS 5: • Body significantly larger than head • Lateral- body significantly convex ventral surface • Lateral- Symmetrical or asymmetrical ventral surface • Dorsal- head visually smaller to a significantly distended abdomen • **Fish is obese (large)**		



A



B

Figure 2. Targeted anatomic regions for BCS assessment.

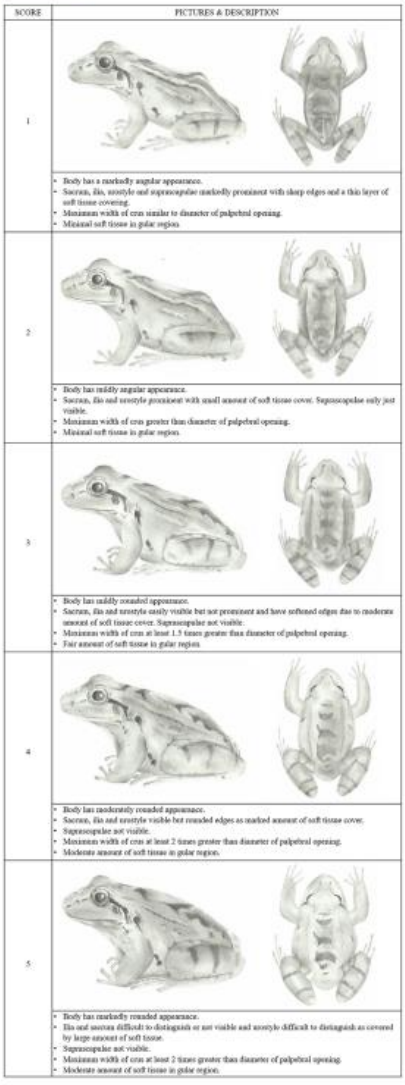


FIGURE 2 Body condition score (BCS) for the mountain chicken frog (*Leptodactylus fallax*)

Appendix C. Log Sheet.

Example Health and Water Quality Monitoring Log

	Daily							Monthly									
Date	H2O T	dO2	Room T	Hum (%)	Mortality	Health Obs	Feed	pH	Hard-ness	Alk	NH3	NO2	NO3	Cond.	Cl	TGP	Comments
1																	
2																	
3																	
4																	
5																	
6																	
7																	
8																	
9																	
10																	
11																	
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31																	

Example Room and System Maintenance Log

	Daily			Weekly							Monthly			
Date	H2O level	UV light	Suction waste	Light timer	Clean sink	Clean counters	Sweep/ mop floors	Empty trash	Change filter	Wipe lids	Carbon filter	Net solution	Clean tanks	Comments
1														
2														
3														
4														
5														
6														
7														
8														
9														
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Approved by IACUC 2/16/22

1. PURPOSE:

Regulations and standards for animal care require that daily observations be made of all animals to assess their health and well-being. This observation may be accomplished by someone other than a veterinarian provided that a mechanism is in place to communicate problems of animal health and well-being to the veterinarian on a timely basis. Recording daily observations informs animal caretakers, investigators, the Purdue University Attending Veterinarian and visiting USDA veterinary officer that the animal(s) have been observed for any abnormalities. An example of a daily observation form may be found on the IACUC website: www.purdue.edu/animals.

Questions regarding the IACUC SOP on Documentation of Animal Care & Veterinary Medical Records, please contact the Laboratory Animal Program office.

2. PROCEDURES

2.1 Routine Record Requirements

2.1.1 The documentation required to conform to the IACUC SOP for Documentation of Animal Care and Medical Records for Research and Teaching Animals includes:

(a) A daily record of animal well-being or evidence of such daily observation. This is needed for both normal and "abnormal" (e.g., post-surgical or ill) animal(s).

(b) For normal animals, documentation is routinely accomplished by providing verification that someone (e.g., animal care staff, research staff or individual able to recognize signs of abnormality) has observed the animal(s) and that no evidence of illness, injury, or abnormal behavior was noted. This documentation is most often This documentation is most often provided in the form of a room "checkoff" list.

2.2 Record Keeping Standards

2.2.1 When providing daily care to or observation of an abnormal research or teaching animal, or administering directed care, documentation should meet certain additional standards as outlined below. The intent is a need to document that the circle of veterinary care is complete.

(a) The documentation required for an abnormal animal (one showing signs of illness, injury or other departure from normal health and well-being) includes:

(i) Animal identification.

(ii) Pertinent history / description of abnormality.

(iii) Examination findings.

(iv) Tentative / provisional diagnosis.

(v) Corrective measures (diagnostic and treatment plan) being taken as the result of this variation from normal health or behavior.

(vi) Assessment of the animal's condition and progress seen over the duration of the treatment/observation period.

(vii) The author of all entries made on the record must be identified. If daily assessment is being performed by a lay person (animal care staff, research staff member, etc.) under the direction of a veterinarian, the record must reflect the guidance provided by the veterinarian or direct involvement of the veterinarian providing primary care concerning diagnosis, treatments, or planning. It is necessary to document that veterinary oversight and authority is in place regarding the veterinary care of animals.

(viii) Record of veterinary care given or directed to include daily treatment provided as well as dosages, routes and frequency of administration of any drugs/medications.

(ix) Records of diagnostic laboratory services that are performed in order to facilitate veterinary medical care that can include gross and microscopic pathology, clinical pathology, hematology, clinical chemistry, microbiology, serology and parasitology.

(x) Resolution of the problem (e.g., diagnosis, treatment, return to a normal state, euthanasia).

(b) For an abnormal animal, it is critical that documentation of the animal(s) condition be available for review.

2.2.2 For small animals or farm animals maintained in a vivarium, treatment record(s) must be maintained in a manner that allows for immediate access

(e.g., in or adjacent to the room where the animals are housed). This is especially critical for animals in the post-operative period or those displaying any abnormality. Having the record in such a location accomplishes several functions.

(a) It explains the condition of the animals to animal care staff (a sedated animal may otherwise be thought to be ill)

(b) It assures animal care staff, the Purdue Attending Veterinarian and visiting USDA veterinary officer that the animal care / treatment is being provided

(c) It informs animal care staff how recently the investigator or a veterinarian has seen the animal. This knowledge helps them decide whether or not there is a need to contact the investigator or the Purdue Attending Veterinarian to inform him or her of the present condition of the animal.

2.2.3 For large animal or farm species maintained in a farm environment, the records must also be readily accessible from the facility manager or the veterinary medicine teaching hospital files.

2.2.4 For agricultural animals used in agricultural research and teaching housed in pasture or other extensive conditions, animal observation should be frequent enough to detect illness or injury in a timely fashion, recognize the need for emergency action, and ensure adequate availability of feed and water as in the "Guide for the Care and Use of Agricultural Animals in Research and Teaching" pg 22.

2.2.5 Although individual records are desirable, a composite record may be used, for example, in the case of a group of rodents or for preventive medical procedures (e.g., vaccinations). A composite record should have a list of the animal numbers and entries made that would include a notation that the animals had been checked, any abnormal observations and a list of any therapeutics given including drugs, doses, and routes of administration as well as date of suture /wound clip removal.

(a) Once the animal(s) returns to a normal state and this is documented on the record, the medical record requires no further entries but should continue to be kept in the area where housed.

(b) When the study is completed or the animal(s) euthanized, the record must still be kept for at least three years. If an animal is

transferred to another location or project, the appropriate records should accompany the animal(s).

2.2.6 There is no one format that would suit all situations and as such, this SOP does not require nor recommend a standard form to be used in each instance. Suffice it to say, the record(s) should be readily available and should contain all clinical information pertaining to the animal with sufficient information being provided to justify the tentative diagnosis and warrant the actions taken and/or treatment provided. Sparse, incomplete or sloppy records make it difficult to ascertain what happened and why.

3. APPLICABLE REGULATIONS AND GUIDELINES

Position statements. (n.d.). Retrieved March 4, 2022, from https://www.aclam.org/about/position-statements

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition

1. POLICY:

The Animal Welfare Act, Public Health Service (PHS) Policy, the "Guide for the Care and Use of Laboratory Animals" (Guide) and the "Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching" (Ag Guide) all specifically require that the IACUC review and the institutional veterinarian oversee surgical procedures as well as pre- and post-operative animal care programs. The following IACUC policy statements will serve to clarify the directives from the USDA and PHS regarding this topic. Surgery considerations apply to procedures involving incisions greater than 0.5 cm in live vertebrate animals. Any exceptions to this SOP must be reviewed and approved by the IACUC.

2. DEFINITIONS

2.1 *Major Surgery* - Penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions. (Examples: penetrates and exposes a body cavity such as the thorax, abdomen, or a joint cavity, substantially impairs physical or physiological function, such as removal of any part of a limb, involves extensive tissue dissection or transection.

2.2 *Minor Surgery* - Does not expose a body cavity and causes little or no physical impairment.

2.3 *Multiple Survival Surgery* - more than one surgical session is performed, and the animal is recovered from anesthesia after each session

2.4 *Survival Surgery* - The animal awakens from surgical anesthesia.

2.5 *Non-Survival Surgery* - The animal is euthanized before recovery from anesthesia (e.g., tissue harvest).

3. PROCEDURES

3.1 Survival Surgery Procedures

3.1.1 All Survival Surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments and aseptic techniques.

3.1.2 Major operative procedures on non-rodent mammalian species may be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions.

3.1.3 Procedures that do not classify as Major Surgery on all species and surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures and in areas of the laboratory or facility where cleanliness can be assured and unnecessary traffic and activities can be minimized at the time of surgery.

3.2 Multiple Survival Surgeries

3.2.1 Multiple Major Survival Surgeries on USDA-covered species, where the surgeries are not part of a single research protocol, require the Institutional Official to submit a request to the USDA/APHIS and receive specific approval.

3.2.2 When Multiple Survival Surgeries not covered under section 3.2.1 above, the Principal Investigator must provide justification in the IACUC protocol application. Examples of scientific justifications that could be used in a protocol include:

(a) Scientific Purposes – The justification would need to show how the Multiple Survival Surgeries are necessary for the research/teaching being performed and why other methods cannot be utilized to achieve the research/teaching goals.

(b) Conservation of a scarce resource – Multiple Major Survival Surgeries could be performed in separate animals, but this would further reduce the scarce resource by increasing the number of animals used. It needs to be determined that the additional Survival Surgery does not cause undue stress to the animal. Application of this reason is discouraged and will be very critically weighed during the review process.

(c) Two surgeries are required that could be performed at the same time, but to do so would sufficiently compromise the animal that it may not survive, whereas if the animal is able to heal from the first before the second, it should survive both procedures.

(d) Salvage value - as in the case of a food animal in which two separate surgeries are required (on a single protocol) at different times and in which, the second could be non-survival; however, to

kill the animal would unnecessarily be a waste of a food source. It needs to be determined that the additional Survival Surgery does not cause undue stress to the animal.

3.3 Post-Surgical Monitoring

3.3.1 Accurate records regarding surgical procedures, anesthesia, recovery and post-procedural care must be kept and be made readily available to the IACUC, LAP veterinary staff and representatives of regulatory organizations.

(a) For non-rodent mammalian species (e.g., dogs, cats, rabbits, pigs etc.), individual records must be kept.

(b) For other species, the procedural records may be entries in laboratory notebooks or other well-organized study records.

3.3.2 Records should include appropriate procedural details, dates, personnel, and pre- and post-procedural condition of the animals.

(a) Notes during the immediate post-procedural recovery period must include frequent (at least every 15 minutes until recovery from anesthesia) written observations of the animal's condition.

(b) Examples of surgical records, criteria that need to be monitored and recommended post-operative/procedure monitoring records are available with this document or can be obtained on the Purdue University IACUC website.

(c) Any animal, including rats and mice, that develops unexpected surgical or post-surgical complications should be reported to the LAP in a timely manner. Animals that die unexpectedly during or after surgery or are euthanized because of post-surgical complications must also be reported to the LAP.

(d) After general anesthesia, at least daily, post-operative monitoring must be performed for a minimum of three (3) days after a surgical procedure. Details about the parameters to be monitored, analgesics given, and length of time to be monitored, must be included in the approved IACUC protocol.

4. RESPONSIBILITIES

4.1 The Principal Investigator (PI) must conscientiously evaluate the need to perform surgery (whether single or multiple) and adequately provide scientific justification in the IACUC application. The PI is also responsible for providing pre- and post-procedural care, seeking Laboratory Animal Program (LAP) veterinary care or consultation, coordinating any specialized animal care, and documenting care of the animal(s) through appropriate record-keeping.

4.2 The IACUC is responsible for review of the protocol in reference to the science and practicality of the study while considering humane treatment of animals proposed for use in research and/or teaching.

4.3 All personnel engaging in surgical procedures on animals must be appropriately trained in aseptic surgical technique and have their training documented with the IACUC prior to performing unsupervised surgeries.

5. APPLICABLE REGULATIONS AND GUIDELINES

Animal Welfare Act, 9 CFR § 2.31

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition.

PHS Policy on Humane Care and Use of Laboratory Animals

REFERENCES TO OTHER APPLICABLE SOPs

Prior Purdue IACUC documents combined and updated for this SOP:

Surgery and Post-Surgical Monitoring of Animals – Last Approved 4/17/2019
Multiple Survival Surgery – Last approved 5/18/2016

1. PURPOSE:

The purpose of environmental enrichment is to provide animals the opportunity to express basic behavior needs, promote species-typical, non-injurious behavior and promote physical and mental health thus enhancing animal welfare. The environmental enrichment provided should be biologically relevant (e.g., hiding, socializing, searching) so that it does not lose its enriching value over time. For social species such as mice and rats, social housing should be the default housing arrangement when possible. Specific areas of enrichment that should be addressed include social, structural, sensory, food, and manipulanda.

2. PROCEDURES

2.1 Social Housing

2.1.1 The Guide states that single housing of social species should be the exception. Social housing will be considered by AAALAC International as the default method of housing unless otherwise justified based on social incompatibility resulting from inappropriate behavior, veterinary concerns regarding animal well-being, or scientific necessity approved by the IACUC (or comparable oversight body.)

2.1.2 When necessary, single housing of social animals should be limited to the minimum period necessary and, where possible, visual, auditory, olfactory and, depending on the species, protected tactile contact with compatible conspecifics should be provided. In the absence of other animals, additional enrichment should be offered, such as safe and positive interaction with the animal care staff, as appropriate to the species of concern; periodic release into larger enclosures; supplemental enrichment items; and/or the addition of a companion animal in the room or housing area. The institution's policy and exceptions for single housing should be reviewed on a regular basis and approved by the IACUC (or comparable oversight body) and/or veterinarian

2.2 Exceptions to Social Housing and Environmental Enrichment

2.2.1 Exceptions requiring IACUC Approval.

(a) Instances will arise when social grouping or enrichment items may be inappropriate for the scientific goals of the study. If an investigator believes that social grouping or providing cage enrichment would have a negative impact on the study or be detrimental to their animals, an exception to the policy for such

social housing or addition of enrichment items may be granted by the IACUC at the time of protocol review.

(b) Food enrichment will be discussed with investigators to ensure that it is appropriate for the study.

2.2.2 Exceptions not requiring IACUC Approval

(a) Social animals may need to be singly housed for a variety of reasons. The following include general categories of exceptions to social housing not requiring IACUC protocol approval. Examples of such situations include:

(i) Separation of aggressive or incompatible conspecifics—for example: male rabbits. However, females that demonstrate to be aggressive or socially incompatible will be housed individually;

(ii) Individual housing due to attrition of cage/pen mates or uneven number of animals;

(iii) Animals used for IACUC approved rodent breeding and is either a breeder male between mating, a pregnant female that is near delivery, or a juvenile that has just been weaned and is the sole male or female in the litter;

(iv) Individual housing in preparation for pending parturition;

(v) Quarantine prior to entering or reentering a facility; Animals housed singly for short term recovery post-operatively; single housing must be for the minimum amount of time post-operatively necessary for recovery and/or healing as determined by the PI in consultation with LAP veterinarians;

(vi) Individual housing when an animal is considered a danger to other animals, to itself, or personnel.

(b) For farm animal / agricultural species housed in an agricultural setting, the Guide for the Care and Use of Agricultural Animals in Research and Teaching, Chapter 4, Environmental Enrichment, should be followed. LAP veterinary staff may require individual

housing of animals when it is for medical concerns/clinical reasons.

(i) The responsible veterinarian will record the period of single housing and the frequency of re-evaluation in the animal's medical record, will monitor the animal as noted and re-house the animal when the clinical concern is resolved.

(ii) These cases will be reported to the IACUC at the discretion of the Attending Veterinarian. Examples of such situations include:

(c) If an animal falls under one of these exceptions, a sticker or tag will be placed on the cage card indicating the corresponding exception.

2.3 Social Group Housing and Cage Enrichment by Species

2.3.1 Social Group Housing and Cage Enrichment for Mice

(a) Mice should be group-housed in breeding or compatible unisex groups on contact bedding with nesting material.

(b) Unfamiliar males or animals separated due to fighting should be housed singly on contact bedding with nesting material.

(c) It is not required that mice housed on Tek-Fresh bedding have nesting material provided. A portion of the nesting material will be transferred to the clean cage with the animals at time of cage change, with additional nesting material provided as necessary.

(i) Examples of nesting material include nestlets; crinkle paper, tissues, paper towel.

(ii) A total of 8g of nesting material must be provided, except for gnotobiotic mice. Gnotobiotic mice must remain easy to visualize to reduce the need to enter the isolator; therefore, 1 nestlet and 1 paper towel are provided to each cage.

(iii) A hut is recommended for strains or disease models causing poor nesting behavior.

(iv) Sunflower seeds or manazita wood chews may be given for mice that grind their food, study permitting.

(d) The provision of food treats by lab members is encouraged if the study permits (examples include cheerios, raisins, sunflower seeds, Bioserv treats).

(e) The following is a list of other enrichment devices that have been successfully used with mice - Chew sticks/blocks, paper rolls, paper shacks, PVC tubes, Nylabones®, corn husks, plastic pipette boxes, wheels, and critter cubes.

2.3.2 Social Group Housing and Cage Enrichment for Rats

(a) Rats should be socially housed on contact bedding. A total of 16g of nesting material should be provided (crinkle paper, nestlets) for breeding dams.

(b) For rats, a PVC pipe section of appropriate diameter or other equivalent shelter or retreat equivalent must be provided.

(c) A chewing device should also be provided (manazita wood, nylabone).

(d) The provision of food treats by lab members is encouraged if the study permits (examples include cheerios, raisins, sunflower seeds, Bioserv treats).

(e) The following is a list of other enrichment devices that have been successfully used with rats - paper rolls, PVC tubes, Nylabones®, plastic huts.

(f) For wire housing, see the IACUC SOP on Wire Bottom Caging for Rodents. When housed on wire, enrichment should be provided. It is recommended to provide a rat retreat (for large cages) and a small nylabone chewing device if it would not interfere with the research being conducted.

(g) For single housed rats, it is recommended to provide socialization by the provision of rat tickling. This is ideally performed for 3 days, then on a weekly basis by lab staff. Acclimatization should occur prior to study use by either rat tickling or gentle handling techniques.

2.3.3 Social Group Housing and Cage Enrichment for Guinea Pigs

(a) Guinea pigs should be kept in social groups and provided shelter space sufficient to contain all of the pen inhabitants simultaneously.

(b) Soft, classical-type music or nature sounds may be played during normal work hours.

(c) Food enrichment of fresh produce and foraging enrichment maybe offered. This may include paper bags or boxes containing treats, hay balls, and other options to promote quality use of the animals' time.

(d) The following is a list of other enrichment devices that have been successfully used with guinea pigs - paper rolls, PVC tubes, cardboard boxes, Ferret Balls, bedding bags, Jingle Balls®, corn husks, "houses" made of old cages.

2.3.4 Social Group Housing and Cage Enrichment for Rabbits

(a) Animals >4 months of age should be housed singly with the ability for visual, auditory and olfactory association with conspecifics unless they have been sterilized (i.e., training rabbits).

(b) Rabbits should be a provided a shelter, ideally in which they can perch on top of as well.

(c) Rabbits housed singly must be provided a toy or other manipulanda on the outside and on the inside of the cage on a regular basis to allow for exploratory behavior, to be rotated at least at each cage change.

(d) Soft, classical-type music or nature sounds may be played during normal work hours.

(e) Food enrichment of fresh produce and foraging enrichment may be offered. This may include paper bags or boxes containing treats, hay balls, and other options to promote quality use of the animals' time.

(f) Other enrichment may include weekly brushing (if temperament allows) and weekly floor pen exercise.

(g) The following is a list of other enrichment devices that have been successfully used with rabbits – Retreats/hiding shelters, baby rattles/keys, corn husks, Bunny Blocks® Jingle Balls®.

(h) Brushing should be included as part of the acclimation process.

2.3.5 Social Group Housing and Cage Enrichment for Chinchillas

(a) Animals housed singly should have the ability for visual, auditory and olfactory association with conspecifics.

(b) Chinchillas must be provided a retreat structure and toy or other manipulanda on the inside of the cage on a regular basis to allow for exploratory behavior. A wood block or other option for chewing should also be provided.

(c) Dust baths should also be provided at least weekly.

(d) Food enrichment of fresh produce and foraging enrichment may be offered. This may include paper bags or boxes containing treats, hay balls, and other options to promote quality use of the animals' time.

2.3.6 Social Group Housing and Cage Enrichment for Dogs

(a) Canines for research use may be housed in compatible pairs or small groups. Dogs housed individually must be within sight of other dogs.

(b) Each dog should have access to at least one toy when in their home enclosure. These toys should be rotated to maintain interest.

(c) If dogs cannot be compatibly housed continuously, intermittent social activity of 30 minutes per day, 5 days per week is allowable, e.g., during pen sanitation or walking.

(d) Dogs should be given human interaction including petting, soothing speech, playing, grooming, and positive reinforcement training.

(e) A bed should be provided at all times unless the animal is destructive.

(f) Soft, classical-type music or nature sounds may be played during normal work hours.

(g) Additional food enrichment may be offered. Options for providing normal feed in a creative manner should be considered.

2.3.7 Social Group Housing and Cage Enrichment for Cats

(a) Behaviorally compatible cats should be socially housed. Group enclosures must have sufficient resting places off the floor to accommodate every cat. Scratching posts and visual barriers should be considered for group housed cats.

(b) Multiple litter boxes, feed and water bowls should be distributed around the enclosure with at least one station for every two to three cats.

(c) If a cat is to be housed singly because of social incompatibility or is post-operative, it should be given a hiding place and opportunities for increased human interaction. Cats housed singly for scientific purposes should be within sight and sound of other cats and given opportunities for increased human interaction.

(d) All cats should be provided toys within the cage at all times, and an opportunity for interactive play at least once weekly.

2.3.8 Social Group Housing and Cage Enrichment for Sheep

(a) Sheep should be socially housed in compatible pairs or small groups, unless exempted for experimental reasons by the IACUC, or for health or behavioral reasons by the attending veterinarian.

(b) If sheep must be individually housed, position them in such a way that they can see at least one conspecific, because visual isolation is stressful for sheep.

(c) Stressful research manipulations (e.g., venipuncture, drug application) should be accomplished within the presence of a familiar conspecific.

(d) Where there is likelihood of a single sheep remaining on census at a single site, experimental plans should account for the timely use of the remaining animal. Isolated sheep must be provided a mirror and additional positive human interaction.

(e) Sheep should be provided a diet high in roughage, to allow species typical feeding and rumination, and to reduce the likelihood of stereotyped behaviors.

(f) Manipulanda such as stall balls or balls with grain inside may be provided at regular intervals.

2.3.9 Social Group Housing and Cage Enrichment for Swine

(a) Behaviorally compatible pigs should be socially housed including, if necessary, combining pigs of compatible size and disposition to meet this need.

(b) Substrates should be provided to enable rooting behavior. Examples of such substrates could include plastic balls loose on the cage floor.

(c) Swine should be provided manipulanda suspended from the pen side, such as hanging ropes, chains, tires or rubber tubes, for play and exploration. Food enrichment of fresh produce and foraging enrichment may be offered.

(d) Isolated pigs must be provided a mirror, additional positive human interaction, and music during normal work hours.

2.3.10 Social Group Housing and Cage Enrichment for Songbirds

(a) Songbirds should be housed in socially compatible groups with perches, feeders, watering devices, and cuttlebone as appropriate for the species.

2.3.11 Social Group Housing and Cage Enrichment for Pigeons

(a) Individually caged birds should have ability for visual, auditory and olfactory contact to allow for some social interaction with conspecifics.

(b) Behavioral training and associated staff interaction is encouraged.

2.3.12 Social Group Housing and Cage Enrichment for Frogs

(a) African clawed frogs should be housed in tanks with a population density not exceeding one per 2 liters tank water volume and as otherwise stipulated by facility SOP. With respect to the latter,

water treatment, circulation and quality may stipulate that greater volumes be accorded per head.

(b) Refuges or retreats should be provided in the form of pipes, flower pots, or submerged plastic boxes.

(c) For terrestrial frogs, shelters should be provided.

(d) The following is a list of other enrichment devices that have been successfully used with frogs – Ramps, perches, PVC tubes, "J" feeders, floating leaves (made from trash bags).

2.3.13 Other Enrichment Devices

(a) The following is a list of other enrichment devices that have been successfully used with species not specifically mentioned in the preceding sections.

(i) Fish – PVC tubes, floating leaves

(ii) Chickens – Perches, red marbles in food, red marbles in water, mirrors, plastic chain links, dust baths

(iii) Chicks – Astro™ turf covered with feed

3. APPLICABLE REGULATIONS AND GUIDELINES

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition. Washington (DC): National Academies Press (US); 2011. Available from: https://www.ncbi.nlm.nih.gov/books/NBK54050/ doi: 10.17226/12910

http://www.aaalac.org/accreditation/positionstatements.cfm#social

Guide for the Care and Use of Agricultural Animals in Research and Teaching; 3rd edition, Federation of Animal Science Societies, Savoy, IL. 2010

Cornell University, IACUC Policy # 550: Exemptions to Social Housing of Animals

1. PURPOSE:

Animals that have been used in teaching and research at Purdue may, under some circumstances, be adopted after their use in Purdue programs has been completed. The faculty member who holds the protocol the animal is on is responsible for that animal (e.g., housing and care costs) until such time that the adoption is finalized.

2. PROCEDURES

2.1 Adoption Criteria

2.1.1 Individuals 18 years of age or older are eligible to adopt animals. If a minor desires to adopt an animal, an adult parent or guardian must also be an adopting co-owner.

2.1.2 Animals that will not, or may not, be eligible for adoption:

(a) Animals that could potentially have a negative impact on human health. (This includes those that have been infected with a biohazard, have a zoonotic disease, or have been given radioisotopes, unless reviewed by Radiological and Environmental Management and determined that it is safe to allow the animal to be adopted.

(b) Any animal that is not clinically and behaviorally normal will not be eligible for adoption. Exceptions to this may be made for animals with manageable conditions (such as seizures or hypothyroidism). All veterinarians who have had contact with the animal should record in its medical record any concerns on the animal's clinical or behavioral condition. These same veterinarians should make a congruent decision as to whether or not an animal is considered adoptable.

(c) Transgenic animals and animals that have had non-FDA approved compounds administered to them are not eligible for adoption.

2.1.3 At the time of adoption, the new owner must assume responsibility for housing, care and medication of the animal being adopted.

(a) The principal investigator (or his/her delegate) must determine that the new owner is capable of adequately providing for the care and needs of the animal, as well as the suitability of the pet for the prospective new owner.

(b) This will be done in consultation with the laboratory animal veterinarians.

2.1.4 Adoptive owners must be given a synopsis (not a copy of the Health Record), by the Principal Investigator, of the medical history and use at Purdue. Information such as number of sedations/anesthesia's, radiographs, and invasive procedures are relevant to the future clinical care of the animal.

2.1.5 All cats and dogs and other small mammals (i.e., rabbits, rodents) must be neutered or spayed at the time of adoption and prior to leaving the premises of Purdue University unless an exception has been granted by the IACUC/LAP office.

(a) At the time of spay or neuter, dogs and cats should be tested for heartworm, and preventative started upon negative results.

(b) Vaccinations of Rabies and DAPP at a minimum, should also be updated for dogs and cats if necessary.

(c) The cost for this will be incurred by the PI. If a microchip was implanted into an animal while at Purdue, this microchip must be transferred to the new owners before the dog/cat leaves the premises. The paperwork for the transfer of the chip will be completed by VLAC personnel and the cost associated with the transfer of the microchip will be incurred by the adopter.

2.2 Adoption Process

2.2.1 To adopt out an animal, the principal investigator must complete the attached "Animal Adoption Form." This record should be maintained by the animal housing facility for a period of 5 years from the date of signature by the new owner.

2.2.2 To adopt an animal, the new owner must complete the attached "Release of Liability" form. This record should be maintained by the animal housing facility for a period of 5 years from the date of signature by the new owner.

2.2.3 Agricultural food and fiber production animals (e.g., cattle, poultry, swine, sheep) that are changing ownership for continued use in an agricultural setting or for agricultural purposes are not considered to be adopted. As such, they are exempt from this policy.

2.2.4 Adoption of animals for transfer to a third party for further adoption is prohibited. If necessary, the PI may contact LAP to work directly with an adoption agency.

1. PURPOSE:

IACUC will follow the recommendations from the Food Animal Residue Avoidance Databank (FARAD).

2. PROCEDURES

2.1 Applicability

2.1.1 A researcher (like a practitioner) may administer to a food animal any drug, or any other substance that produces a measurable physiologic change in the animal, that he or she can legally obtain and administer under the Animal Medicinal Drug Use Clarification Act (AMDUCA) and subsequently market the animals. This includes pain relievers, anesthetics, antibiotics, etc.

2.1.2 Both practitioners and researchers administering extra-label treatment to food animals to be marketed must prescribe an extended withdrawal time based on adequate scientific data. If adequate scientific data does not exist, then the researcher/practitioner must ensure that the treated animal does not enter the human food chain. AMDUCA does not allow practitioners or researchers to use extra-label drug administration for production purposes (oxytocin for milk production, hormones to regulate reproductive cycles).

2.1.3 A researcher can give an unapproved, experimental drug to food animals that DO NOT enter the food chain. Researchers doing so are obligated to fulfill record-keeping requirements outlined under 21 CFR 511.1(a).

2.1.4 A researcher can give an unapproved experimental drug, or any other substance that produces a measurable physiologic change in the animal, to and market food animals ONLY if he or she has obtained an Investigational New Animal Drug (INAD) permit (with slaughter authorization) through the Food and Drug Administration's Center for Veterinary Medicine.

2.1.5 None of these federal obligations address requirements that an individual research institution might have, such as protocol review by an Animal Care and Use Committee.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 511.1(a), Federal Food, Drug, and Cosmetic Act

Recommendations from the Food Animal Residue Avoidance Databank (FARAD)

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1. PURPOSE:

Food or water restriction/deprivation involving animals used for research, teaching, or testing, other than pre-surgical fasting, may be necessary for some physiological, neuroscience and behavior studies. Because these procedures may cause more than momentary or slight distress to the animals, the Purdue Animal Care and Use Committee established the following SOP.

2. DEFINITIONS

2.1 *Standard Food Intake.* Animals should be fed palatable, non-contaminated diets that meet their nutritional needs at least daily, or according to their particular requirements.

2.2 *Standard Water Intake.* Animals should have access to potable, uncontaminated drinking water according to their particular requirements.

2.3 *Food or Water Restriction:* Any deviation from the standard food or water intake that is less than what is minimally required for that species.

2.4 *Full Review.* Level of review pertaining to research activities that must be evaluated by a quorum of the convened IRB.

2.5 *Food Deprivation.* Withholding food for longer than 24 hours for simple stomach animals, or longer than 48 hours for ruminants.

2.6 *Water Deprivation*. Withholding water for longer than 12 hours.

3. PROCEDURES

3.1 Required Information

3.1.1 Dietary or water restriction/deprivation must be scientifically justified and approved in the IACUC protocol.

3.1.2 Alternatives to food or water restriction/deprivation must be considered in the IACUC protocol search for alternatives.

3.1.3 The least restriction/deprivation that will achieve the scientific objective should be used.

3.1.4 The amount of food and water consumed daily must be recorded.

3.2 Animal Care

3.2.1 Cages with food or water restriction must be identified with a husbandry card and a restriction form must be completed and signed each day when food/water is provided. (See form below)

3.2.2 Animals must be weighed prior to food restriction/deprivation. Once restriction/deprivation has begun, animals must be weighed at least weekly as a minimum, or more often for animals requiring greater restriction/deprivation and weights recorded. Body weights must not drop below 80% of normal (taking into account normal anticipated growth for that animal). Note that rodents, especially mice, have a very high metabolism and gastrointestinal transit time and can become dehydrated very quickly.

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3.2.3 A program for monitoring animals must be described in the IACUC protocol. This should include physiological and behavioral parameters for assessment of pain and/or distress and describe criteria such as degree of weight loss/dehydration indicating a need for temporary or permanent removal of the animals from the experiment.

3.2.4 Special attention should be given to ensure that animals consume a balanced diet as food consumption may decrease with fluid restriction.

4. APPLICABLE REGULATIONS AND GUIDELINES

1. The Guide for the Care and Use of Laboratory Animals 8th Ed.

2. OLAW- Frequently Asked Questions
https://olaw.nih.gov/faqs/#/guidance/faqs?anchor=question52964

3. Lab Animal (38)10: October 2009. Regulatory Issues Regarding the Use of Food and Water Restriction in Laboratory Animals.

1. PURPOSE:

The Guide for the Care and use of Laboratory Animals 8th edition states the following concerning Humane Endpoints for research, teaching and testing animals. "While all studies should employ endpoints that are humane, studies that commonly require special consideration include those that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock.

2. DEFINITIONS

2.1 *Experimental Endpoint.* the experimental endpoint of a study occurs when the scientific aims and objectives have been reached.

2.2 *Humane Endpoint.* The humane endpoint is the point at which pain or distress in an experimental animal is prevented, terminated, or relieved.

3. PROCEDURES

3.1 Endpoint Selection

3.1.1 Humane endpoints should be selected based on their ability to accurately and reproducibly predict or indicate pain and or distress, imminent deterioration, or death. The selection of appropriate humane endpoints requires detailed knowledge of the impact of the procedure on the animal to allow for intervention before unpredicted distress or pain develops.

3.1.2 To develop humane endpoints for a particular Purdue Animal Care and Use Protocol (IACUC) protocol, the principal investigator should describe the clinical progression that a particular animal or group of animals could experience as a result of experimental manipulation or spontaneously occurring disease.

3.1.3 Endpoints that will address this progression may coincide with the Experimental Endpoint of the project but must also include criteria for removing an animal from a study prior to the Experimental Endpoint.

3.2 Morbidity or Disease State as an Endpoint

3.2.1 Animal Care and Use Protocols that include morbidity, a diseased state, as an endpoint or that include animal procedures that have the potential to cause pain and/or distress must address the following as applicable to the IACUC protocol being submitted:

(a) Rapid or progressive weight loss of more than 20% of the body weight

(b) Loss of body condition - especially in studies where loss of body condition may occur without loss of weight (e.g. animals with large tumors.) See attachment for example of body condition scoring of mice and rats.

(c) Unrelenting/unresolved diarrhea

(d) Dehydration determined by an increase in skin tenting, sunken eyes, and weight loss

(e) Abdominal swelling and/or ascites

(f) Progressive dermatitis and/or self-induced trauma

(g) Rough hair coat/poor grooming

(h) Hunched posture

(i) Lethargy, an inability to stand or loss of righting reflex

(j) Respiratory symptoms such as labored breathing, nasal discharge, coughing, or cyanosis

(k) Ataxia, progressive paralysis or paresis, head tilt/circling or any other severe neurological symptom

(l) Any condition interfering with daily activities ie eating, drinking, ambulation etc.

(m) Prolonged increase or decrease in body temperature

(n) Abnormal vocalization/aggressive behavior upon handling

(o) Infection unresponsive to treatment

(p) For aquatic species additional signs could include scoliosis, emaciation, significant skin lesions, exposure of muscle or other tissue

(q) Other signs judged by experienced veterinary staff to be indicative of a moribund condition (hemorrhage, icterus, anemia, anuria).

3.3 Death or Moribundity as an Endpoint

3.3.1 The moribund condition is defined as an irreversible condition leading inevitably to death.

3.3.2 Signs of an animal displaying the moribund state include but are not limited to:

(a) A lack of responsiveness to manual stimulation

(b) A lack of mobility

(c) An inability or failure to eat or drink

3.3.3 Animal studies proposing death or moribundity as an endpoint should contain the following:

(a) What alternatives to death or moribundity as an end point were considered;

(b) Why measures to relieve pain and or distress cannot be used if applicable;

(c) The number of animals and justification for animals that will be allowed to reach moribundity or death as an endpoint;

(d) If animals are not to be euthanized when reaching a moribund condition, what information will be gained by allowing them to proceed to death;

(e) A plan must be in place for monitoring animals involved in experiments that lead to moribundity or death to include the frequency of monitoring. The frequency of monitoring should be at least once a day but more frequent as the above signs become apparent;

(f) Records must be kept of monitoring.

3.4 Studies Involving Genetically Modified Animals

3.4.1 Genetically modified animals may display phenotypes that are expected or unexpected.

(a) Expected phenotypes that may impact the health and welfare of the animals should be included in the IACUC protocol to alert animal care staff as to expected conditions the animals may display and to appropriate care for these animals. IACUC protocols should also include endpoints for these animals.

(b) Unexpected phenotypes that may impact the health and welfare of the animals must be reported to the Laboratory Animal Program

veterinary staff and be provided with appropriate veterinary treatment, be monitored for deteriorating condition if treatment would impact the research project or be euthanized if found to be moribund, unable to obtain food or water, or cachectic. If the unexpected phenotype impacts the experimental results, the animal should also be euthanized.

3.4.2 A plan should be in place for monitoring these animals both before and after any changes in the animals condition arises. This should include providing appropriate care if needed and increasing the level of monitoring as is necessary to provide treatment or euthanasia as appropriate.

3.5 Endpoint Criteria for Rodent Tumor Studies

3.5.1 This section includes guidelines for solid tumors and liquid or non-palpable tumors that have been implanted, as well as naturally occurring tumors to help ensure the health and well-being of animals used in neoplastic studies.

3.5.2 The Guide for the Care and use of Laboratory Animals 8th edition states the following concerning humane endpoints for research, teaching and testing animals. “While all studies should employ endpoints that are humane, studies that commonly require special consideration include those that involve **tumor models**, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock.

3.5.3 Animals in tumor studies should be monitored at least weekly, and at least twice a week once palpable tumors are evident. More frequent monitoring may be necessary when rapid tumor growth is expected, when the tumors are nearing endpoint, or when the animal condition begins to deteriorate.

3.5.4 In studies involving neoplasia, endpoints include but are not limited to:

(a) Tumor Size: For an adult mouse, a tumor is allowed to grow to mean diameters of 2.0 cm. For an adult rat, a tumor is allowed to grow to mean diameters of 4.0 cm. Formulas for determining tumor volume are detailed in references at the end of this document.

(b) Multiple Tumors: The total size of all tumors combined should not exceed 3.0 cm, nor should any one tumor exceed 2.0 cm for mice.

Function: Tumors that interfere with normal functions such as eating, ambulating, eliminating.

(c) Body Condition Score: As the tumor itself could cause the animal to weigh more, and the animal may become cachexic, weight loss should be assessed in the form of a body condition score (BCS), which should be performed at least weekly or more often depending on the study. A BCS of <2/5 must be euthanized. A BCS of 2/5 may need euthanized if the activity level is decreased. A standard BCS chart is provided below.

(d) Overall Condition of the Animal: Animals displaying signs of pain, lethargy, labored breathing, or lack of responsiveness should be euthanized. For rats, the total should not exceed 5.0 cm, or 4.0 cm for any one tumor.

(e) Ulceration: Tumors that ulcerate and become necrotic or infected. Ulceration should be treated with antibiotic ointment 3x/week and the animal should be monitored daily.

(f) Function: Tumors that interfere with normal functions such as eating, ambulating, eliminating.

(g) Body Condition Score: As the tumor itself could cause the animal to weigh more, and the animal may become cachexic, weight loss should be assessed in the form of a body condition score (BCS), which should be performed at least weekly or more often depending on the study. A BCS of <2/5 must be euthanized. A BCS of 2/5 may need euthanized if the activity level is decreased. A standard BCS chart is provided below.

(h) Overall Condition of the Animal: Animals displaying signs of pain, lethargy, labored breathing, or lack of responsiveness should be euthanized.

3.5.5 For liquid (leukemia) or non-palpable tumors, BCS and overall condition of the animal are typically used to evaluate the state of the animal. In these cases, a scoring system should be developed within the protocol to determine humane endpoints.

3.5.6 These endpoint criteria are required to be followed for tumor studies. Exemptions must be justified and approved by the IACUC. Implementation will occur immediately for all new protocols and at the triennial review for currently approved protocols.

4. APPLICABLE REGULATIONS AND GUIDELINES

1. National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition. Washington (DC): National Academies Press (US); 2011. Available from: https://www.ncbi.nlm.nih.gov/books/NBK54050/ doi: 10.17226/12910

2. NIH Guidelines for Endpoints in Animal Study Proposals revised 05/11/11.

3. Canadian Council on Animal Care (1998) Guidelines on Choosing an appropriate endpoint in experiments using animals for research, teaching, and testing.

4. Humane endpoints in laboratory animal experimentation.

5. University of Pennsylvania. IACUC Guideline Rodent Tumor Production approved 04/27/10.

6. Euhus,D. M., Hudd, et al. Tumor Measurement in the Nude Mouse. Journal of Surgical Oncology 31:229- 234 (1986).

7. Tomayko M. M., Reynolds C. P. Determination of subcutaneous tumor size in athymic (nude) mice. Cancer Chemother Pharmacol 24: 148-154 (1989).

8. Brown University IACUC Rodent Tumor Policy; approved 6/25/14.

9. The University of North Carolina at Chapel Hill Standard on Tumor Production and Cancer Research in Mice and Rats. May 2018.

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1. PURPOSE:

The purpose of this SOP is to ensure safe population densities and conditions in mouse and rat colonies at Purdue University. Overcrowded mouse and rat cages can be a significant animal welfare concern and violate federal policies which require that space recommendations of The Guide for the Care and Use of Laboratory Animals (The Guide) be appropriately applied.

2. PROCEDURES

2.1 Population Densities for Mice

2.1.1 Standard cages measuring (11" x 7"x 5") or (11" x 6.25"x 5")

(a) Breeding animals may be housed one adult male and one adult female mouse or one adult male with two adult female mice.

(b) If one adult male and two adult females are housed together for breeding, female mice must be placed in separate cages as soon as pregnancy is apparent unless approved otherwise by IACUC. The male mouse may remain with one of the females.

(c) An adult female mouse plus her own pups will be considered a single entity until the pups are 21 days old. At that time, the space requirements in The Guide must be applied.

(d) Pups must be weaned by 21 days unless IACUC approval for delayed weaning has been given.

(e) If a female mouse delivers a second litter of pups prior to the older pups weaning date, the older litter must be weaned.

(f) Overcrowded cages are those standard mouse cages that have greater than 5 adults of the same sex or 5 weanlings of the same sex in a cage. Overcrowded cages must have the number of animals reduced immediately.

2.1.2 For large breeder cages measuring (11" x 19" x 5")

(a) Breeding animals may be housed one male plus up to three females.

(b) When the dam is separated/removed and mice are weaned (regardless of their age), they are considered adult mice and the Guide and IACUC Policy must be followed.

(c) Any pups may remain until weaning at 21 days of age at which time they must be weaned unless IACUC approval for delayed weaning has been given.

(d) As the potential for newborn pups being in the cage along with litters of 2-3 week old mice exists, extra care may be needed to assure that ample food and water are available at all times and that cages do not become excessively soiled.

2.2 Population Densities for Rats

2.2.1 A maximum of two rats is allowed in any standard size cage post-weaning.

2.2.2 If at any time the weight of the two animals combined reaches 1000g, the animals must be separated and housed singly. It is recommended to weigh paired adult rats over 400g each at least monthly to ensure compliance with this SOP.

2.2.3 In the event that an odd number of animals is present on a study, to facilitate social housing one cage may contain three rats. The total of the rats may still not exceed 1000g, therefore animals approaching 300g should be weighed at least monthly.

2.2.4 Densities for common cage sizes at the Purdue West Lafayette campus

(a) From Allentown: 11.818” L X 7.638” W X 15.533”H = 142 sq. inch of floor space.

(b) From Alternative Design: 10.25” L X 18.75” W X 8”H = 141 sq. inch of floor space.

(c) From Innovive: 17"L x 13.4"W x 9.9"H = 141 sq. inch floor space.

2.2.5 Densities for common cage sizes at the Purdue Fort Wayne campus.

(a) For large rat cages (22 x12.5 in.), a maximum of 4 rats is allowed post-weaning.

(b) If at any time the total weight exceeds 2000g, the cage must be separated, preferably by splitting the rats into 2 pairs.

2.3 Wire Bottom Caging for Rodents

2.3.1 It is the IACUC's policy that, whenever feasible, rodents be housed in solid bottom caging with bedding.

2.3.2 Wire-bottom caging is acceptable for housing rodents, except for:

(a) Long-term rodent housing, defined as greater than twelve (12) months.

(b) Housing rats with a body weight in excess of 500 grams for longer than two months

(c) In the referenced cases described in 2.2.2 (a) and (b), the use of solid-bottom cages is the standard.

2.3.3 All wire-bottom caging currently in use at Purdue University, that houses rodents exceeding the time and body weight limits listed above, are to be modified with either solid resting boards that cover one-third of the floor space, by providing an enrichment PCV tube, or replacing with solid bottom caging. Modification should occur only after review by and discussion with impacted research groups. Request for exceptions to this policy will require review and approval by the IACUC.

2.3.4 Wire-bottom cages may be considered for approval for long-term housing of rodents or housing large rodents, as long as foot health is maintained. Each situation must be reviewed and approved by the IACUC. There may be justifications for the use of wire-bottom instead of solid-bottom cages. An example of such justification might include contact (e.g., dermal application) or oral dosing studies, in which there may be a risk of the animal having additional contact with the compound if housed in a solid bottom cage with bedding.

2.3.5 When the use of wire-bottom cages is approved, an evaluation process must be in place to closely monitor the health of the animals, particularly the feet of larger animals on longer studies. The evaluation of the animals will be through the direct and frequent visual examination during the regular cage changes by the animal caretakers and interaction of the animals by the research staff. A mechanism that immediately alerts the veterinary staff should lesions develop needs to be part of the program.

2.3.6 If wire bottom caging is in use, the management of the animal facility where the animals are housed should be prepared with a sufficient number of resting boards or other ways (e.g., solid bottom caging) to provide animals that develop foot lesions relief from the wire and time to heal.

Rodents with evidence of foot / leg lesions cannot be housed solely on wire-bottom caging.

2.3.7 In addition, rodents housed in wire bottom cages should be provided environmental enrichment such as but not restricted to PVC tubes or small nyla-bones. Environmental enrichment objects should only be added after review by and discussion with impacted research groups. Request for exceptions to this policy will require review and approval by the IACUC.

2.4 Providing Nesting Material for Mice

2.4.1 The Guide recommends room temperatures for rodents between 68 – 79 degrees Fahrenheit. The Guide goes on to say that the thermal neutral zone of mice ranges from 78.8 – 93 degrees Fahrenheit. At lower temperatures, mice thermoregulate by building nests and huddling together. Thus, mice should be provided with adequate nesting material to avoid cold stress and improve welfare. Research has shown that mice need at least 6 grams of nesting material to build a fully enclosed nest but that up to 10 gm of nesting material may be necessary to alleviate thermal stress in typical animal facility temperatures of 68 – 79 degrees Fahrenheit.

2.4.2 For all mouse cages, 6 – 10 grams of nesting material should be provided in addition to the usual bedding provided in each facility. Some breeding mice, especially genetically modified mice may need 8-10 grams (gm) of nesting material to successfully rear healthy pups. The amount of nesting material may vary with type of bedding provided.

(a) For example, cages bedded with aspen shavings, an adequate amount of nesting material may be 6 grams.

(b) For cages bedded with corn cob bedding, an adequate amount of nesting material may be 8 grams. Visibility of the housed mice inside the nest along with the comfort of the animals should be considered.

2.4.3 Examples of approved nesting material include nestlets (~2.66 gm/nestlet), 8 gm of paper whether in loose crinkled form or in 4 gm or 8 gm compressed pucks, or combinations of the above.

(a) The use of contrasting colored paper to mouse coat is recommended to improve mouse visibility (e.g., white paper increases visibility of C57BL/6 mice).

(b) Provision of paper or plastic huts in addition to nestlets or crinkle paper are also approved.

(c) Huts may be more beneficial for certain disease models who do not readily build nests but may inhibit visibility and instigate territorial fighting over the huts.

(d) For Investigators: Any research project that requires a different type of nesting material, different amount of nesting material outside the approximate 6-10 gm, or a complete lack of nesting material for mice, must include scientific justification in the protocol attachment.

(e) For Animal Care Staff: Any changes to the amount or type of nesting material provided to an individual PI's mouse colony must be approved by the PI so that any experimental results from ongoing experiments are not inadvertently altered.

3. RESPONSIBILITIES

3.1 Breeding colonies must be attended to every day by investigative staff including weekends and holidays.

3.2 Investigators not complying with the population policy will receive a Non-Compliance IACUC Housing notification and be given 24 hours to correct the situation unless the welfare of the animals requires immediate separation.

3.3 Failure to correct the situation in the time allotted will result in EVPRP/LAP staff weaning the cage and charging tech time (separation of overcrowded cages is not covered under the per diem).

3.4 A report of Non-Compliance IACUC Housing Policy occurrences will be sent to the IACUC office monthly.

4. APPLICABLE REGULATIONS AND GUIDELINES

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition.

Gaskill, B. N. et al, 2012. Heat or insulation: Behavioral titration of mouse preference for warmth or access to a nest. PLoS ONE 7: e32799.

Gaskill, B. N. et al, 2013. Impact of nesting material on mouse body temperature and physiology. Physiol Behav 110: 87-95.

Gaskill, B. N. et al, 2013. Energy reallocation to breeding performance through improved nest building in laboratory mice. PLoS ONE 8: e74153.

1. INTRODUCTION:

All animals covered under an Institutional Animal Care and Use Committee (IACUC) approved protocol or standard operating procedure (SOP) will be protected from potential distress associated with non-routine visitation, photography, videography, or observations. Images will be maintained securely and shared only in a way that is respectful of the animals. Contents of photographs or videos should be taken with respect, reviewed with discretion, and not contain any identifying features (i.e., building, room number, farm location, etc.).

Animals located at the Animal Science Research and Education Center (ASREC), SIPAC, and Feldun are covered under a separate SOP written by the Department of Animal Sciences.

2. DEFINITIONS

2.1 *Animal Use Area* – animal housing facilities, farms, and PI laboratories where animals are housed, tested, or used and conveyances in which animals are transported between animal use areas.

2.2 *Audio Recording* – The capture of sounds onto any compatible medium, or posting to the internet, by any means or devices now in use or that may be invented in the future including but not limited to, electronic devices such as personal computers, mobile phones or personal digital devices.

2.3 *Filming* – The capture of moving images of Purdue University property (i.e., animals, facilities, or equipment) by any means on any media now in use or that may be available in the future, including but not limited to, film, videotape, digital disk, or any electronic transmission to another medium or the internet.

2.4 *Photography* – The capture of still images onto any compatible medium, or posting to the internet, by any means or devices now in use or that may be available in the future, including but not limited to, film cameras, digital cameras, electronic devices such as personal computers, mobile phones or personal digital devices.

2.5 *Social Media Channels or Networks* – Web-based and mobile platforms that allow the use of online social connections to broadcast communication. With social media, user-generated content is highly accessible online, and is also a powerful digital equivalent of "word-of-mouth." Examples of online social media channels include but are not limited to Facebook, Twitter, Instagram, Google Plus, Snapchat, and YouTube.

3. PROCEDURES

3.1 Recording

3.1.1 The use of any recording device (e.g., film camera, digital camera, phone camera, digital recorder, sound recorder, etc.) is only permitted in animal use areas under the following conditions:

(a) When performed by government inspectors (e.g., USDA Veterinary Medical Officer-VMO).

(b) When performed by or on behalf of the IACUC during an inspection or post-approval monitoring visit for purposes of reporting animal care concerns to the IACUC.

(c) When performed by Laboratory Animal Program (LAP) veterinary staff and/or animal care staff when required to assist in clinical diagnosis of disease or illness.

(d) When performed by a Principal Investigator (PI) or his/her designee when required for scientific reasons (e.g., publications, scientific documentation, submission of a grant proposal).

(e) When performed by a PI or his/her designee for instructional purposes (e.g., for training members of the lab, collaborators, or for course work).

(f) When performed by a member of the media under escort by a PI (or designee).

3.1.2 Unauthorized electronic devices (e.g., tape or audio recorders, video recorders, cell phones, cameras) must not be used to collect, audio, video, or other media in animal use areas (e.g., research and teaching areas). Release of information, photographs or recordings related to the Animal Care and Use Program at Purdue University without appropriate authorization is strictly prohibited.

3.1.3 Violation of this policy or any of its parts may be considered insubordination, including disobedience or failure to carry out assignments or instructions; and/or noncompliance with IACUC policy. IACUC acknowledges that it is difficult to control those who are taking pictures or video; however, Purdue personnel are encouraged to remind those doing these activities that they should not post pictures or video of Purdue-owned animals on their personal media sites.

3.2 Posting on Personal Social Media Sites

3.2.1 Regardless of the audience or distribution method, all recordings must be in accordance with the following stipulations:

(a) Photos, videos, or images of animals or cadavers owned or used by Purdue for purposes of teaching or research, or client-owned animals who are patients in the Veterinary Teaching Hospital, may not be put on personal social networks or web sites.

(b) Protect confidential information. In reference to Purdue University policy, do not post confidential, health, proprietary or protected information about students, employees, clients, patients, or other members of the Purdue University community. Personal contact information must be protected from others.

(c) Moderate comments and discussions. Because of the participatory nature of social media, it is extremely important that other user-generated content posted to the site is closely monitored. Watch for off-topic or abusive comments and promptly remove them. If possible, develop a comments policy and encourage respectful use.

(d) Protect Purdue's Institutional Voice. If you identify yourself as a Purdue faculty, staff member, or student online, make a clear statement that the views expressed in your personal site are not those of the institution. When your page/group mentions Purdue, users who read your posts may perceive that you are representing the university, even if you state that the views are your own and do not represent your affiliation with the university. Therefore, do not post anything that you would not be comfortable saying in a public setting, at a conference, or to a member of the media. Posts should protect Purdue University's institutional voice. Your page should always have its own identity and should not be misconstrued as representing Purdue University as a whole. Name your social media page or group accordingly.

(e) Posting images and video. Images online are easily appropriated by other users. Photos and videos must comply with PACUC's Policy on Visitation, Photography, Videography, and Observations within Vertebrate Animal Facilities.

3.2.2 Other important considerations relative to standard Purdue University policies include;

(a) Do not post material that infringes on the rights of any third party, this includes intellectual property.

(b) Do not post material that is unlawful, obscene, defamatory, threatening, harassing, abusive, slanderous, or hateful.

(c) Follow posting and social media standards outlined by Purdue University, including but not limited to, Policy VII.C.2, "University-Sponsored Social Media Outlets."

3.3 Conditions for Media Use and Storage

3.3.1 Regardless of the audience or distribution method, all recordings must be in accordance with the following stipulations:

(a) Animals that have visible lesions or research alterations (e.g., implants, tumors, cannulas), or are noticeably sick cannot be photographed or video recorded without specific authorization or permission from the PACUC Administrator, the PACUC Chair/Vice Chair, and the Attending Veterinarian or designee.

(b) A request to publicly distribute materials must be approved by the PACUC Administrator or the PACUC Chair/Vice Chair who may consult with the full PACUC and/or Institutional Official. This includes requests from media outlets who interview faculty regarding their research and may want to include photographs or video.

(c) Animals are not to be used as props during an interview. There should be a specific reason an animal must be present during an interview.

3.3.2 Filming for general public or commercial presentations have additional stipulations and requirements:

(a) All procedures to be recorded or shown must be described in the approved Animal Use Protocol.

(b) No references to identifying information should be visible in the photograph/video, paying close attention to minimize photo and video capture of background and items (e.g., cage cards, names).

(c) Appropriate handling, restraint and research methods for the species must be used.

(d) Appropriate personal protective equipment (PPE) must be worn by all persons in the photograph/video, keeping species of animal and procedure demonstrated in mind.

(e) All attempts should be made to have animals in clean surroundings, clean cages, or clean pens with clean accessories. Water bottles and feeders should be full if visible in the photograph or recording.

(f) No references to identifying information should be visible in the photograph/video, paying close attention to minimize photo and video capture of background and items (e.g., cage cards, names).

(g) Appropriate handling, restraint and research methods for the species must be used.

(h) Appropriate personal protective equipment (PPE) must be worn by all persons in the photograph/video, keeping species of animal and procedure demonstrated in mind.

3.3.3 All attempts should be made to have animals in clean surroundings, clean cages, or clean pens with clean accessories. Water bottles and feeders should be full if visible in the photograph or recording. Media storage must occur, at a minimum in the following way to protect unauthorized use.

(a) Videos, photos, and audio recordings made by Purdue personnel (not applicable to outside media) must be stored securely in a locked cabinet or drawer; or behind a password protected, preferably encrypted, electronic storage device or computer.

(b) Additionally, if a personal electronic device was used to capture the image or sound(s) then the data should be transferred to a password protected computer and the image deleted from the personal device in case the personal device was lost or misplaced.

4. RESPONSIBILITIES

The IACUC Administrator, while reviewing a request for authorization by an individual

to make recordings, may consult the IACUC Chair/Vice Chair or Institutional Official when considering the health and well-being of the animals being recorded and when ensuring that the proposed justification for taking media recordings is appropriate and rational. The IACUC Administrator may also consult with Media Relations, particularly if print or broadcast journalists are involved with the request.

Individuals are responsible for:

- receiving appropriate permission or authorization, if needed, prior to taking photographs, audio or video recordings;
- ensuring that personal information (e.g., someone's face or contact information) is not visible and if it is, that the individual has given permission to be so recorded;
- securely storing the videos, photos or audio recordings;
- Ensuring that any photographs, recordings or videos are not released where the content could be taken out of context or jeopardize Purdue University.

Principal Investigators must:

- ensure that the act of taking photographs, audio or video recordings accurately portrays what is described and approved in their Animal Use Protocol and that visual media capture as small a view as possible;
- review policies and guidelines for the use of research or teaching animals with personnel—including students in classes—and assuring that use of animals strictly adheres to these documents, including any media recordings.

5. APPLICABLE REGULATIONS AND GUIDELINES

This SOP applies to all persons who work in or visit Purdue animal care and use operations.

Animals located at the Animal Science Research and Education Center (ASREC), SIPAC, and Feldun are covered under a separate SOP written by the Department of Animal Sciences.

REFERENCES TO OTHER APPLICABLE SOPs

1. PURPOSE:

It is the policy of IACUC that whenever compounds are administered to animals and whenever pharmaceutical grade compounds are available, they must not be substituted with non-pharmaceutical grade compounds.

2. PROCEDURES

2.1 Pharmaceutical Grade

2.1.1 A pharmaceutical grade compound is a drug, biologic, reagent, etc. which is approved by the FDA or for which a chemical purity standard has been written/established by a recognized pharmacopeia (e.g., USP, NF or BP).

2.1.2 Issues such as sterility, pyrogenicity, stability, pharmacokinetics and quality control have usually been addressed during the course of pharmaceutical grade compound production – the same may not be true for substances formulated in a laboratory.

2.2 Applicability

2.2.1 Compounds used for the clinical treatment of animals or used to reduce / eliminate pain or distress must be pharmaceutical grade and used within expiration date unless justified and approved by IACUC.

2.2.2 The above requirements also apply to acute/terminal procedures.

2.2.3 For compounds used to accomplish the scientific aims of a study, if available, pharmaceutical grade compounds are preferred.

3. APPLICABLE REGULATIONS AND GUIDELINES

U.S. Department of Health and Human Services. *Frequently asked questions about the public health service policy on humane care and use of Laboratory Animals: 2003*. National Institutes of Health. https://grants.nih.gov/grants/olaw/references/lab_animal2003v32n9_wolff.htm

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. Guide for the Care and Use of Laboratory Animals. 8th edition. p. 31.

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1. PURPOSE:

The use of expired medical materials such as drugs, fluids or sutures in research animals is not considered to be consistent with adequate veterinary care and therefore materials must be labeled with an expiration date. In addition, in order to ensure sterility of supplies to be used in survival surgery, sterilized instruments and devices must also be labeled. This policy will provide information for determining the expiration dates of medical materials intended for use in all animal research at Purdue University.

2. PROCEDURES

2.1 General Recommendations

2.1.1 Order drugs and other medical supplies in quantities that can easily be used within the vendor's expiration date.

2.1.2 All areas where drugs and other medical supplies are stored should be inspected on a monthly basis to ensure that expired items are identified and discarded appropriately.

2.2 Dating of Materials

2.2.1 Sterile and Surgical Materials

(a) Pre-packaged sterile medical products such as suture material or surgical gloves marked with an expiration date by the vendor cannot be used for survival procedures after that date, and should be discarded.

(b) Sterilized surgical packs, supplies, devices or any other instruments used in survival surgeries must be marked with the date of sterilization and an expiration date based on the date of sterilization.

(c) Cloth wrapped packs sterilized and stored appropriately should have an expiration date of six months from the date of sterilization.

(d) Peel packs sterilized and stored appropriately should have an expiration date of one year from the date of sterilization.

(e) Autoclaved materials should contain a chemical sterilization indicator within the package and be marked with an external chemical sterilization indicator such as autoclave tape. Chemical sterilization indicators such as heat sensitive autoclave tape turn

color when the appropriate temperature for sterilization has been reached. A chemical indicator within the pack should also be used.

(f) Sterilized materials should be stored in enclosed cabinets/drawers away from moisture and dust.

2.2.2 Medications

(a) All medications intended for use in live animals must be labeled with an expiration date.

(b) Drugs without manufacturer's expiration dates should be dated upon receipt. The researcher should determine the stability of the drug in order to predict a reasonable shelf life. This is commonly obtained from the manufacturer. If stability is unknown, the drug should not be used beyond one year from purchase.

(c) If drugs are reconstituted they must be marked with the contents, concentration, date of reconstitution and manufacturer's recommended expiration date.

(d) If drugs are aliquoted so that they are no longer in the original container, they must be marked with the contents, concentration and manufacturer's expiration date.

2.2.3 Drug Mixtures and Fluids

(a) If refrigerated between uses, multi-dose containers of fluids, entered using aseptic technique, used for IV, IP, SC administration (e.g. normal saline, lactated Ringers) expire 30 days after opening if kept refrigerated and after 7 days if not refrigerated.

(b) If a drug is transferred unchanged into a sealed, sterile container (e.g. empty sterile vial) using aseptic technique it should retain its original expiration date.

(c) If a drug is diluted or mixed with another compatible drug and transferred to a sealed, sterile container using aseptic technique, it expires in 30 days (or at the earliest expiration date of the component drugs, whichever comes first).

2.3 Veterinary Care

2.3.1 The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice

and is not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act. The facility should either dispose of promulgated under the Animal Welfare Act. The facility should either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials.

2.3.2 For acute terminal procedures, where an animal is put under anesthesia, the research is carried out (surgery or testing of a compound) and the animal is euthanized without ever waking up, medical materials may be used beyond their "to be used by" date if such materials use does not adversely affect the animal's wellbeing or compromise the validity of the scientific study. Anesthesia, analgesia, emergency drugs and euthanasia drugs that are within their expiration dates are required for all such procedures.

2.3.3 Facilities allowing the use of expired medical materials in acute terminal procedures should have a policy covering the use of such materials and/or require investigators to describe in their animal activity proposals the intended use of expired materials.

2.3.4 The attending veterinarian and the Institutional Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. APHIS has determined that these responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired medical materials

3. REFERENCES

University of Connecticut IACUC Policy: Policy #SI-10-2013

Centers for Disease Control and Prevention (CDC) – Infection Control

1. PURPOSE:

Instruction using live animals is an important part of the veterinary school curriculum. In the process of training DVM students and veterinary nursing students, however, the welfare of the animals being used must be considered at all times. No animal should be subjected to excess use - either daily, weekly, or cumulatively over the course of a semester or academic or calendar year – in order to meet curricular goals. A qualified veterinary nurse or supervising DVM, listed on the approved protocol, should be present in all labs in which live animals are used to monitor animal health and welfare.

In addition to specific techniques, using live animals allows students to become familiar with concepts of animal welfare and the ethical use of animals. Animal welfare principles, the ethics and obligations that are attendant with animal use, and how to determine humane treatment of animals should be part of every course's curriculum in which live animals are to be used.

The Five Freedoms are globally recognized as the gold standard in animal welfare, encompassing both the mental and physical well-being of animals; they include: freedom from hunger and thirst; freedom from discomfort; freedom from pain, injury, and disease; freedom to express normal and natural behavior (e.g., accommodating for a chicken's instinct to roost); and freedom from fear and distress. (See: Fraser D, Anim Welfare 2003;12:433.) In all cases these should be considered when using teaching animals.

2. PROCEDURES

2.1 Guidelines

2.1.1 Going forward, the following guidelines should be followed when considering the use of animals for teaching within the DVM and veterinary nursing curricula:

(a) With the exception of animals donated to the VTH due to a medical problem, all animals used in teaching laboratories should be healthy and in good body condition. SOPs that address vaccination, parasite control, and other husbandry concerns appropriate for the individual species must be developed and followed.

(b) Surgeries and other procedures that are performed for the health of the animal such as sterilization (OHE or castration) or teeth cleaning/floating are not counted towards the animal's semester total of invasive procedures.

(c) Animals must receive time off or rest times between invasive procedures. For procedures that are classified as B to E, animals

that are used in more than one course, or transferred between teaching and research protocols (e.g., horses), must be given a minimum of 1 week rest period between uses. This limitation does not apply to the Pet Professors. Pet Professors are privately-owned animals that are used in multiple courses for non-invasive procedures.

(d) The number of students assigned to any one teaching animal should be limited so that the animal is not over-used while the learning objectives for the students are met.

(e) Instructors are encouraged to integrate procedures. For example, rather than subject an animal to an IV injection of saline, use the IV injection to provide a sedative when preparing to perform a more invasive technique.

2.1.2 Procedures have been grouped into Invasiveness Categories, A through E. In all instances, number of attempts rather than number of successful attempts is counted for any procedure. For example, in a blood collection laboratory, students may make a total of 4 attempts to collect blood. No more may be attempted, even if none of the attempts were successful.

2.1.3 Procedures are categorized as A (not stressful) to E (terminal event). This classification is intended to cover individuals of all species that are used multiple times throughout the year.

2.1.4 The classification system cannot cover all the possible procedures that might be done when an animal is on a research protocol. For that reason, procedures performed while an animal is on a research protocol will not be counted towards the total. However, any research animal that undergoes a procedure that could reasonably be classified as Classification B or higher must be given 1 month rest before it is used again.

2.1.5 If a PI wishes to add a technique that is not mentioned in this document, they must place it in the most appropriate categorization when applying for IACUC approval.

2.2 Procedure Classification

2.2.1 Classification A

(a) This category includes all routine evaluation procedures that provide basic health information about the animal without causing even transient pain.

(b) These procedures are common parts of a physical examination and must be practiced repeatedly for students to gain the necessary skills of interpretation. They are common parts of many courses, with increasing skills in interpretation expected with progress through the curriculum.

(c) Procedures in this category include: visual evaluation; external palpation of body parts; aging by oral examination, paste tube or oral syringe; digital rectal exams in dogs; external ultrasound; radiography; visual ophthalmic and otic exams; auscultation of heart, respiratory and gastrointestinal systems; echocardiograms; collection of data on temperature, pulse rate and respiratory rate; foot examination; observation of gait with flexion tests or wedge tests; hoof testers; remove shoes; thermography; examination of mucous membranes; basic handling and movement; halter application; placing a collar and leash, body condition scoring; non-sedated neurologic examination, lameness examination, non-sedated orthopedic exam, limb lifting and foot trimming; limb bandaging or temporary splint placement; and saddle fitting.

(d) Limit: These procedures may be performed without specific limits. The only cutoff will be the observation of signs of unusual (species specific) restlessness or agitation by a supervising nurse or clinician. These individuals are trained in observation of these species and in recognizing signs of unusual distress. If this occurs, it will be noted on a master observation form and that animal will be retired from all use for a minimum of 2 days.

2.2.2 Classification B

(a) This category includes those procedures that produce transient minor distress including venipuncture; catheter placement; intramuscular injection; IV injections; SQ injections; sedated examinations; routine rectal palpation and transrectal ultrasound in all species, except digital rectal exams in dogs; passage of insemination pipettes; uterine biopsy; urethral catheterization; vaginoscopy; cystocentesis or urinary catheterization; epidural blocks; nerve blocks; joint blocks; lumbosacral CSF taps; joint taps; anal gland expression in dogs, oral medication by balling gun; stomach tube; upper and lower respiratory endoscopy; treadmill exam with or without endoscopy; gastric endoscopy; oral exam; float teeth; and casting into recumbency (bovine); manual

semen collection; abdominocentesis; fine needle aspirates; skin scraping.

(b) Also in this category are atraumatic procedures that require deep sedation/anesthesia for the logistics of the procedure (i.e. Cast application).

(c) Limit: There will be a limit of 4 attempts of any single procedure and of 8 attempts for the total number of B procedures in a day. There will be a limit of 8 of any single procedure and of 12 for the total number of B procedures in any week, meaning 7 days rest between the last procedure and the next procedure. If 4 or more B procedures are performed in a single day, the animal will be allowed a rest for the following 24 hours where no B or more invasive procedures are conducted. For example, if the animal has 6 injections Monday, Tuesday would be a rest day. If the animal then has 6 blood draw attempts on Wednesday, no more category B procedures may take place until the following Wednesday. The administration of an anti-inflammatory agent, sedative, or anxiolytic, either *per os* or parenterally will not be counted towards an animal's total injection or treatment count if it will help facilitate the lab.

2.2.3 Classification C

(a) This category includes those procedures that produce some degree of pain and/or distress and that therefore require the use of appropriate sedation/anesthesia and/or analgesia. 1) Minor surgical procedures with limited tissue trauma (Caslicks, vaginoplasties, tarsorraphy, check ligament resection, cunean tenectomy, periosteal stripping, inferior check desmotomy, neurectomy, distal splint bone removal; liver biopsy; thoracocentesis; trans-tracheal wash; sinus tap; muscle biopsy; bone marrow collections; skin punch biopsy; small animal dental prophylaxis that is being performed solely for teaching; and electroejaculation.

(b) Limit: Each C procedure can only be performed one time per semester, and no more than a total of 8 C procedures may be performed on any animal. Animals that have had a C procedure will not be eligible for other procedures for 7 days. Anti-inflammatory therapy will be given for at least 24 hours and additional pain medications may be prescribed, if they are determined to be medically needed by the Lab Animal Program attending veterinarian. The administration of an anti-inflammatory

agent, sedation, or anxiolytic, either *per os* or parenterally will not be counted towards an animal's total injection or treatment count if it will help facilitate the lab.

2.2.4 Classification D

(a) This category includes survival procedures that involve: 1) surgical incision into body cavities including abdominal exploratory alone, omentopexy, abomasopexy, enucleation, rumenotomy, laparoscopy, cannula or feeding tube placement, arthroscopy, and cystotomy, or 2) multiple C procedures under general anesthesia. Appropriate anesthesia, analgesia, anti-inflammatory therapy, and antimicrobial therapy will be applied for all D procedures. Faculty surgeons or house staff will scrub in on any such procedure. This provision is excluded for approved teaching protocols such as the small animal and large animal surgery laboratories.

(b) Limit: Animals that have had a D procedure will not be eligible for a C procedure for 2 weeks and B procedures will be limited to those related to case monitoring and care for 2 weeks. A maximum of 1 D procedure/animal will be scheduled during any animal's time at Purdue. If an animal develops a medical condition that requires either a diagnostic or treatment technique described above, the PI involved is encouraged to pursue treatment and perform any medically-indicated procedures up to and including surgical exploration. Such cases represent excellent teaching opportunities for students and reduce the need for involved students to perform mock procedures in healthy animals. If a D procedure is required for health reasons before a scheduled D is performed, that animal will not be eligible for the scheduled D procedure.

2.2.5 Classification E

(a) This category includes all NON-SURVIVAL laboratories. These laboratories are all performed with the animal under general anesthesia. More invasive procedures including enterotomy, gastrotomy, intestinal resection/anastomosis, rib resection, claw amputation, arthrotomy, and AO or AA CSF tap may only be performed as a part of a non-survival laboratory. Non-survival labs may be conducted after any class of procedures without a time break.

(b) Length of stay as a teaching animal

(i) Every animal is different, and what some teaching animals may find stressful, others can tolerate with no ill effect. Because of this, it is difficult to place a single number on the length of time an animal may be used. At any point, any animal that has a serious and irreversible adverse event in a research study that results in removal from a protocol prior to the completion of the study will be immediately euthanized, adopted, or otherwise removed from the teaching herd. Given that, the following guidelines will be applied:

(1) For animals on a single research protocol, the length of stay will be dictated by the disposition outlined in their approved protocol.

(2) Animals that are on a teaching protocol for any portion of a calendar year will be assessed annually for fitness. If they cannot be maintained at an adequate condition score, suffer from chronic musculoskeletal disease, have poor dentition to the point that they cannot ingest food adequately, or exhibit undesirable behaviors, they will be removed from the teaching herd. (Chronic musculoskeletal disease that requires removal from the teaching herd is defined as an animal who exhibits a gait deficit at a walk or who has trouble getting up and down.)

(3) Animals that have been on a teaching protocol for any portion of a calendar year for 3 consecutive years will be placed "on leave" for a 2 month period of time. During their "on leave" time they must be kept on pasture or their usual housing and not used for any research activities. Category A teaching acitivities may still be permitted during this time. Exceptions are that fistulated cows may be used as rumen fluid donors and animals may be used as blood donors. Animals that are used as blood donors should have their use carefully monitored to ensure they do not become anemic or develop signs of stress or ill health.

3. APPLICABLE REGULATIONS AND GUIDELINES

Fraser D, "Assessing animal welfare at the farm and group level: the interplay of science

1. PURPOSE:

To identify which animals are appropriate for donating to wildlife rehabilitation centers, zoos, etc., which centers are approved for donations, and how to donate to such entities.

The Purdue University IACUC authorizes the donation of rodents as a food source according to the criteria described below. Non-profit organizations with the mission of rehabilitating and releasing injured and orphaned raptors back into the wild may wish to obtain mice and rats previously used for research and/or teaching purposes as a source of food for raptors and other species in its care.

2. PROCEDURES

2.1 Rodent Donation Procedure

2.1.1 To donate mice or rats as feed, an investigator must select the "Other" box in the Carcass Disposition section of the IACUC protocol

(a) The protocol must specify where the animals are being donated.

(b) The IACUC protocol must be approved.

(c) A Donations must be delivered to an animal facility manager who will transport the carcass(es) to the appropriate location.

(d) Donations will be picked up by the accepting entity on a monthly basis, as coordinated with the Laboratory Animal Program (LAP).

2.1.2 The animals must meet all the following criteria to be acceptable for donation;

(a) The animals must be on an approved IACUC protocol for use in research or teaching;

(b) Animals have not experienced any manipulation that permanently altered their anatomical, physiological, metabolic, or locomotor function; physiological, metabolic, or locomotor function

(i) Post-mortem examination in which the abdomen and/or thoracic cavity has been opened are acceptable for donation.

(ii) Animals where reproductive organs have been removed post-mortem are acceptable for donation.

(c) Animals have not received any type of device implantation;

(d) Animals have not received any chemical or drug, excluding isoflurane anesthesia when used in recovery procedure;

(e) Appear free of any detectable infectious or physical abnormality that would threaten animal or public health;

(f) Have been euthanized only through the use of CO2 or cervical dislocation alone;

(g) Ear tags must be removed prior to donation.

2.2 Acceptance of Carcasses for Feed Donation

2.2.1 The accepting entity acknowledges and has accepted the following, signed by a waiver of release.

(a) That the animals have been a subject in research, teaching, or testing;

(b) Any and all risks of accepting this animal into their premises;

(c) That the animal carcasses are being donated as a food source for animals and that the carcasses will not be sold or given away or otherwise released from his/her care.

(d) To be responsible for all transportation of rodents by coordinating pickup with the Purdue Laboratory Animal Program.

1. PURPOSE:

The Purdue Institutional Animal Care and Use Committee (IACUC) and the Laboratory Animal Program (LAP) strive to maintain an animal use environment that is safe for both humans and animals. This policy serves as a basis for understanding classifications of hazards and proper handling and disposal along with Personal Protective Equipment (PPE) requirements.

2. PROCEDURES

2.1 Classifications of hazards commonly used in animal research.

(a) Biological/Biohazards are biological substances that pose a threat to the health of living organisms, primarily that of humans.

(i) The Purdue Institutional Biosafety Committee (IBC) reviews animal use protocols involving the use of recombinant DNA (rDNA), synthetic nucleic acids, and/or biohazardous agents that present a risk to humans, animals, and plants.

(1) Recombinant DNA (rDNA) – formed artificially by combining constituents from different organisms.

(2) Synthetic nucleic acids – molecules that are constructed by joining nucleic acid molecules and that can replicate nucleic acids.

(3) Biological source toxins:

a. Poisonous substances produced by certain microorganisms, animals, and plants.

b. Examples include: cardiotoxin, diphtheria, pertussis, tetanus, and lipopolysaccharide endotoxin (LPS). Note: LPS does not require IBC approval.

(4) Other potential pathogens, human tissue, fluids, and/or cell lines.

(b) Hazardous Drugs and Chemicals are Any chemical which can cause a physical or a health hazard (OSHA).

(i) Physical: explosive, flammable, pyrophoric, oxidizing

(ii) Health: chemical hazards and toxic substances pose a wide range of health hazards (refer to Safety Data Sheet).

(1) The Safety Data Sheet (SDS) will indicate if a chemical/drug is a health hazard (e.g., carcinogen, mutagenicity, reproductive toxicity, respirators sensitizer, target organ toxicity, and aspirator toxicity).

(iii) Environmental hazards (may not be a health hazard, requires REM pick-up).

(1) The SDS may contain the following statements:

a. Do not let product enter drain (per SDS).

b. Follow University, local, state, federal guidelines.

2.2 General Requirements and Responsibilities

2.2.1 Assessing hazards – IACUC and Environmental Health & Safety (EHS)

(a) The Animal Safety Verification Form (ASVF) that is associated with the protocol identifies the hazards (e.g., biological, chemical/drug, etc.…).

(b) Applicable EHS programs must be followed.

2.2.2 Using hazards – Principal Investigator and Research Staff/Investigators

(a) It is the Investigator's responsibility to notify animal care staff prior to hazardous material administration.

(b) It is the Investigator's responsibility that all animal facility training is completed, and all requirements are followed.

(i) A cage labeling card must be used to identity all hazards, date of initial injection, and date of final injection.

(c) Identify, collect, and label hazardous materials that require waste pick-up and disposal through EHS (e.g., chemicals/drugs introduced in the animal facilities).

2.2.3 Handling and disposal of animal/waste hazards – Animal Care Staff

(a) Animal Care Staff will handle and dispose of hazards in the following manner:

(i) Biological: Cages and bedding must be autoclaved, regular waste route.

(ii) Biological Source Toxin: Cages and bedding must be autoclaved, EHS pick-up.

(iii) Chemical/Drug: Waste is considered hazardous for 72 hours (3 days) after the final injection; EHS pick-up.

(iv) If both biological and chemical/drug hazards are used, the biological hazard will be handled first (autoclaved) and then the chemical hazard (EHS pick-up).

(v) CMAF management will schedule hazardous material/waste pick-up through EHS.

2.2.4 Personnel Requirements

(a) Personal Protective Equipment (PPE)

(i) Basic/standard PPE = disposable gown, gloves, eye protection, long pants, etc.…

(ii) Biological/Biohazards and Biological Source Toxins:

(1) Personnel must participate in the Animal Exposure Occupational Health Program (AEOHP).

(2) Personnel must be qualified to use respiratory protection (e.g., N-95 respirator and comply with Purdue's Respiratory Protection Program.

(iii) Hazardous Drugs and Chemicals:

(1) N95 respirators and safety glasses may be required while administering hazardous drugs and chemicals and while handling open cages (even under the cabinet) contaminated with these agents.

(2) Please refer to the Animal Safety Verification that is associated with the protocol.

(3) Please note, your lab may not require the use of an N95 respirator while performing tasks with certain hazards, but the animal facilities may require it because of task related hazards (e.g., contaminated bedding becomes a particulate/respiratory hazard)

2.3 Engineering controls commonly used in the animal facilities.

(a) Biosafety cabinets (BSC). Primary purpose is to protect the person and surrounding environment from exposure to biological hazards.

(b) Animal Transfer Station (ATS). Primary purpose is to create a sterile environment for the animals during cage changes while offering allergen protection for technicians.

(c) Animal refuse/disposal (dump) stations. Primary purpose is to offer protection from dusts and allergens from the bedding wastes.

3. APPLICABLE REGULATIONS AND GUIDELINES

Occupational Safety and Health Administrations (OSHA): https://osha.gov

EHS (formerly REM) Standard Operating Procedures (SOP) for Animal Research High Hazards: https://www.purdue.edu/ehps/rem/laboratory/HazMat/sops.html

Purdue University Biological Safety Manual:
https://www.purdue.edu/ehps/rem/documents/programs/bioman.pdf

Purdue University Respiratory Protection Program:
https://www.purdue.edu/ehps/rem/documents/programs/rpp.pdf

Purdue University Hazard Communication Program:
https://www.purdue.edu/ehps/rem/documents/programs/hazcom.pdf