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1. Overview

Preface/Code of Ethics

Proper care, use, and humane treatment of animals used in research, testing and education requires scientific and professional judgment based upon the knowledge and needs of the animals and special requirements of the research, teaching, and educational programs. Drexel University is deeply committed to ensuring the humane care, maintenance, and use of all vertebrate animals in research, research training, teaching and biological testing activities. This commitment includes providing training so that researchers, clinicians, educators and Institutional Animal Care and Use Committee (IACUC) members can fulfill their duties in accordance with Public Health Service (PHS) policies, the National Institutes of Health (NIH) Guide for the Care and Use of Laboratory Animals (the Guide), the Animal Welfare Act, and other applicable policies and guidance.

The use of animals imposes moral, scientific, and legal obligations for humane care and treatment. The purpose of this document is to assist and educate Drexel University faculty, students and staff in the preparation and submission of protocols involving live vertebrate animals for review by the IACUC and to provide procedures for the subsequent conduct of those protocols. This document, which serves as the official governance document for the care and use of live vertebrate animals at Drexel University, reflects the Animal Welfare Act (Public Law 89-544, 1966; as amended P.L. 91-579, P.L. 99-198); the PHS Policy on Humane Care and Use of Laboratory Animal (NIH Guide for Grants and Contracts, Vol. 14, No. 8, June 25, 1985, revised and reprinted 2015); the NIH Guide for the Care and Use of Laboratory Animals (2011); the AAALAC, International Guidelines, and the United States Department of Agriculture (USDA) Implementing Regulations of the Animal Welfare Act (9CFR, Parts 1, 2, 3).

Drexel University is committed to the judicious, humane use of animals in research and teaching. In support of this commitment, the institution obtained and maintains full accreditation by AAALAC, International. In accordance with this commitment, the University adheres to the requirements of all regulatory authorities for the care and use of animals.

1.1 AAALAC, International

AAALAC, International ensures that an animal care program meets the standards as set forth in the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act and other reference resources. On-site accreditation reviews are conducted at least every three years and include inspection of housing and research facilities, review of animal care standards, and evaluation of institutional procedures as they relate to the care and use of animals in research and teaching. Compliance requirements include an annual report detailing any changes in staff, equipment, or programs and an annual usage report for all vertebrate animals, and prompt reporting of adverse events.

1.2 United States Department of Agriculture (USDA)

The Regulatory Enforcement and Animal Care Branch of the Animal and Plant Health Inspections Service (APHIS) of the USDA is responsible for enforcing the regulations established by the Secretary of Agriculture under the mandate of the Animal Welfare Act (AWA). The regulations set standards for humane handling, housing, space, feeding and watering, sanitation

and ventilation, adequate veterinary care, and transportation. Compliance requirements include semi-annual inspections and reports documenting adequate veterinary care and periodic unannounced inspections by APHIS personnel.

1.3 Office of Laboratory Animal Welfare (OLAW)

OLAW is responsible for the general administration and coordination of NIH policy regarding animal use and care. Public Health Service (PHS) awarding units may not make an award for a project involving animals unless the institution submitting the application or proposal has an OLAW approved description of their animal welfare program (referred to as the Animal Welfare Assurance or Assurance for short), and approval by the IACUC is verified by the individual at the institution delegated to have responsibility for the animal welfare program (referred to as the Institutional Official or IO). All records that directly relate to applications, proposals, and proposed changes in research reviewed by the IACUC must be maintained for at least three years after completion of the research and must be accessible to OLAW with reasonable notice.

1.4 Drexel University's Code of Ethics with respect to the care and use of animals is as follows:

1. When live animals are used in research or biological testing, there must be a reasonable expectation that such utilization will contribute to the enhancement of human or animal health, the advancement of knowledge, or the good of society. The relative value of the study is a particularly important consideration in potentially painful experiments where there is an ethical imperative that the benefits of the research clearly outweigh any pain, discomfort, and distress experienced by the animals.

2. It is recognized that in many research protocols there is simply no alternative to the use of live animals. Despite this social imperative for animal experimentation, all investigators have an ethical obligation to explore ways in which animals can be partially or totally replaced by other biological or computational systems. When a research question can be pursued using reasonably available non-animal or in vitro models and still result in sound scientific conclusions, the investigator should choose these alternatives.

3. Selection of an appropriate animal model is an important consideration. It is the investigator's responsibility, therefore, to select the optimal species for a particular project. In addition, the number of animals utilized in a protocol should be minimized consistent with sound scientific and statistical standards. It is also the investigator's responsibility to consider the source of the animal and ensure that all animals used for experimental purposes are lawfully acquired.

4. When animals are used in a research project, the investigator has an ethical obligation to seek the least painful techniques feasible that will allow the protocol objective(s) to be achieved. If a procedure has associated pain, discomfort, or distress, it is imperative that the investigator estimates the probable occurrence, magnitude, and duration of the pain, discomfort, or distress, and adequately plan for its relief.

5. In potentially painful procedures, the investigator must take all necessary steps to assess and monitor pain as well as discomfort and distress. In assessing pain, the investigator should use behavioral signs based on the normal behavior pattern of the species under study. In some circumstances, physiological parameters may be used (e.g., plasma cortisol, catecholamines, white blood cell counts, and cardiovascular parameters).

6. The use of humane endpoints, the point at which pain and distress in an experimental animal is prevented, terminated, or relieved, must be developed for experiments that may result in pain and distress to the research animals. The humane endpoint should be relevant, reliable, and scientifically sound, and provide an alternative to experimental endpoints that result in unrelieved or severe animal pain and distress, including death. The identification of humane endpoints is often challenging, and should involve the investigator, the veterinarian, and the IACUC, and should be defined before the start of the study.

7. If a procedure will cause more than slight momentary pain or distress to the animal, the pain must be minimized both in intensity and duration through the administration of appropriate anesthetics, analgesics, and tranquilizers consistent with acceptable standards of veterinary medicine. It should be emphasized that the requirement for the alleviation/reduction of pain applies not only at the time the procedure is being conducted but also following the procedure until such time when the pain is at an acceptable tolerance level without intervention.

8. In no case should experiments be conducted on an awake animal while under the influence of a paralytic or curarizing drug without the concomitant use of an appropriate anesthetic and appropriate monitoring methods.

9. It is recognized that in certain research protocols the administration of appropriate anesthetics and/or analgesics will compromise the scientific validity of the experiment. Such experiments must be justifiable in terms of scientific design and value, and not administering these drugs should be based on referenceable scientific fact or experimental data and not intuition. In addition, pain, discomfort, and distress levels should be carefully monitored. The investigator must limit the pain to which an experimental animal may be exposed by choosing the earliest possible endpoint at which pain and discomfort are abated. An animal that is observed to be in severe pain that cannot be alleviated or reduced to an acceptable tolerance level should be immediately euthanized.

10. No animal should be subjected to multiple survival surgeries, except when they are interrelated and essential to the primary research objective.

11. Prolonged physical restraint procedures should be used on awake animals only after alternative procedures have been considered and found to be inadequate. When restraint is utilized, the animal should be trained or conditioned to the restraining device, using positive reinforcement before beginning of the experiment. The restraining device should provide the least amount of restraint consistent with the maximum security and comfort of the animal. In

addition, the restraining device should provide the animal with the greatest possible opportunity to assume its normal postural adjustments and observations should be made at appropriate intervals. The period of restraint should be the minimum required to accomplish the research objectives. Refer to ACU-215 Physical Restraint Procedures.

12. It is the responsibility of the investigator to ensure that adequate post-surgical/procedural care is provided to all animals. This care must meet acceptable standards in veterinary medicine and be provided as long as necessary, including evenings, nights, weekends, and holidays. The provision of this care must be documented.

13. Euthanasia is the act of inducing painless death. The proposed method of euthanasia must be consistent with recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia.

14. Procedures involving the use of animals should be performed by or under the immediate supervision of an individual with the appropriate qualifications and experience relative to the procedures being performed.

2. IACUC MEMBERSHIP

The IACUC is composed of at least ten members. At least one voting member shall be a veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the University. At least one member will be a non-scientist and at least one member will be a scientist working with animals. At least one member of the committee must have no affiliation with Drexel University. To have a well-balanced, effective committee, it is highly recommended that the committee have at least one biostatistician and one ethicist serving as voting members. No department may have more than 3 members on the IACUC. The president of the University has delegated the authority to appoint members to the IACUC to the Senior Vice Provost for Research. Members are appointed for a specified term, normally four years, subject to periodic review and renewal. When a new president of the University is hired, IO responsibilities will be re-delegated in writing. IACUC Appointments may be renewed at the end of a four-year term. Members may be removed from the IACUC by the Institutional Official (IO)for inadequate participation (e.g., poor attendance) or other reasons as specified in the University Faculty By-Laws. In the event of a change in president or IO, the IACUC does not require reappointment by the new president or IO, unless that individual specifically wants to make some changes in the Committee's membership.

2.1 IACUC Member Conflict of Interest

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. (Animal Welfare Act, Public Law 89-544, 7 U.S.C. § 2131 et seq). When an IACUC member has a conflict of interest, the member should notify the IACUC Chair and/or the

IACUC Office and recuse themselves from the IACUC review and approval of an activity or inspection of an area.

2.1.1 IACUC Chair Absence or Conflict

A Scientific Member who is currently appointed to the committee will serve as the acting IACUC Chair if the Chair is absent or has a real or perceived conflict of interest. That member, referred to as "designated chair" within this document, will maintain the same qualifications, authority, and duties as the IACUC Chair. The designated chair is temporary for the sole purpose of continuity of committee business. The designated chair selected to review amendments and related business will primarily be determined by the attending vet; designated chairs selected for all other purposes will primarily be determined by the Director of Animal Welfare. However, there may be instances when the attending vet and Director of Animal Welfare need to select designated chairs in place of the other.

3. IACUC Procedures

The IACUC has developed a number of procedures which are required to be followed to ensure compliance with institutional and federal requirements for the use of animals in research. Review of these procedures will facilitate writing of IACUC protocols. These procedures are reviewed by the IACUC at least every three years. These documents can be found on the Office of Research and Innovation website.

4. IACUC Meetings

The IACUC generally meets once a month, usually on the second Wednesday of the month. Principal Investigators or their representatives may attend the meeting at which their protocol is being reviewed. If an investigator wishes to attend, they should contact the IACUC Administrator prior to the meeting. Investigators may not be present during the IACUC discussion and vote on the protocol. The IACUC Administrator will provide a calendar of scheduled meetings for the academic year and will notify a Principal Investigator when the protocol will be reviewed. The calendar of scheduled meetings will also list the dates for the submission of protocols for committee pre-review and full committee review.

5. Standard Protocol Review Process

All research or teaching involving the care and use of live vertebrate animals must be approved by the IACUC. The Principal Investigator should refer to the Deadlines for Submissions for submission timelines. The standard process for submitting a protocol to the IACUC is as follows:

1. Principal Investigator submits application material to the IACUC.
2. Primary and secondary reviewers and the veterinarian conduct a pre-review of the application.
3. Principal investigator receives pre-review comments from the primary reviewer.
4. Principal investigator revises application and submits it to the IACUC.
5. The IACUC reviews protocol at the next convened meeting.

The IACUC may approve, require modifications to secure approval, or withhold approval. The specific elements of this process are described in greater detail in the following sections.

5.1 Application Submission

Refer to ORI 002: Procedures for Principal Investigator Eligibility and Responsibilities for PI eligibility requirements and responsibilities. In addition, federal law requires that all individuals who use animals in research or teaching must have the appropriate qualifications. To this end, all individuals named on the application form must receive general and species-specific training prior to the approval of the application by the IACUC. (A Principal Investigator who does not handle animals is not required to take species-specific training.) Documentation of this training (i.e., certification) must be provided as an attachment to the IACUC application. A description of the training program offered by the institution is provided elsewhere in this document.

The IACUC application consists of the following essential elements:

1. IACUC Application Form
2. The technical portion of the proposal or contract, if applicable, that describes the proposed use of the animals

If applicable, the following additional materials must be submitted to the appropriate committee:

3. Institutional Biosafety Committee Application
4. University Radiation Safety Application

If the protocol for the use of animals in research or teaching involves biohazardous or radioactive materials, the appropriate University committees must review and approve this use (based on information provided in the forms listed above) prior to the IACUC granting final approval of the animal protocol. Therefore, it is important that these forms be submitted to the Office of Research and Innovation, Regulatory Compliance unit at the same time that the IACUC application is submitted.

All application materials must be submitted electronically to the IACUC Office with enough time to allow for pre-review and full committee review. Applications that are not submitted by the deadline in the Deadlines for Submission calendar will be held for the next meeting review cycle.

5.2 Pre-Review Process

In order to facilitate the approval of protocols at IACUC meetings, a pre-review process has been developed. This is intended to identify and solve as many potential problems as possible before the full committee meeting, and thus to facilitate the approval process. The pre-review process does not ensure that all questions relating to a protocol will be asked prior to full committee review. The full committee may raise other issues, concerns, or questions.

For each protocol, the IACUC Chair or designated chair assigns a panel of at least three pre-reviewers: a primary and secondary reviewer and a veterinarian. Other pre-reviewers such as a non-affiliated member and a statistician may also be assigned. The Director of Animal Welfare will distribute the reviewer assignment and protocols following the deadline submission.

A proper pre-review entails a careful reading of the protocol by all pre-reviewers and a thorough presentation of concerns to the principal investigator prior to the IACUC meeting. The primary reviewer will collate the reviews of the secondary reviewer and the veterinarian. The pre-review is then communicated to the principal investigator electronically. The primary reviewer will be available to answer questions from the principal investigator in a timely way to allow for the principal investigator to revise and resubmit their IACUC application to the IACUC Administrator in time for full review at the next scheduled meeting.

The researcher must then submit the revised protocol to the IACUC Administrator that has incorporated the changes / additions / deletions / clarifications requested by the pre-review panel. The changes must also be described point-by-point in a cover letter. To facilitate communication, the cover letter should include the original text of the pre-review and a specific explanation of how each point was addressed. Letters that simplify the response for complicated requests to "Completed" or "Fixed" can lead to further questions in the meeting and delay approval. The revised protocol will be forwarded to the full committee for review. If the researcher believes that changes are not necessary, this should also be communicated in a letter to the IACUC with appropriate reasoning.

5.3 IACUC Review and Review Actions

Full Committee Review

The IACUC generally meets on the second Wednesday of each month. Each new protocol reviewed at the IACUC meeting will normally have already been through the pre-review process as described above. Amendments and procedures will normally have been reviewed by the chair or designated chair and veterinarian. Principal Investigators or their representatives are welcome to attend the IACUC meeting if they have a protocol on the agenda to answer any questions or concerns of the IACUC, but they may not be present in the meeting during discussion and voting. The primary and secondary reviewers and the veterinarian assigned to the new protocol pre-review application and present their review to the full committee. The full committee will take any one of the following actions by majority vote of a quorum of its members:

Approved as Submitted: This action indicates that the protocol, amendment, or policy has the approval of the committee, and no further revisions or changes are required. The principal investigator will be sent an approval notice within eight working days that includes additional information regarding their responsibility regarding activation and notification of any changes and/or problems with the protocol. New protocols are approved for a three year period beginning on the date of approval.

Require Modifications to Secure Approval: This action indicates that the protocol, amendment, or policy requires revisions or clarifications before it can be approved by the committee. A memo requesting these revisions or clarifications of the proposed experiments will be sent to the investigator within five working days. The investigator must submit a revised protocol with changes highlighted to the IACUC Administrator. It must be resubmitted to the IACUC Administrator within 90 days. If it is not received by the IACUC Administrator within 90 days, the protocol may be administratively withdrawn. Administratively withdrawn applications will need to be resubmitted and the entire review process will be repeated.

In accordance with NIH policy for designated review of protocols requiring modifications, all IACUC members voted unanimously in advance and in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use Designated Member Review when the IACUC, through Full Committee Review, has determined that modification of the protocol is needed to secure approval. If any member opposes the action, Full Committee Review of the revised protocol will be required to secure approval. Additionally, any member of the IACUC may, at any time, request to see the revised protocol and/or request Full Committee Review of the protocol.

In accordance with the preceding paragraph, protocols that require modifications to secure approval can be approved by the IACUC chair or designated chair upon receipt of the revised protocol, amendment, or policy that satisfactorily meets the conditions that were identified. However, the chair or designated chair reserves the right to return the protocol for full committee review, if necessary. The IACUC may also request review of the revision by other committee members. The approval period is for three years.

Withhold Approval: This action indicates that the IACUC has major concerns with the protocol, amendment, or procedure such that it cannot be approved or it requires substantial revision to secure approval. The investigator will be sent a letter within five working days describing the reasons for approval being withheld and outlining the necessary revisions for reconsideration by the IACUC. The pre-review panel will confer with the investigator to review committee concerns and issues. A revised copy of the protocol must be submitted to IACUC Office for re-review by the full committee. **The changes to the protocol, amendment, or procedure must also be described point-by-point in a cover letter.**

Should the IACUC protocol include hazardous agent committee review, these approvals must be obtained before the IACUC protocol can be approved.

5.4 Designated Member Review

Refer to ACU-004 DMR Procedures

5.5 Amendments

Any proposed modification to an approved protocol must be approved by the IACUC **prior to** implementation. This includes, but is not limited to, changes to procedures, housing requirements, pre- or post-operative care, and euthanasia. Investigators who wish to initiate a change in a protocol must submit an amendment form or addition of personnel form to the IACUC Administrator describing in detail the proposed modifications, justification for the proposed changes, and any effects that the modifications may have on the animal(s). A revised version of the protocol including the changes should be submitted as well.

Administrative amendments that do not involve animal handling or welfare may be approved by the IACUC Administrator. These include:

- Non-substantive changes such as correction of typographical errors and/or grammar
- the addition of trained personnel
- contact information updates

Minor amendments more substantive than those above may be reviewed and approved by the Chair or designated chair. Examples of minor amendments include:

- administration or substitution of another compound in the same class of drug
- minor procedural changes that do not increase pain or distress
- changes in sponsor
- changes in title

The following changes are considered significant that may be approved by the Chair or designated chair

- increases in number of animals if less than 10% of the total originally requested

Significant amendments must either be reviewed by the IACUC as described for protocol review, except they do not undergo the pre-review process, or in a few specific cases, approved by the Veterinarian (see section 5.6). Significant amendments include changes in:

- the objective of the study
- the class of surgery (such as from non-survival to survival)
- procedures that could lead to greater discomfort or greater degree of invasiveness
- the species or approximate number of animals used (if the increase is 10% or more of the originally approved number)
- the Principal Investigator
- an administration or substitution in anesthetic agents, sedation or analgesia that are not consistent with Drexel University procedures, formulary, and attending veterinarian's consultation
- additions or changes in experimental substances
- the withholding of analgesics
- the method of euthanasia (See Section 5.6)
- the duration, frequency, or number of procedures performed on an animal (See Section 5.6)
- a change in housing or use of animals in a location that is not part of the animal program overseen by the IACUC
- a change that impacts personnel safety

The chair or designated chair may decide that an amendment represents significant procedural changes requiring the submission of a new IACUC protocol.

5.6 Veterinary Verification and Consultation

Refer to ACU-008 VVC Procedures

5.7 Renewal

IACUC protocols are approved for a three-year period. To renew a protocol, the principal investigator must submit a new application and follow the standard review process (i.e., pre-review and full IACUC review). To avoid a period when work on the protocol is temporarily

suspended due to an expired approval, this process should be started well in advance of the expiration date of the initial protocol.

6. Exceptions to the Standard Review Process

Certain proposed activities involving the use of vertebrate animals in research or teaching are either exempt from IACUC review or follow a procedure that is different from the standard review process for IACUC applications described above. These situations are as follows:

6.1 Exempt from IACUC Review

Activities that involve using animal tissue or cells obtained from an outside source or a previously approved protocol may be exempt from IACUC review and approval. Nevertheless, the IACUC Administrator requests that the principal investigator submit a brief letter to the IACUC Administrator stating the intended use of the animal tissue or cells, the sponsor of this activity, and the proposed methods for obtaining such material. Also, the principal investigator should keep records of the procurement of all animal tissues and/or cells regardless of source.

6.2 Live Animal Work Conducted at Another Institution and Approved by that Institution's IACUC

If animal work is funded by Drexel or being performed by Drexel personnel at another institution, Drexel's IACUC will obtain a formal written agreement, known as an MOU, with the IACUC at the institution where work will be conducted to establish IACUC oversight. The IACUC should be contacted when animal work is planned to be conducted at another institution to initiate the MOU process. See Section 8: Inter-Institutional Agreements and Collaborations for more details of the MOU process.

7. Termination or Inactivation of Protocol

As noted above, protocols are approved for a maximum of three years. A protocol may be terminated or inactivated by the principal investigator at any time during this approval period by notifying the IACUC with the submission of ACU-402-FORM-Close-out Request Form or ACU-403-FORM-Wildlife Close-out Request Form.

8. Inter-Institutional Agreements and Collaborations

Prior to a Drexel University investigator conducting animal work at a non-Drexel University institution or company, or contract or sub-contact animal work to a collaborator at another institution, a formal written agreement known as a memorandum of understanding (MOU) or a contract must be established. The MOU should address the responsibility for offsite animal care and use, animal ownership, IACUC review and oversight, and ensure compliance with federal regulations.

All institutions and locations where live vertebrate animal work takes place using federally sponsored funds must be covered under a PHS Animal Welfare Assurance. Animal use sites which produce custom antibodies, tissues, or other bodily fluids which are specifically collected for a federally sponsored research project also fall under this mandate.

All institutions and locations which house or perform research with USDA covered species owned by Drexel University must be registered as a research facility with the USDA-APHISAC. All institutions where research occurs with Drexel University owned live animals must be accredited by AAALAC, International.

Protocols approved by an IACUC at another institution, but which will be conducted at Drexel University (e.g., grant transfer) must be reviewed and approved by the Drexel University IACUC before work can begin.

9. Process for Responding to Animal Welfare Concerns and Protocol Noncompliance

Refer to ACU-012 Investigating Animal Welfare Concern and Non-compliance Activities

10. IACUC Protocol Approval for Granting Agencies

For all federally funded grant proposals, the information contained on the IACUC application form **must reflect accurately the animal welfare sections of the grant proposal.** Part of the IACUC review consists of comparing the IACUC application and the relevant sections from the proposal for congruency. If IACUC approval is post-grant submission, the IACUC protocol must be approved and submitted "just in time."

11. Animal Use Training and Certification Program

11.1 Personnel Training and Certification Requirements

The Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals, and the PHS policy require institutions to ensure that people caring for or using animals in research are qualified to do so. All persons planning to use animals in their research or teaching protocols must complete the Drexel University general and species-specific certification program before IACUC approval to conduct activities involving the use of animals will be granted. Occupational health certification is also required (see Section 17). General training in the appropriate care and use of laboratory animals and occupational health and safety is provided though the Collaborative Institutional Training Initiative (CITI) online training. Species-specific training is accomplished by way of species-specific CITI on-line training modules and demonstration of proficiency of certain basic technical skills to the Animal Welfare Education Specialist. Research specific training is the responsibility of the PI. The program relies on experienced certified people teaching and testing others. CITI training modules are available on-line and may be viewed at the individual's convenience. Arrangements for hands-on certification can be made by completing the training request form and contacting the Animal Welfare Education Specialist. The Office of Research and Innovation web site has further information on CITI module access and how to schedule species-specific hands-on training. https://drexel.edu/research/compliance/animal-care-use/training-requirements/

11.2 Visiting Researcher Policy

A visiting researcher is a non-Drexel affiliated employee or student granted temporary, escorted animal laboratory and facility access for scientific collaboration or training.

1. If the visiting researcher will not perform work directly with live animals:
    - The visitor must review and complete the Animal Facility Requirements for Non-Employees form. The form should be maintained by the PI.
2. If the visiting researcher will perform live animal work and requires access to the animal facility and laboratories for 30 consecutive days or less:
    - An amendment to add personnel must be completed to add this person to the protocol.
    - Appropriate documentation of the visitor's certification of occupational health and animal handling and use training from the home institution must be submitted to the within the amendment (appropriate documentation may be determined by the IACUC chair, Attending Veterinarian and IACUC Administrator)
3. If the visiting researcher will perform live animal work and require access to the facility and laboratories for more than 31 consecutive days:
    - An amendment to add personnel must be completed to add this person to the protocol.
    - The visitor must satisfy the training requirements laid forth in Section 11.1.

12. Transfer of Animals

It is common for principal investigators to request transfer of animals from one protocol to another (including from breeding protocols), between investigators, or between institutions. All transfer of animals requires approval by ULAR, as assigned by the IACUC. Transfer of animals from one protocol to another or to another institution requires approval each time an animal is transferred. However, transfer of animals from a breeding protocol can be accomplished as a one-time transfer.

For transfer of animals from one protocol to another, between investigators, or between institutions, please use the appropriate animal transfer form. The form must include the exact number of animals to be transferred and the protocol numbers to ensure proper record keeping by the University Laboratory Animal Resource (ULAR). These forms also request information on whether the animals transferred had any procedure or surgery performed in the original study at Drexel University or at any other institution and, if so, justification for the transfer of second use animals.

An investigator receiving animals from another institution must comply with all federal, state, local, and Drexel University regulations or policies. Approval from the Drexel veterinarian to import these animals must be obtained. If a Drexel investigator is releasing animals to another institution, the Drexel University ULAR will contact the receiving institution's veterinarian or research animal facility to ensure that they are ready to accept them and will then arrange for transfer of the animals. Once the transfer is approved by ULAR, the number of animals involved are appropriately added to or subtracted from the protocols. ULAR will arrange transfer, transportation and the Drexel veterinarian will determine the necessity and length of quarantine required before the animals may enter the Drexel animal facilities.

13. Post-Approval Monitoring

Post-approval monitoring of animal research involves a variety of mechanisms outlined below.

Under PHS and AWR regulations, at least every six months, the IACUC must inspect all institutional animal housing facilities including satellite housing rooms, and areas where animals are used. These inspections provide an ongoing mechanism for ensuring that the institution maintains compliance with the applicable animal care and use policies, guidelines, and laws. The inspections focus on the following areas: 1) physical plant condition including functional space, facilities for sanitizing cages, general features of animal housing rooms, composition of floors, walls, and ceilings, lighting, heating, ventilation, and noise control, 2) laboratory animal facilities including social environment, enrichment, bedding, water, food sanitation, waste disposal, animal identification, and 3) individual laboratories including the physical appearance of the work area, sanitation, use of sterile procedures, storage of anesthetic agents and drugs, record keeping, equipment used for surgery and euthanasia procedures. Inspection subcommittees must have at least two IACUC members as required by USDA regulation; however, no IACUC member will be excluded if they want to attend a particular inspection. The semiannual program review is conducted by a subcommittee of at least 2 members the IACUC using a form obtained from the NIH web site following the format of the Guide. No IACUC member will be excluded from participation in the semiannual program review. Based on the findings from the inspections and program review, a report is prepared listing minor and significant deficiencies and a timetable and plan for the correction of all deficiencies. The report will be reviewed by a quorum of the IACUC and signed by a majority of the quorum present. Minority views will be included in the report. The principal investigator is informed in writing of any deficiency observed by the IACUC inspections subcommittee in their area and asked for a report on action taken or planned within 15 days. IACUC will send a report to the Institutional Official describing deficiencies identified during the inspection and program review. Any significant deficiency involving USDA covered species that are not corrected within the time required by the IACUC will be reported to the USDA.

Drexel University employs a full time Animal Welfare Education Specialist to oversee post approval compliance. The Animal Welfare Education Specialist confirms compliance through the Post Approval Monitoring (PAM) program which consists of both observation and document review. Protocols are selected for review based on animal welfare risk factors. The PAM process is positioned to convey IACUC procedures on matters of animal care and use, identify opportunities for improvement and make recommendations on how to achieve improvement. Ultimately, the PAM process confirms that the manner in which animal procedures are performed and conducted is consistent with the IACUC approved. Please see ACU-502 Post Approval Monitoring Procedures for more information.

The animal caretakers monitor the animals at least once per day (at least twice per day for large animal species). The veterinary staff observes the care and use of animals during weekly rounds, clinical case monitoring, during follow-up checks, laboratory visits, and when assisting the investigators in their research. The research staff should report any animal welfare issues that they may observe. The Department of Environmental Health and Radiation Safety inspects all

laboratories and animal facilities on a semiannual basis. Any animal care and use concerns noted through these mechanisms are reported to the IACUC for investigation.

14. Reporting Requirements

The Institution must report at least annually to the USDA that the provisions of the Animal Welfare Act (AWA) are being followed and that professionally acceptable standards governing the care, treatment and use of animals are being followed by the University during research and teaching. In these annual reports, the University provides information on the species and number of animals per species involved in IACUC approved activities. Also included are the number of animals involved in activities likely to produce pain or distress. The University provides assurance it is adhering to the standards as described in the AWA. Any deviations from the standards as described in the AWA must be reported and fully explained.

The IACUC must, through the Institutional Official, make an annual report to OLAW on: 1) any change in the program or facilities that would place the institution in a different category from that stated in the assurance; 2) any changes in the program for animal care and use or IACUC membership; and 3) the dates that the IACUC conducted its semiannual evaluations of the facilities and submitted said report to the Institutional Official.

If the IACUC suspends or terminates a protocol sponsored by PHS funds, the Institutional Official must report this action with full explanation to the Office of Laboratory Welfare (OLAW). Suspension or termination of a protocol approved for use of USDA species must be reported to the USDA.

The attending veterinarian, who is the AAALAC, International Unit contact, submits the Accredited Unit Annual report and significant animal welfare issues on a timely basis. Any deficiencies reported to OLAW or USDA are also copied to the AAALAC, International office.

15. IACUC Forms

IACUC Protocol Forms, Amendment Forms, Animal Order Forms: https://dragonspot.drexel.edu/

Other Forms and Templates: Animal Care and Use Procedures | Office of Research & Innovation | Drexel University

16. Animal Welfare Assurance

The Animal Welfare Assurance is available from the IACUC Office.

17. Occupational Safety Program

17.1 Animal Users

The IACUC, Attending Veterinarian, Institutional Official, safety officers, and occupational health physician from Concentra are involved in the planning, oversight and operation of the institutional occupational health and safety program.

Medical care is provided by Concentra and is administered by the Department of Environmental Health and Radiation Safety. Employee health records, and vaccination and allergy histories,

along with pre-assignment medical evaluations are maintained by the medical group. Risk assessment, based on species worked with and individual health conditions, is used to determine the need for vaccinations and other preventive practices. The occupational medical specialist will provide certification that personnel are approved to work with animals. This certification must be obtained annually and whenever there is a change in the health of personnel or change in species of animals worked with.

Certification of personnel by Occupational Health is required prior to access to the animal facility and before personnel can work with animals. IACUC protocols and personnel amendments must include annual health certifications approving personnel to work with animals prior to approval by the committee.

17.2 Laboratory Personnel Who Do Not Directly Interact with Animals But Work Within Shared Laboratories Where Animal Work is Conducted

A risk assessment was performed to identify and evaluate any potential health risks to laboratory personnel who do not directly interact with animals but work within shared laboratories where small rodent (e.g. mouse, rat) work is conducted. A shared laboratory refers to a laboratory space that is used by multiple individuals or groups for different purposes, The spaces included in the risk assessment are used by both **animal users** (researchers working with animals) and **non-animal users** (researchers using other methods or materials).

The assessment identified that the small rodents that enter the shared laboratories were housed in cages with microisolator tops and were only removed from cages for surgery or short-term procedures or behavioral testing. In addition, the laboratory air exchanges were sufficient to minimize exposure to animal allergens.

The risk assessment verified that the health risks were minimal when the following is performed in a shared laboratory space. Laboratory personnel who do not directly interact with small rodents do not require the medical clearance component of the occupational health program.

- Health checks
- Surgeries
- Recovery from surgery in cages with microisolator lids
- Injections/euthanasia/perfusions/other activities under a hood
- Administration of compounds
- Satellite housing in cages with microisolator tops
- Behavior studies with limited time spent in open spaces and not in close proximity to non-animal users or performed in a separate room within a shared lab space.

All laboratory personnel should be informed of the risks associated with working near small rodents. If health concerns arise or laboratory personnel exhibit symptoms related to allergens, those laboratory personnel should report these issues to the appropriate laboratory manager for potential further evaluation.

The health risks associated with the use of larger mammals or their body parts (e.g. pigs, rabbits, sheep) in shared laboratories should be assessed on a case-by-case basis. Please contact EHRS to conduct a risk assessment.

Behavioral studies for any animal that requires the animal to be out of the cage and active within a shared laboratory space in close proximity to non-animal users should be assessed on a case-by-case basis. Please contact EHRS to conduct a risk assessment.

Website: http://drexel.edu/research/compliance/animal-care-use/training-requirements/#

18. Responsibilities

18.1 Principal Investigator's Responsibilities

Principal investigators involved in projects with laboratory animals are responsible for:

- ensuring that research projects are conducted as approved by the IACUC by trained personnel and notifying the IACUC in writing of any changes to the protocol, then waiting for IACUC approval before instituting those changes;
- overseeing and communicating with their staff about their responsibilities concerning institutional procedures to implement a research project as approved by the IACUC; and
- abiding by the provisions of the Guide for the Care and Use of Laboratory Animals, all federal, state and local laws and regulations, and any institutional policies regarding the use of animals in teaching and research.

18.2 Veterinary Care and Veterinarian's Responsibilities

Veterinary medical care is an essential part of an animal care and use program. Therefore, Drexel University has made a commitment to provide adequate veterinary care including access to all animals for evaluation of their health and well-being. The Executive Director of Veterinary Services serves as the Attending Veterinarian for Drexel University. A contract is in place with a backup veterinarian to provide veterinary care and oversight during the absence of the Attending Veterinarian. In order to provide adequate veterinary care, the institution follows the guidelines provided in the 2011 edition of the Guide for Care and Use of Laboratory Animals compiled by the Institute of Laboratory Animal Resources Commission on Life Sciences, National Research Council. The effective program will include, but not be limited to providing:

- Preventive Medicine
- Surveillance, diagnosis, treatment, and control of disease, including zoonosis control
- Management of protocol-associated disease, disability, or other sequelae
- Anesthesia and Analgesia
- Surgery and post-surgical care
- Assessment of animal well-being
- Euthanasia

The veterinarian's responsibilities must include but are not limited to involvement in planning or providing consultation to the investigators as set forth in 9 CFR part 1, section 2.31, 8d iv B for procedures that may cause more than momentary or slight pain or distress to the animals. The investigator and the veterinarian share responsibility for ensuring that post-surgical care is appropriate. Therefore, the veterinarians must review all protocols involving surgery.

The veterinarian has the right to stop work, treat, or euthanize any animal on any protocol in which a deficiency in animal care and treatment that threatens the quality of life or health of an animal has been identified or observed. When the work is stopped on any protocol for veterinary reasons, the veterinarian will immediately submit a written report to the Chair of IACUC describing the nature of the problem with appropriate recommendations for corrective measures to ensure proper use and treatment of animals in research or teaching protocols. The Chair of the IACUC will present these findings to the full IACUC to evaluate the nature of the problem/concerns as reported. The committee may take further action, including suspension of the protocol, as described above (Section 9).

18.3 Director of Animal Welfare

The role of the Director of Animal Welfare is to ensure the effective functioning of the IACUC and to aid the Institutional Official in the responsibility of overseeing the animal welfare program. The Director of Animal Welfare is responsible for providing information and continuing education regarding current regulations and guidelines issued by the Department of Health and Human Services, the US Department of Agriculture, and other applicable federal, state, and local agencies. The Director of Animal Welfare is charged with negotiating the required Assurance with the Office of Laboratory Animal Welfare/Office of Extramural Research at the National Institutes of Health to protect the welfare of animals involved in research or teaching conducted by Drexel University The Director of Animal Welfare will also participate in the preparation for site visits and the accreditation process of the AAALAC, International. All documents associated with the IACUC, i.e., minutes, protocols, committee membership and correspondence are maintained by the Director of Animal Welfare.

The Director of Animal Welfare's role is to coordinate the processing of research or teaching protocols involving the care and use of animals throughout the review process including the initial, renewal and modification reviews in accordance with federal regulations and institutional procedure. The Director of Animal Welfare is available to answer questions about institutional procedures, the calendar of scheduled meetings and the status of a current protocol. The Director of Animal Welfare prepares all minutes of IACUC meetings and prepares all correspondence to investigators regarding their protocols.

18.4 University Laboratory Animal Resources

http://drexel.edu/research/compliance/animal-care-use/Laboratory-Animal-Resources/

The Associate Director, ULAR is responsible for the overall operation of all University Laboratory Animal Resources operations including feed and bedding orders, unresolved animal care issues, and facility emergencies. The animal care technicians observe each animal at least

daily including weekends for signs of illness, injury, or abnormal behavior, and to ensure animals have access to food and water.

Veterinary technical assistance for research studies is available on a limited basis. Assistance can be arranged with the veterinary technician either directly or through the attending veterinarian(s).

ULAR is responsible for animal orders and other related charges. To place an animal order:

- Obtain IACUC approval
- All animal requests are submitted through DragonSPOT following instructions found here: Drexel University DragonSPOT Animal Ordering User Manual
- Animal orders must be received by noon on the Tuesday preceding the week the animals are to arrive. Please allow more time if you anticipate any problems in having the order filled.

The attending veterinarian and veterinary technician are available for all campuses to observe animals and treat any health problems, give advice on anesthesia/analgesia, and be available for medical emergencies.

Emergency contact information, including weekend, after-hours, and holiday contact information, for the Facility managers, veterinary technicians and the Attending Veterinarian are posted in all animal facilities.

19. Resources

- University Laboratory Animal Resources (ULAR)
- IACUC Procedures and Forms
- IACUC Training Requirements
- PHS Policy on Humane Care and Use of Laboratory Animals
- A Word from OLAW and USDA. New CEO, new IACUC?

20. Revisions

Edition 001/Effective Date: 04/2019
Edition 002/Revision Date: 9/11/2024 Effective Date: 9/17/2024 – Revised Document.

- Updated formatting to new template.
- Section 1.4.11- Reference to ACU-215 Physical Restraint Procedures
- Section 2 - Addition of guidance for new president IO designation
- Section 5.1 - Reference to ORI 002: Procedures for Principal Investigator Eligibility and Responsibilities
- Section 5.4 - Reference to ACU-004 DMR Procedures
- Section 5.6 - Reference to ACU-008 VVC Procedures
- Removal of Continuing Review Procedures
- Section 6.2 - Procedures added
- Section 7 - Reference to close out forms

- Section 9 - Reference to ACU-012 Investigating Animal Welfare Concern and Non-compliance Activities
- Section 13 - Reference to ACU-502 Post Approval Monitoring Procedures
- Section 15 - Form links updated
- Section 17 - Occupational Safety Program provider changed to Concentra
- Section 18.4 - Changed Animal Order procedures

Edition 003/Revision Date: 2/12/2025 Effective Date: 02/12/2025 – Revised Document.

- Section 17.2 - Addition of Laboratory Personnel Who Do Not Directly Interact with Animals But Work Within Shared Laboratories Where Small Rodent Work is Conducted Risk Assessment and Guidance

Edition 004/Revision Date: 8/13/2025 Effective Date: 8/18/2025 – Revised Document.

- Section 2 – Addition of a conflict of interest statement
- Section 2 – Addition of the responsibilities and assignment of the designated chair role.