# DREXEL

# UNIVERSITY

# INSTITUTIONAL

# ANIMAL CARE AND

# USE COMMITTEE

# (IACUC)

# POLICIES AND PROCEDURES MANUAL

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## I. Preface/Code of Ethics

Proper care, use, and humane treatment of animals used in research, testing and education require 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 safeguarding the 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 guidelines for the subsequent conduct of those protocols. This document, which serve 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 September 1986); 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.

### A. 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 and the Animal Welfare Act. 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 policies 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, and programs and an annual usage report for all vertebrate animals.

### B. 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.

C. 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 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.

D. 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 potentially painful 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 a state of 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 prior to the 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. Awake animals should not be subjected to prolonged physical restraint.

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.

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. If an animal will not be subjected to euthanasia at completion of a research protocol, it is the responsibility of the investigator to ensure that the final disposition of the animal is both humane and acceptable.

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.

## II. IACUC Membership

The IACUC membership 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 biostatician 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. Appointments may be renewed at the end of a four-year term. Members may be removed

from the IACUC by the Senior Vice Provost for Research for inadequate participation (e.g., poor attendance) or other reasons as specified in the University Faculty By-Laws.

## III. IACUC Policies and Guidelines

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

## IV. 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 list the dates for the submission of protocols for committee pre-review and full-review.

## V. 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.
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, requires modifications to secure approval, or withholds approval. The specific elements of this process are described in greater detail in the following sections.

### A. Application Submission

Only Drexel University faculty (instructor or above), are permitted to submit applications for the use of animals in research or teaching to the IACUC. Post-doctoral fellows, residents, and visiting faculty may submit applications to use

animals in research or teaching under the sponsorship of a member of the faculty of Drexel University. 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 that does not handle animals is not required to take species specific training.) Documentation of this training (i.e., certification) must be on file in the IACUC Administrator. A description of the training program offered by the institution is described 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 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, Regulatory Compliance unit at the same time that the IACUC application is submitted.

All application material must be submitted electronically to the IACUC Administrator 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.

B. 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 assure 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 Chair of the IACUC 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 IACUC Administrator will contact the pre-reviewers for each protocol to alert those individuals to the coming protocols and to verify their availability.

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 his or her 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. 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.

C. 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 gone through the pre-review process as described above. Amendments and policies will normally have been reviewed by the 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 who were assigned to the new protocol pre-review the application present their review of the revised application 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 his or her responsibility in regard to activation, continuing review and notification of any changes and/or problems with the protocol. New protocols are approved for a three year periodic beginning on the date of approval.

Require Modifications to Secure Approval: This action indicates that the protocol, amendment, or policy requires minor revisions or clarifications before it can be approved by the committee. A memo requesting these revisions or clarifications in 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 upon receipt of the revised protocol, amendment, or policy that satisfactorily meets the conditions that were identified. However, the 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 problems with the protocol, amendment, or policy 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 the IACUC Administrator within 90 days for re-review by the full committee. **The changes to the protocol, amendment, or policy must also be described point-by-point in a cover letter.**

**Designated Member Review**

In keeping with the federal regulations and in an effort to efficiently manage the IACUC workload and to provide timely turnaround for investigators, the IACUC has developed a process to facilitate the review of certain protocols and changes to approved protocols, or IACUC policies. This method of review is referred to as the Designated Member Review (DMR). This process involves submitting the full application package or significant amendment as described above to the IACUC Administrator. The attending veterinarian, IACUC chair, and IACUC administrator will confirm the submission is appropriate for DMR. Prior to the review, the IACUC Administrator will distribute the submission to all IACUC members. Any member of the IACUC may request that the proposed submission be reviewed by the full

committee. If Full Committee Review (FCR) is requested by any individual member of the IACUC 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.

If, after 2 business days, FCR is not requested by any member, the Chair of the IACUC will select a minimum of two reviewers and the veterinary member to evaluate new submission applications, a minimum of one reviewer and the veterinary member to evaluate significant amendments, and a minimum of two reviewers to evaluate new or revised policies. If reviewers agree that no comments or revisions are necessary, the protocol may be approved by the reviewers. If the protocol is not approved unanimously, the reviewers may call the protocol for FCR or may require modifications in order to secure approval. All reviewers must review identical versions of the protocol and if modifications are requested by any one of the reviewers then all reviewers must be aware of and agree to the modifications. Requests for modifications will be compiled and submitted back to the PI within 5 business days and a copy of the modification requests should be provided to the IACUC administrator. The investigator shall, upon completion of the requested modifications, submit the revised protocol or amendment to the IACUC administrator who will disseminate it to the designated reviewers. This process is repeated until all reviewers unanimously agree that the protocol can be approved. If agreement cannot be reached between all reviewers, the submission will be reviewed through FCR.

D. 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 additional 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).

Administrative amendments may be handled administratively without IACUC-approved policies, consultations, or notifications and include:

- the addition of trained personnel
- correction of typographical errors
- correction of grammar
- contact information updates

Minor amendments may be reviewed and approved by the 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

- increases in number of animals if less than 10% of the total originally requested.
- changes in sponsor
- changes in title

Significant amendments must be reviewed by the IACUC as described for protocol review, except that they do not undergo the pre-review process. 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
- anesthetic agents or the withholding of analgesics
- the method of euthanasia
- the duration, frequency or number of procedures performed on an animal

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

E. Veterinary Verification and Consultation

The Drexel University Attending Veterinarian may administratively approve certain significant changes without review by full committee or designated member review. Any change approved through Veterinary Verification and Consultation (VVC) must be preapproved by the IACUC and adhere to established policies. The changes must also be consistent with the following:

- Changes in anesthesia, analgesia, or sedation to drugs and species based dosages as described in the ULAR "Drug Formulary of Anesthetic and Analgesic Agents for Laboratory Animals"
- Changes to euthanasia to any method acceptable or acceptable with conditions approved in the current AVMA Guidelines for the Euthanasia of Animals if those conditions and appropriate training requirements have been met.
- Changes in duration, frequency, type, or number of procedures performed on an animal which adhere to established policies reviewed and approved by the IACUC. Significant changes regarding the duration, frequency, type, and number of procedures performed must not be new procedures that are added to the protocol. All new procedures must have IACUC approval through the FCR or DMR method.

F. Continuing Review

Federal regulations and University policy require that all activities involving the care and use of animals be reviewed at least annually. To this end, each principal investigator of an approved IACUC protocol must complete a Periodic Report Form each year prior to the anniversary date of the initial IACUC approval. The Periodic

Report Form solicits information which includes any changes to the protocol which had not been approved by the IACUC, any complications or pre-mature deaths associated with the protocol, the training and occupational health status of personnel, breeding colony information, and the active status of the protocol. Additionally, protocols which involve the use of USDA covered species or Wildlife research must also include the number of animals used in the previous year.

The IACUC Administrator will send the Periodic Report Form to each principal investigator two months prior to the anniversary date and, if necessary, a second notice will be sent one month prior to the anniversary date. If **the completed form is not returned to the IACUC Administrator by the anniversary date may result in a delay in the processing and arrival of animal orders and approval of any requested changes (amendments, animal transfers, personnel additions) to the protocol and/or suspension of the protocol.**

The Periodic Report Form is reviewed by a committee appointed member, typically the IACUC Administrator, by the Designated Member Review process. If there are no problems, the protocol may remain active for another year. If problems are observed or suggested, the designated member may refer the periodic report form to full committee. All periodic reports are provided to all IACUC members, and any may request Full Committee Review. The Designated Member Review procedures are detailed in Section VI.B. infra. Further investigation by the IACUC may be necessary and suspension or termination of the protocol may be required. The investigator will be notified in writing regarding the outcome of the IACUC review of the Periodic Report Form.

G. Renewal

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

## VI. Exceptions to the Standard Review Process

Certain proposed activities involving the use of 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:

A. 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.

B. Live Animal Work Approved by Another Institution's IACUC

## VII. 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 in writing or, as part of the continuing review process, by completing the appropriate section of the periodic report form. A protocol may also be administratively inactivated by the IACUC if the principal investigator fails to submit the Periodic Report Form as required by the annual continuing review process.

## VIII. 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 vertebrae 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-APHIS-AC.

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.

## IX. Process for Responding to Animal Welfare Concerns and Protocol Noncompliance

Any allegation concerning the misuse of animals or noncompliance of an approved protocol in research or teaching and improperly implementing an approved protocol or any allegation of misuse of animals or noncompliance with an approved protocol (or any other concern regarding activities involving animals) will be brought to the attention of the full Drexel University IACUC for its consideration.

The allegation of misuse of animals or noncompliance with an approved protocol may be expressed either orally or in writing and will be kept confidential to the extent possible.

There may be no reprisal against the reporting individual. It is the responsibility of the IACUC to determine whether there is sufficient reason for further investigation. If so, the Chair (or acting Chair if the allegation is against the Chair) will appoint a sub-committee of the IACUC consisting of no less than three members to evaluate the concern. As part of the investigation, the IACUC may also request that the Animal Welfare Analyst investigate and provide a report. The IACUC may also decide to suspend the protocol pending the outcome of the sub-committee's action.

The Institutional Official, the sub-committee members, and the respondent will be notified in writing of the nature of the complaint, the composition of the sub-committee, and a general description of the process. This process will usually consist of interviewing the complainant, the respondent, and other individuals as needed, and reviewing all pertinent records. At any point in the process, the veterinarian or sub-committee may stop work on the protocol, pending further investigation, if there are significant concerns about the welfare of animals.

Following the investigation, the sub-committee will report its findings at a meeting of the IACUC. The IACUC may then decide that 1) the allegation or misuse of animal or noncompliance of an approved protocol cannot be substantiated and therefore it is dismissed or 2) the allegation of misuse of animals or noncompliance of an approved protocol is substantiated and a letter indicating this finding will be sent to the investigator, the Institutional Office and the funding agency.

When the allegation or misuse of animals or noncompliance is substantiated, the IACUC may take actions such as, but not limited to, a warning, reprimand, suspension of protocol, or termination of protocol. The IACUC may also suggest remedial actions to prevent the problem for from recurring. If the IACUC suspends or terminates a protocol involving improper use of animals in research or teaching, the Institutional Official, in consultation with the IACUC, shall review the reasons for the suspension or termination, take appropriate corrective action, and report action with a full explanation to the OLAW, USDA, and the funding agency, if applicable. The investigator cannot appeal the IACUC's decision.

## X Principal Investigator's Responsibility

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 and waiting for IACUC approval before instituting any changes;
- overseeing and communicating with their staff about their responsibilities concerning institutional policies and 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.

## XI. 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."

## XII. Animal Use Training and Certification Program

A. 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 full approval for activities involving the use of animals by the IACUC approval can be granted. Occupational health certification is also required (see item XXI) 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 ULAR veterinary staff. 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 contacting the ULAR veterinary technical staff. The Office of Research web site has further information on CITI module access and how to schedule species-specific hands-on training. http://www.research.drexel.edu/compliance/IACUC/info.aspx

B. Visiting Researcher Policy

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

I. 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.

II. If the visiting researcher will perform live animal work and require access to the animal facility and laboratories for 30 consecutive days or less:
   - The visitor must review and complete the Animal Facility Requirements for Non-Employees form.
   - 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 IACUC Administrator (appropriate documentation may be determined the IACUC chair, Attending Veterinarian and IACUC Administrator)

III. 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

- The visitor must satisfy the training requirements in laid forth in Section XII A.

## XIII. 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

If an investigator is receiving animals from another institution, he or she 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 facilities 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 and he Drexel veterinarian will determine the necessity and length of quarantine required before the animals may enter the Drexel animal facilities.

## XIV. 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 ULAR serves as the Attending Veterinarian for Drexel University. A contract is in place with a back up 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 be involved reviewing 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 VIII).

## XV. 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 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 focuses 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 he/she wants 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 his/her area and asked for a report on action taken or planned within 15 days. IACUC will send a report to the Institutional Official describing this inspection and program review. Any significant deficiency involving USDA covered species which are not corrected within the time required by the IACUC will be reported to the USDA.

Drexel University employs a full time Animal Welfare Analyst to oversee post approval compliance. The Animal Welfare Analysts 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 policies 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 under an approved protocol is consistent with what the IACUC approved.

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 investigator staff is also asked to monitor the animal procedures conducted by other labs and report any animal welfare issues that they may observe. The Department of Environmental Health and Safety inspects all laboratories and animal facilities on a semiannual basis. Any animal care and use issues noted by these mechanisms are reported to the IACUC for investigation.

## XVI. 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 semi-annual 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. Any deficiencies reported to OLAW or USDA are also copies to the AAALAC, International office.

## XVII. IACUC Administrator

The role of the IACUC Administrator 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 IACUC Administrator 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 Regulatory Compliance 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 IACUC Administrator 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 IACUC Administrator.

The IACUC Administrator 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 policy. The IACUC Administrator is available to answer questions about institutional procedures, the calendar of scheduled meetings and the status of a current protocol. The Administrator prepares all minutes of IACUC meetings and prepares all correspondence to investigators regarding their protocols.

**XVIII.** 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.

Veterinary technical assistance 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
- Complete an Animal Order Form (available from department office or ULAR website)
- Email the form ular@drexel.edu
- 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 problems in having the order filled.

The attending veterinarian is available for all campuses to observe all animals and treat any health problems, give advice on anesthesia/analgesia, and generally be available at any time for medical emergencies. The attending veterinarian coordinates security access to the animal facilities.

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.

**XIX. IACUC Forms**

Website http://drexel.edu/research/resources/documents-forms/compliance/

**XX. Animal Welfare Assurance**

The Animal Welfare Assurance is available from the IACUC Administrator

## XXI. Occupational Safety Program

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

Medical care is provided by the Drexel University College of Medicine and Worknet and is administered by the Department of Environmental Health and 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.

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

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