

**DREXEL UNIVERSITY**

**AND**

**DREXEL UNIVERSITY COLLEGE OF MEDICINE**

**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 and Drexel University College of Medicine are deeply committed to safeguarding the care, maintenance and use of all vertebrate animals in research, research training, teaching and biological testing activities. The commitment extends to researchers and the IACUC members of their responsibilities, providing training relative to their respective roles and fulfills their duties in accordance with PHS policies, AWA, AWAR, the *Guide* 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 and Drexel University College of Medicine 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. The IACUC Guidelines, which serve as the official governance document for the care and use of live vertebrates at Drexel University and Drexel University College of Medicine, reflect 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 Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) Guidelines, and the USDA Implementing Regulations of the Animal Welfare Act (9CFR, Part 1, 2, 3; January 1, 1992; 1 and 9CFR, Parts 1, 2; July 22, 1993).

Drexel University and Drexel University College of Medicine are committed to the judicious, humane use of animals in research and teaching. In support of this commitment, the institution has obtained and is maintaining full accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC). In accordance with this commitment, the Universities adhere to the policies of all regulatory authorities for the care and use of animals.

- A. Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC)
  - a. AAALAC certifies 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. U.S. Department of Agriculture (USDA)

- a. 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 Security 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 inspection and reports documenting adequate veterinary care and periodic unannounced inspections by APHIS personnel.
- C. Office of Laboratory Animal Welfare (OLAW)
- a. 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 is on the list of institutions that have an Assurance on file with OLAW, and the responsible institutional official has provided verification of approval by the Animal Care Committee. All records that directly relate to applications, proposals, and proposed changes in research reviewed by the Institutional Animal Care and Use Committee (IACUC) must be maintained for at least three years after completion of the research and must be accessible to OLAW with reasonable notice.

Drexel University and Drexel University College of Medicine's Code of Ethics with respect to the care and use of animals is listed below:

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 mathematical/computer 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 alternatives.
3. Selection of an appropriate model is an important consideration, particularly at a time when alternative models for animal research are being emphasized. 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 consistently 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 pursued adequately. 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 in order to adequately plan for the treatment of pain.
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 which 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 momentary slight 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 either alleviated or reduced to an acceptable tolerance level.
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.
9. Research in which painful stimuli are used should be so designed as to provide a means of escape from pain by the animal.
10. 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 the deletion of 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. There is a limitation on the pain to which an experimental animal may be exposed. Investigators should choose the earliest possible endpoint in order to minimize pain and discomfort. 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.

11. No animal should be subjected to multiple survival surgeries, except when they are interrelated and essential to the primary research objective.
12. 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 minimal 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.
13. 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 during non-duty hours.
14. 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.
15. 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 carried out on live animals.

### IACUC Membership

The Institutional Animal Care and Use Committee (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 Universities. 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 or Drexel University College of Medicine. To have a well balanced, effective committee, it is highly recommended that the committee have at least one biostatistician and one ethicist, both of whom serve as voting members. No department may have more than 3 members on the IACUC. Members will be appointed by the Institutional Official for a term of four years subject to annual renewal. Members may be removed from the IACUC by the Provost for inadequate participation (e.g., poor attendance) or other reasons as specified in the University Faculty By-Laws.

#### IV. IACUC Meetings

The IACUC generally meets once a month, usually on the second Wednesdays of the month. Principal Investigators or his/her representative may attend the meeting at which their protocol is being reviewed. If an investigator wishes to attend, they must contact the Office of Regulatory Research Compliance prior to the meeting. Investigators are not present at the time of discussion and voting. The Office of Regulatory Research Compliance will provide a calendar of scheduled meetings for the academic year and will notify a Principal Investigator when his or her protocol is to 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 animals must be approved by the Institutional Animal Care and Use Committee. In submitting applications, the PI should refer to the Deadlines for Submissions to the IACUC for monthly due dates. The standard process for submitting a protocol to the IACUC is as follows:

1. Application materials submitted by principal investigator to IACUC
2. Applications pre-reviewed by primary and secondary reviewers and by a veterinarian.
3. Pre-review comments provided to principal investigator.
4. Principal investigator submits revised application to IACUC.
5. IACUC reviews protocol at the next scheduled meeting.

IACUC approves, requires modifications to secure approval, or withholds approval. The specific elements of this process are described in greater detail below.

##### A. Application Submission

Only Drexel University and Drexel University College of Medicine faculty (instructor or above), post-doctoral fellows, residents, and visiting faculty are permitted to submit applications for the use of animals in research or teaching to the IACUC. However, post-doctoral fellows, residents, and visiting faculty may submit applications to use animals in research or teaching only under the sponsorship of a member of the faculty of Drexel University and Drexel University College of Medicine. 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 (if the PI is not handling animals, species specific training is not required). Documentation of this training (i.e., certification) must be on file in the Office of Regulatory Research Compliance. 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. Project Submission Transmittal Form
2. Conflict of Interest Form
3. IACUC Application Form
4. The technical portion of the grant 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:

5. University Biosafety Committee application
6. 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 Regulatory Research Compliance at the same time that the essential elements needed by the IACUC are also submitted.

All application material must be submitted electronically to the Office of Regulatory Research Compliance with enough time to allow for pre-review and full committee review. Applications that are not submitted early enough to allow for pre-review 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 non-affiliated member and a statistician may also be assigned. The Office of Regulatory Research Compliance will contact the three pre-reviewers for each protocol (especially the primary reviewer) 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 three pre-reviewers and a thorough, thoughtful 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 generally communicated to the principal investigator by e-mail. 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 Office of Regulatory Research Compliance in time for full review at the next scheduled meeting.

The researcher must then submit the revised protocol to the Office of Regulatory Research Compliance **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 no changes are necessary, this should also be communicated in a letter to the IACUC with appropriate justification.

### **C. IACUC Review and Review Actions**

The Institutional Animal Care and Use Committee meets on the second Wednesday of each month. Each full protocol reviewed at the IACUC meeting should have already gone through the pre-review process as described above. Principal investigators or the representatives are invited to attend the IACUC meeting if they have a protocol on the agenda to answer any questions or concerns of the IACUC, but they will not present in the meeting during discussion and voting. . The primary and secondary reviewers and the veterinarian who were assigned to pre-review the application present their review of the revised application to the full committee. The full committee will then go into executive session and take any one of the following actions:

Approved as Submitted: This action indicates that the protocol 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. The approval period is generally three years.

Require Modifications to Secure Approval: This action indicates that the protocol requires modifications due to 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 Office of Regulatory Research Compliance. It must be resubmitted to the Office of Regulatory Research Compliance within 90 days. If it is not received by the Office of Regulatory Research Compliance within 90 days, the protocol will be considered administratively withdrawn and will have to go through the entire review process (i.e., pre-review and full review) again.

In accordance with NIH policy for designated review of protocols requiring modifications, all IACUC members voted in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use designated reviewer subsequent to Full Committee Review when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request Full Committee Review of the protocol.

Protocols that require modifications to secure approval can be approved by the IACUC chair upon receipt of the revised protocol 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 generally for three years.

**Withhold Approval:** This action indicates that the committee has major problems with the protocol such that it can not be approved without substantial revision. The investigator will be sent a letter within five working days describing the reasons for tabling the study 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 Office of Regulatory Research Compliance within 90 days for re-review by the full committee. **The changes to the protocol must also be described point-by-point in a cover letter.**

#### 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, euthanasia, the addition of animals, or the addition or deletion of personnel. Investigators who wish to initiate a change in a protocol must submit a letter to the Office of Regulatory Research Compliance describing in detail the proposed modifications, justification for the proposed changes, and any effects that the modifications may have on the animal(s).

Minor amendments may be reviewed and approved by the Chair. Examples of minor amendments include:

- the addition of trained personnel
- 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.

Major amendments must be reviewed by the full IACUC committee as described for full protocol review. Major 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 the amendment represents significant procedural changes that require the submission of a new IACUC protocol.**

## **E. 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 regarding the number of animals used in the previous year, whether there have been any changes to the protocol, whether there have been any complications or pre-mature deaths associated with the protocol, and whether the protocol is currently active.

The Office of Regulatory Research Compliance 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 Office of Regulatory Research Compliance by the anniversary date, the protocol will be administratively inactivated and animals will not be released for research until the form is submitted.**

The Periodic Report Form is reviewed by the IACUC at its monthly meetings. If there are no problems, the protocol may remain active for another year. If problems are observed or suggested, 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.

## **F. Renewal**

IACUC protocols are approved for up to a three year period. To renew a protocol after the approval period, the principal investigator must submit a full 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 are exempt from IACUC review and approval. Nevertheless, the Office of Regulatory Research Compliance requests that the principal investigator submit a brief letter to the Office of Regulatory Research Compliance 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. Designated Review**

The policy of the IACUC is to discourage expedited review of new protocols except in certain rare circumstances. If necessary, given sponsor deadlines or other mitigating conditions, the IACUC will review an application in an expedited fashion. This process involves submitting the full application package as described above to the Office of Regulatory Research Compliance. The Chair of the IACUC will select one or two reviewers and the veterinary member to evaluate the application. At the same time, the Chair will notify the other members of the IACUC that an application has been received for expedited review (the protocol, sponsor, and principal investigator will be named) and any member may request full Committee review. If no such request is made, the application will be reviewed and acted upon by the selected reviewers and the IACUC chair.

**A protocol that is the same as a previously approved protocol, but is being submitted to a different sponsor, resubmitted to the same sponsor, or being renamed, may also receive expedited review and approval.** The principal investigator need only complete the first part of the IACUC application (in particular, listing the protocol number of the previously approved application) and submit the remaining elements of the application package described above (Section V, Part A). The Chair of the IACUC will review this application and the previously approved protocol and if they are indeed the same, the protocol will be approved.

Protocols that are to be **conducted at another institution and that have already received approval by the IACUC at the other institution** may also be eligible for designated review and approval. The principal investigator needs to submit a copy of the approval letter from the IACUC at the other institution, a copy of the protocol that was reviewed by the other institution, and evidence that the other institution has an Animal Welfare Assurance approved by the Office for the Protection from Research Risks. In addition, the principal investigator should submit a copy of the technical section of the grant proposal describing the proposed activity involving animals and any other approval letters from applicable regulatory committees at the other institution (e.g., Biosafety, Radiation Safety). This material will be reviewed by the chair of the IACUC and, if acceptable, approved on an ad-hoc basis.

Finally, **protocols approved by an IACUC at another institution, but that will be conducted at Drexel University and Drexel University College of Medicine (e.g., grant transfer) must be reviewed and approved by IACUC.**

## **VII. Termination or Inactivation of Protocol**

As noted above, protocols are generally approved for a three year period. 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. A. 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 and Drexel University College of Medicine IACUC for its consideration.

The allegation of misuse of animal or noncompliance with an approved protocol may be expressed either orally or in writing and will be kept confidential to the extent possible. It is the responsibility of the IACUC to determine whether there is sufficient reason for further investigation. If so, the Chair or Vice 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. 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 sub-committee may stop work on the protocol, pending further investigation, if there are significant concerns about the welfare of animals in the protocol.

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 from recurring. In addition, 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.

## **VIII Principal Investigator's Responsibility**

Principal investigators are responsible for ensuring that research projects are conducted as approved by the IACUC and notifying the IACUC in writing of any changes to the protocol and waiting for IACUC approval before instituting any changes. Principal investigators are also responsible for oversight and communicating with their staff about their responsibilities concerning institutional policies and procedures to implement a research project as approved by the IACUC. Investigators are also responsible for 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.

## **IX. IACUC Protocol Approval for Granting Agencies**

If an investigator intends to submit a grant proposal for federal funding, IACUC review and approval is required. The information contained on the IACUC application form **must reflect accurately the animal welfare sections of the grant proposal**. As mentioned previously, part of the IACUC review will consist of comparing the IACUC application and the relevant sections from the proposal for consistency. If IACUC approval is post-grant submission, the Office of Regulatory Research Compliance the IACUC protocol must be approved and submitted “just in time.”

## **X. Animal Use Training and Certification Program**

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 and Drexel University College of Medicine general and species-specific certification program before full approval for activities involving the use of animals by the IACUC approval can be granted. General training in the appropriate care and use of laboratory animals and OSHA is provided through the Laboratory Animal Training Association (LATA) on-line training. Species-specific training is accomplished by way of species-specific LATA on-line training modules and demonstration of proficiency of certain basic technical skills to the ULAR staff. The program relies on **experienced** certified people teaching and testing others. LATA 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 LATA module access and how to schedule species-specific hands-on training. <http://www.research.drexel.edu/compliance/IACUC/info.aspx>

## **XI. Transfer of Animals**

During the course of research, it is common for principal investigators to request transfer of animals from one protocol to another or to another institution. This transfer of animals also includes those animals transferred from a breeding protocol. All transfer of animals requires IACUC approval. 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 or to another institution, please use the form entitled Transfer of Animal Form. Please make sure that the exact number of animals to be transferred and the protocol numbers are clearly mentioned on the form to ensure proper record keeping by the University Laboratory Animal Resource (ULAR). These forms also request investigators to provide information on whether the animals transferred were part of any other study in this or at any other institution.

If an investigator is receiving animals from another institution, he or she must comply with all federal, state, local, and Drexel University and Drexel University College of Medicine

regulations or policies. The originating institution's attending veterinarian or IACUC chair's signature is required on the form mentioned above and approval from the Drexel veterinarian to import these animals must be obtained. If an investigator is releasing animals to another institution, the Drexel University and Drexel University College of Medicine ULAR will contact that institution's veterinarian or research animal facilities to assure that they are ready to accept them. Once the transfer is approved by the Chair of the IACUC, a copy of the approval will be sent to the principal investigators and to the ULAR to ensure that the number of animals involved are appropriately added to or subtracted from the protocols. The Drexel veterinarian will determine the necessity and length of quarantine required before the animals may enter the Drexel animal facilities.

## **XII. Veterinary Care and Veterinarian's Responsibilities**

Veterinary medical care is an essential part of an animal care and use program. Therefore, Drexel University and Drexel University College of Medicine have 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 and Drexel University College of Medicine. 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 in planning all surgical protocols that involve postoperative care.

The veterinarian has the right to stop work on any protocol wherein he/she identifies or observes a deficiency in animal care and treatment that threatens the quality of life or health of an animal. 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 (Sections VIII).

### **XIII. IACUC Inspections and Program Review**

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 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, 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. Inspection subcommittees must have at least two 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 takes place during a scheduled IACUC meeting with a quorum of the IACUC using a form obtained from the NIH web site following the format of the Guide. 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 within 15 days. IACUC will send a report to the Institutional Official describing this inspection and program review.

In addition to the semiannual program inspections, post approval monitoring involves a variety of other mechanisms. 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, 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 Office of Health and Safety also inspects all laboratories on a semiannual basis. Any animal care and use issues noted by these mechanisms are reported to the IACUC for investigation.

### **XIV. 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 actual research or teaching. In these annual reports, the University shall provide information on the species and number of animals per species involved in IACUC approved activities. The report must also list the number of animals involved in activities likely to produce pain or distress and provide assurances that the University are 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 there have been no changes, the IACUC shall submit a letter, through the Institutional Official, stating that there are no changes and provide dates of the IACUC inspections.

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).

#### **XV. Office of Regulatory Research Compliance**

The role of the Office of Regulatory Research Compliance is to ensure the effective functioning of the IACUC and to aid the Institutional Official in his or her responsibility of overseeing the animal program and animal procedures. The Office of Regulatory Research Compliance 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 Vice- Provost for Research Compliance of the Office of Regulatory Research Compliance is charged with negotiating the required Assurance with the Division of Animal Welfare, Office for Protection from Research Risks at the National Institutes of Health to protect the welfare of animals involved in research or teaching conducted by Drexel University and Drexel University College of Medicine. The Office of Regulatory Research Compliance will also participate in the preparation for site visits and the accreditation process of the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC). All documents associated with the IACUC, i.e., minutes, protocols, committee membership and correspondence are maintained in the Office of Regulatory Research Compliance.

Within the Office of Regulatory Research Compliance there is an IACUC Coordinator whose 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 Coordinator is available to answer questions about institutional procedures, the calendar of scheduled meetings and the status of a current protocol. The Coordinator prepares all minutes of IACUC meetings and prepares all correspondence to investigators regarding their protocols.

#### **XVI. University Laboratory Animal Resources**

Drexel 215-895-1348  
Center City 215-762-7969  
Queen Lane 215-991-8163

1. Day to Day Animal Care Questions/Problems

Drexel: 215-895-1348  
Center City: 215-762-7969  
Queen Lane: 215-991-8162

2. 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.

Associate Director ULAR: 215-762-7969

3. 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).

Veterinary Technician Queen Lane: 215-991-8162  
Veterinary Technician Center City: 215-762-1129

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

- a. Obtain IACUC approval
- b. Complete an Animal Order Form (available from department office or ULAR website)
- c. Fax the form (215-762-7449)
- d. 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.

5. There is an attending veterinarian 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.

Attending Veterinarian: 215-762-7970

6. Emergencies

Drexel: 215-895-1348  
Center City: 215-762-7970  
Queen Lane: 215-991-8163

Weekends, after-hours, etc.: Emergency contact information for the Facility managers, veterinary technicians and Attending Veterinarian are posted in all animal facilities.

## **XVII. IACUC Forms**

Website: <http://www.research.drexel.edu/compliance/IACUC>  
- forms are located under IACUC Information and Forms

## **XVIII. Animal Welfare Assurance**

The Animal Welfare Assurance is available from the Office of Regulatory Research Compliance

## **XXI. Occupational Safety Program**

The IACUC, attending veterinarian, Institutional Official, Safety Officers and Occupational health physician from the Drexel University College of Medicine Department of Medicine 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, Department of Medicine. 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.

Website: <http://www.research.drexel.edu/compliance/IACUC>

Forms are located under Training Requirements

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