

Drake University
Institutional Animal Care and Use Committee

INVESTIGATORS' MANUAL FOR THE CARE AND USE OF ANIMALS IN RESEARCH

IACUC POLICIES AND PROCEDURES



Institutional Animal Care and Use Committee
<http://www.drake.edu/iacuc>

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	also see: https://www.drake.edu/iacuc/	

APPENDIX A

Protocol Application for Animal Use

also see: <http://www.drake.edu/academics/iacuc/>

APPENDIX B

Protocol Continuing Review Form
also see: <https://www.drake.edu/iacuc/>

APPENDIX C

Drake University Sample Semiannual Program and Facility Review
Checklists
also see: <https://www.drake.edu/iacuc/>

1.0 Introduction

The Drake University Institutional Animal Care and Use Committee (IACUC) is dedicated to the humane care and use of animals in activities related to research and teaching conducted at Drake University or by individuals associated with the University. The IACUC is guided by federal regulations and ethical principles intended to ensure the humane care and use of animals in research. All research involving vertebrate animals that is conducted or authorized under the jurisdiction of Drake University is subject to review by the IACUC.

1.1 Definitions & Acronyms

The IACUC uses the following definitions and acronyms in reference to its activities:

Animal – An unqualified use of the term “animal” refers to live vertebrates beyond the fetal stage (mammals) or that have hatched (other vertebrates). The IACUC does not regulate activity associated with non-vertebrate animals or animal carcasses (see section 5.1).

Animal Use – Any contact with live vertebrates, including care and handling, for research or teaching purposes is classified as “animal use” and is governed by the IACUC.

Application – This refers to the IACUC Protocol Application for Animal Use. The term indicates that the protocol has not yet been approved.

APHIS – Animal and Plant Health Inspection Service.

Attending Veterinarian – The Drake University Attending Veterinarian serves on the IACUC, has delegated authority for all protocols, animal facilities and all animals at the University. The Attending Veterinarian is available to make recommendations and provides veterinary care.

AWA – Animal Welfare Act of 1966. This term is normally used for both the Act itself and the resulting regulations. The AWA governs use of USDA-covered species (all mammals and birds except mice, rats and birds bred for research purposes).

Designated Reviewer(s) – An individual or individuals granted the authority by the IACUC Chair or IACUC to perform the activities set forth in Section 5.2.2.

The Guide – *The Guide for the Care and Use of Laboratory Animals* is published by the National Academy of Sciences under the auspices of the National Research Council (NRC), and serves as a standard for laboratory animal welfare.

IACUC – Institutional Animal Care and Use Committee. When not qualified, the term

“IACUC” in these policies and procedures refers specifically to the Drake University Institutional Animal Care and Use Committee.

Investigator – Any faculty member using animals (live vertebrates) in research or teaching is classified as an Investigator for IACUC purposes. In addition, any other person serving as Principal Investigator on a research grant is also considered an Investigator, regardless of whether or not they will have physical contact with animals.

Investigator Manual – The *Investigators’ Manual for the Care and Use of Animals in Research* available to each Drake University investigator.

NIH – The National Institutes of Health, a part of the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting medical research.

Noncompliance – Any action or inaction that does not follow the procedures or design specified in an approved protocol, and/or that violates animal welfare regulations, or Drake University IACUC Policies and Procedures.

NRC – National Research Council.

OLAW – Office of Laboratory Animal Welfare.

Personal Supervision – IACUC defines “personal supervision” as meaning the supervisor is present in the room with the person being supervised while animals are being used.

PHS – Public Health Services, an agency that serves the office of the Surgeon General, includes agencies whose mission is to improve the public health.

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

Principal Investigator (PI) – A single individual who has overall responsibility on a Protocol Application for Animal Use. In the case of projects funded by government sources, this individual must be the same as the Principal Investigator on the grant. The Principal Investigator on a protocol is normally a Drake University faculty member. Any other Investigators involved with the project must be listed on the Protocol Application as Co-Investigators.

Protocol – Normally refers specifically to a protocol that has been approved by the IACUC, as opposed to an Application submitted for review. Subcategories include:

- **Open** – An approved protocol that has not yet expired or been closed.
- **Closed** – A protocol that was approved but has either expired or been terminated at the request of the Principal Investigator or by IACUC action.
- **Active** – An open protocol under which work is being conducted and/or animals are being held.
- **Inactive** – An open protocol under which the Principal Investigator is not currently conducting any work or holding any animals.
- **Administrative hold** – A protocol on administrative hold is one in which no work is being conducted and any animals have been transferred to a holding protocol.
- **Suspended** – A protocol on which the IACUC has halted activity, for example, for reasons of noncompliance.

Compliance officer – The Compliance officer monitors compliance and corrective actions and works with IACUC chair in submission of IACUC reports.

USDA – United States Department of Agriculture.

2.0 Regulatory Authorities Governing Animal Use

The Drake University IACUC Policies and Procedures were developed by the IACUC based upon requirements set forth by the following:

- U.S. Department of Agriculture (USDA) under statutory law (Title 7, Section 2131 of the United States Code [7 USC 2131]) and regulations (Title 9 of the Code of Federal Regulations [9 CFR 2.31 et seq.]).
- Public Health Service (PHS) under statutory law [42 USC 289d], the PHS Policy on Humane Care and Use of Laboratory Animals (*PHS Policy*), and the Guide for the Care and Use of Laboratory Animals (*The Guide*).

2.1 U.S. Department of Agriculture

The U.S. Department of Agriculture (USDA), through its division of the Animal and Plant Health Inspection Service (APHIS), administers the Animal Welfare Act of 1966 (AWA) and its amendments, codified at 7 USC 2131 et seq. and 9 CFR 2.31 et seq. The AWA regulates the transportation, purchase, care and treatment of animals used for exhibition, sold as pets, or used in basic and biomedical research, education and product safety testing. The AWA specifically applies to the use of all warm-blooded vertebrates (Mammalia and Aves), with the exception of mice of the genus *Mus*, rats of the genus *Rattus*, and bird species bred specifically for use in research.

The AWA requires the establishment of an IACUC at all institutions that use animals in research, teaching or testing. The IACUC is responsible for reviewing all activities that involve animals in research, teaching or testing to ensure humane use of animals. The IACUC is also responsible for conducting semiannual assessments of the Drake University IACUC Policies and Procedures for animal care and use programs, including inspections of all animal study areas and facilities. As a research facility, Drake University is subject to random inspections by USDA and must file an annual report concerning its IACUC Policies and Procedures. Failure to comply with USDA laws and regulations pertaining to the use of live animals can result in civil or criminal prosecution and suspension of animal research activities.

Every Investigator at Drake University can access a current copy of the AWA and related regulations (included in the Drake University *Investigators' Manual for the Care and Use of Animals in Research*). In addition, a current copy of the AWA and related regulations are accessible to everyone who works with animals through the APHIS Animal Care Publications website at <http://www.aphis.usda.gov/ac/publications.html>.

2.2 Office of Laboratory Animal Welfare at the National Institutes of Health

The *PHS Policy* was created to implement the provisions of the Health Research Extension Act of 1985. The Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) administers the policy. The policy applies to institutions conducting PHS-supported projects involving live vertebrate animals.

The *PHS Policy* requires that such institutions establish an IACUC. In accordance with the policy, the IACUC, using *The Guide*, is responsible for reviewing the use of animals and conducting semiannual assessments of the Drake University IACUC Policies and Procedures, including inspections of all animal study areas and facilities.

Drake University is required to file an Animal Welfare Assurance of Compliance Statement (Assurance) every five years with OLAW, providing written documentation of the institution's commitment to animal welfare and detailed information on the Drake University IACUC Policies and Procedures. The Assurance commits Drake University to compliance not only with the *PHS Policy* and *The Guide*, but also with the AWA.

Failure to comply with the *PHS Policy* and/or *The Guide* may lead to various actions, including the termination of PHS funding for all projects at Drake University involving the use of animals.

A current copy of the *PHS Policy* and *The Guide* are accessible to everyone who works with animals from the website at <http://www.aphis.usda.gov/ac/publications.html>.

3.0 Administrative Organization

Regulations and guidelines governing the use of laboratory animals apply to all persons at Drake University involved in animal use. A quality animal care and use program requires the integrated support of many individuals at Drake University, including the IACUC, Institutional Official, Compliance officer, Attending Veterinarian, Investigators, students, and the animal care staff.

3.1 Institutional Official

The Drake University Provost serves as the Institutional Official and has the authority to legally commit, on behalf of Drake University, that regulatory requirements will be met under the AWA and PHS policy. The Provost is responsible for appointing members to IACUC. As Institutional Official, the Provost signs Drake University's Institutional Assurance.

3.2 Attending Veterinarian

The Drake University Attending Veterinarian serves on the IACUC as a voting member and has delegated authority and responsibility to implement the *PHS Policy* and recommendations of *The Guide* and the AWA. The Attending Veterinarian routinely inspects the animal facilities and all animals at Drake University. The Attending Veterinarian is available to make recommendations concerning preventive health programs for animals, disease treatment, analgesia, anesthesia, post-operative recovery, euthanasia, general animal welfare and technical training. The Attending Veterinarian provides on-call emergency care and consultation for Drake University's animals. The Attending Veterinarian has the authority to immediately suspend any protocol if animal welfare is endangered.

3.3 Institutional Animal Care and Use Committee

The IACUC was established pursuant to the AWA and the *PHS Policy* and reports to the Drake University Provost. The Provost appoints the members of the IACUC, who serve three-year terms, or until they are removed or resign.

3.3.1 Membership

The IACUC consists of at least seven members, of varying professional and personal backgrounds, including at least one veterinarian, one designee from the Office of the Provost to serve ex-officio, one person who is not affiliated with Drake University in any way other than as a member of the IACUC (for example, a community member), and four faculty members, at least three of whom shall be tenured. Three of the faculty members will be experienced in animal research, and one must have expertise in a nonscientific area. The community member may be either a scientist or non-scientist and will not be a member of the immediate family of a person who is affiliated with the

University and is expected to represent general community interests in proper care and use of animals. The IACUC members, including the community member, may be reimbursed for expenses related to their duties on the IACUC (for example, travel or mileage, meals, parking, IACUC seminars).

The chair of the IACUC, who will serve a two-year term, will be selected from the tenured faculty by the Institutional Official. The IACUC can appoint one person from among its members as Vice Chair of the IACUC. The Vice Chair serves as the IACUC Chair in the temporary absence of the Chair or when the Chair has a conflict of interest with an IACUC review or other activity. The IACUC may, from time to time, consult with other professionals e.g., legal counsel in fulfilling its responsibilities.

All members serve two-year staggered terms. Reappointment is permitted. It is permissible to appoint alternate members to fulfill the role of a member who must be absent for a meeting or a specified period of time. The alternate must fill the same role as the member for whom he/she is substituting (i.e. non-scientist, scientist, community member), but the alternate should vote according to his or her own conscience, not based on how the absent member would have voted.

3.3.2 Meeting and Quorum Requirements

The IACUC schedules monthly meetings. A quorum is required at any meeting at which formal action is taken by the IACUC, and a majority vote of those present at the meeting is required for any formal action (for example, approval or suspension).

A quorum requires the presence of a majority of the current voting members of the IACUC. Members must be physically present at a meeting to be counted toward a quorum. Any member who has a conflict of interest in a matter under consideration by the IACUC (for example, is personally involved in the matter) shall not be counted toward a quorum for that portion of the meeting. If a quorum is lost at any time during the meeting, the meeting shall be adjourned and no further formal action shall be taken until a quorum is attained.

3.3.3 Responsibilities

The IACUC has general oversight responsibility for Drake University IACUC Policies and Procedures. Specific responsibilities of the IACUC include the review of animal use, inspection and review of facilities Standard Operating Procedures, compliance activities, record keeping and community relations.

Review of Animal Use:

- Review and approve, require modifications or withhold approval of all new Applications or revisions to existing protocols involving animals;
- Conduct continuing reviews of approved protocols, not less than annually;

- Conduct *de novo* review (similar to an initial review) of all active protocols at least once every three years;
- Review all animal incident reports and determine whether any additional action is necessary.

Inspection and Review of Animal Facility Standard Operating Procedures:

- Recommend procedures to be followed for the proper care and humane treatment of animals and review them every six months using Title 9 CFR (USDA) and *The Guide* (OLAW) as a basis of review, providing a written report to the Institutional Official;
- Inspect every six months all of Drake University's animal facilities using Title 9 CFR and *The Guide* as a basis of inspection, providing a written report to the Institutional Official;
- Provide recommendations to the Institutional Official regarding any aspect of the animal program, facilities or personnel training.

Compliance Activities:

- Review and investigate noncompliance with the Drake University IACUC Policies and Procedures, applicable regulations, *PHS Policy* or *The Guide*.
- Suspend any activity that is not in compliance with the *PHS Policy* and *The Guide*, the USDA regulations, or IACUC guidelines.

Record Keeping:

- Maintain records of IACUC activities as required by regulation or the *PHS Policy*.

Community Relations:

- Serve as the liaison between the University and the community for matters involving animal research and welfare.

3.4 Animal Facility Personnel

Animal Vivarian and Support Staff – The Animal Vivarian and Support Staff work closely with the animals. These personnel should be well qualified, by training or experience, to handle and care for the animals in the facility. They should be knowledgeable about the requirements for the species involved and about any special requirements imposed by specific research, testing or teaching programs. The Animal

Vivarian should communicate any problems or concerns to the Attending Veterinarian or the IACUC Chair. The Animal Vivarian, in conjunction with the IACUC Chair and Attending Veterinarian, also serves as a resource to the Principal Investigator and staff on appropriate procedural techniques involving animals.

3.5 Personnel Using Animals

All personnel using animals are responsible for complying with applicable government regulations and University policies. The following sections provide an overview of these responsibilities. More complete information is provided by federal and organization publications, including those included with the *Investigators' Manual for the Care and Use of Animals in Research*.

3.5.1 General Responsibilities

All individuals using live animals in the context of research or teaching, except those personnel classified as exempt (see section 4.2.1), are governed by the following regulations and policies. Personnel classified as Investigators have additional responsibilities (see section 3.5.2). Questions regarding these responsibilities may be addressed to the IACUC Chair or the Institutional Research and Academic Compliance Office (iacuc@drake.edu).

The IACUC requires that all personnel using animals:

- Receive and maintain IACUC Basic Certification (see section 4.4);
- Follow the procedures for animal care and use described in approved protocols;
- Report noncompliant activity to the IACUC Chair or Academic Compliance office. Reports can be made anonymously (see section 8.1).

3.5.2 Responsibilities of Investigators

The IACUC relies on Investigators to uphold high standards in animal care and use. The following policies are designed to ensure that these standards are maintained and that applicable regulations are followed. Investigators also have the same responsibilities as all other personnel working with animals (see section 3.5.1).

Requirements:

- Receive and maintain IACUC Investigator Certification (see section 4.4.3);
- Submit the Application (see Appendix A), as described in this document for any work involving animals;
- Provide a copy of each approved protocol to every person participating in the

research project, and ensure that each person understands his/her duties as well as the project as a whole;

- Be certain that all project personnel follow the procedures for animal care and use described in approved protocols (see Appendix A);
- Request approval for any modifications of procedures or other animal use before implementing such modifications (see section 5.5.2);
- Receive IACUC approval for additions to project personnel prior to activity by these individuals;
- Ensure that all personnel on the protocol have adequate training and/or experience to carry out their designated roles;
- Consult the Attending Veterinarian, the Animal Vivarian or other appropriate IACUC personnel for assistance with unexpected health or care problems with animals;
- Submit an Animal Incident Report within 72 hours of unanticipated incidents (see section 6.1);
- Maintain complete records of procedures undertaken during all animal experiments;
- Maintain a scholarly, sensitive and respectful environment during all animal experimentation;
- When using animals for instructional purposes in classrooms or laboratories, ensure that animals receive the same humane care and treatment as those used for research purposes.

Recommendations:

While the IACUC is available to assist Investigators in fulfilling their responsibilities under government regulations and University policies, each Investigator is responsible for his/her conduct in the care and use of animals. In addition, the Principal Investigator bears ultimate responsibility for all aspects of each project, including the activities of all project personnel. The continued use of vertebrate animals in research depends in part on an understanding by the public that such work is scientifically important and is carried out in a humane manner. The following recommendations are therefore directed to Investigators conducting research.

Research:

- Participate in continuing education and training programs designed to keep investigators abreast of the latest techniques and procedures in animal research;
- Discuss with students, technicians, animal care workers and others participating in research the ethics of animal use in scientific studies, including the issues of humane treatment as well as replacement, reduction and refinement alternatives. Be sensitive to the needs of newcomers to adjust to participating in research performed on animals;
- Devote time and effort to institution-wide activities to promote a general understanding within the academic community and the lay public of the need for animals in research and instruction;
- Emphasize the role of laboratory animals when presenting research results or discussing human diseases with lay audiences and describe the contributions of humanely conducted animal studies for the discovery of new knowledge and development of new technologies and treatment capabilities.

Although there has been a dramatic reduction in the use of animals for instructional purposes over the past two decades, live animals remain an important and necessary adjunct teaching model in certain courses. The following recommendations are therefore directed to faculty members or others involved in this type of instruction.

Teaching:

- Promote sensitivity and concern among students for the need for humane care and treatment of animals;
- Promote understanding among students of the importance of humanely conducted animal studies for the discovery of new knowledge and for the development of new technologies and treatment capabilities.

4.0 Education and Training

4.1 IACUC Members

Initial Training— All IACUC members must complete training which includes an overview of applicable federal government regulations, including the AWA and the *PHS Policy*. One place training can be completed by creating an account at <http://aalaslearninglibrary.org/> and taking the applicable “free courses”. Each member of the IACUC receives a copy of Drake University *Investigators’ Manual for the Care and Use of Animals in Research*, and the *Institutional Animal Care and Use Committee Guidebook*.

Continuing Education-- The primary forum for continuing education of IACUC members is regular attendance at meetings, which will include discussions of criteria for approval of proposed research, observations and suggestions by the animal care staff, changes to regulations and guidelines, results of program reviews and inspections, and questions and concerns brought to the attention of the IACUC. For members who have previously completed online training, it will need to be renewed every three years.

4.2 Personnel Working with Animals

Drake University is required by federal regulations to make available training for all personnel including the Principal Investigator and staff involved in the use and/or care of live vertebrate animals in research, testing or teaching. *PHS Policy* and USDA regulations require that training be made available in the following areas:

- Humane methods of animal maintenance and experimentation, including the basic needs of each species used, proper handling and care for the species, proper pre- and postprocedural care of animals and aseptic surgical techniques;
- Research and testing methods that minimize the number of animals required to obtain valid results with minimum pain and distress;
- Proper use of anesthetics, analgesics and tranquilizers for any animals used;
- Zoonoses, chemical safety, microbiological and physical hazards, handling of waste materials, personal hygiene, and other considerations to improve safety and reduce risk;
- Reporting of deficiencies in animal care and treatment;
- Access to database search resources to obtain information on alternatives to the use of live animals, prevention of unnecessary duplication, and methods of animal care and use.

4.2.1 Classification of Personnel

Individuals using animals at Drake University or participating in University-affiliated projects in other locations are classified at the following levels for IACUC purposes:

- **Exempt Personnel** – These include laboratory course participants, observers and external consultants. Laboratory course participants are students or other personnel working under the Personal Supervision of IACUC-approved personnel in a formal laboratory course. These participants are typically not listed on an IACUC protocol. Observers are individuals who do not participate in animal care or handling but may be present during a procedure. External consultants are individuals who will provide expertise or training for a project and are thus listed on a protocol, but who will not otherwise participate in animal care or handling at Drake University. When exempt personnel use live animals, they must do so under the personal supervision of personnel authorized under the protocol to provide such supervision. As with all protocols, the Principal Investigator bears ultimate responsibilities for the treatment of animals by personnel working under his or her supervision. Supervisors are also responsible for providing appropriate instruction to exempt personnel on any health and safety issues and on any care and handling techniques related to animal use.
- **IACUC Basic Certified Investigators and other Personnel** – These include investigators, technicians, post-doctoral researchers, fellows, residents, students and visiting scientists who have met the requirements for IACUC Basic Certification. Certified personnel may work independently. Investigators have responsibility for the welfare of animals covered by a protocol and for the activities of project personnel.

4.3 Education and Training Components

Online training for animal care staff and Investigators is provided through <http://aalaslearninglibrary.org/>. The principal investigator will determine which courses are applicable based on species, techniques, etc. All Investigators and staff must complete training prior to engaging in work on an approved protocol. Records of completion must be maintained by the investigator and submitted to IACUC. All training must be renewed every three years for continued eligibility to participate in animal care or research activities.

Personnel with previous experience may not require additional training for specific surgical procedures; however, it is the duty of the Principal Investigator to confirm the skill level resulting from this experience.

4.4 Certification Requirements

All personnel, except those classified as exempt, must be IACUC certified before working with or using animals. The IACUC will not approve any Application unless all personnel listed on the protocol have IACUC Basic Certification or are in-training. IACUC Investigator Certification is required for all investigators. Initial certification is valid for three years.

Formal recertification training will be required at least every three years. Personnel will be notified when they must be recertified. The recertification process may include on-line training courses or seminars on specialized topics and on changes in federal regulations or Drake University's requirements. Updates and changes in federal or University regulations will be communicated to the Investigators via e-mail and posted on the IACUC website.

4.4.1 IACUC Basic Certification

All personnel coming in contact with animals must complete all requirements for IACUC Basic Certification to be listed on a protocol. The Principal Investigator is responsible for continuing education of project personnel on changes in federal laws or Drake University procedures. For personnel not affiliated primarily with Drake University, education received at other institutions may be accepted in place of some components if deemed equivalent by IACUC or the IACUC Chair. The following components are required for IACUC Basic Certification:

Training/Education:

- <http://aalaslearninglibrary.org/>

Receipt by the IACUC/Academic Compliance Office:

- Animal Occupational Health and Safety Program Risk Assessment Acknowledgement;
- Acknowledgment of access to the Drake University *Investigators' Manual for the Care and Use of Animals in Research* and agreement to read the Drake University IACUC Policies and Procedures;
- Disclosure of Financial Relationship for Sponsored Projects (Required Annually).

5.0 PROTOCOL REVIEW PROCESS AND PROCEDURE

Every live animal used in teaching, testing and research at Drake University must be under an IACUC-approved protocol. Animal use is not allowed until it has been approved by the IACUC, regardless of funding status. The process for reviewing and approving animal use is described in this section.

5.1 Activities Requiring IACUC Approval

The following activities involving live animals must be approved by the IACUC before any action is initiated:

- **Drake University Facilities** – All research, teaching, biological testing projects and breeding work conducted by anyone at Drake University in institutionally operated facilities regardless of the source of funding.
- **Drake University Personnel** – All research, teaching, biological testing projects and breeding work conducted at another institution, in natural habitat or elsewhere by faculty, students, staff, or other representatives of Drake University in connection with the investigator's institutional responsibilities. Field studies, which are defined as research that involves studying free-living, wild animals in their natural habitat, require IACUC approval when (1) the study is funded by the PHS, National Science Foundation, or other funding agency that requires review, (2) the animals are warm-blooded and the study has the potential to cause harm or alter the behavior of the animals under study, or (3) state regulations or the respective permitting agency requires IACUC review. The IACUC may accept oversight by another PHS-approved IACUC (see section 5.6).

The following activities involving animals do not require IACUC approval:

- The study of animals in their natural habitat without investigator intervention;
- The study of preserved specimens or tissues obtained from recognized vendors of scientific supplies, research institutions or museums;
- The study of tissues obtained from a USDA-approved slaughterhouse or any vendor selling such tissue;
- Any activities not associated with teaching or research.

5.2 Types of Review

The IACUC uses two mechanisms for reviewing Applications and Protocols. These are

Full Committee Review and Designated Review.

5.2.1 Review by Full Committee

Full committee reviews are conducted by a quorum of members at an IACUC meeting. Any action by the committee following review (see section 5.5) requires a majority vote by those members present. In addition, items that were assigned to the Designated Review process will be reviewed by full committee if the item is not approved by all Designated Reviewers.

Review by full committee requires that materials be submitted no later than one week prior to the next scheduled meeting.

Full committee reviews are used in the following capacities:

- **Initial Application Review** – All Applications are subject to full committee review on initial submission (see section 5.5.1).
- **Tabled Application Review** – Applications designated “Tabled” after initial review are subject to full committee review on resubmission (see section 5.5.1).
- **Review of Significant Modification to an Approved Protocol** – Modifications or amendments to approved protocols that are classified as Significant will be reviewed by the full IACUC if requested by the Principal Investigator or an IACUC member (see section 5.5.2). If a full committee review is requested, then the request will be reviewed at the IACUC meeting following the next regular protocol submission deadline.
- **Continuing Review of Open Protocol** – All open protocols must be reviewed on an annual basis, initially by full committee (see section 5.5.3).
- **Renewal (de novo) Review** – Requests for protocol renewal are reviewed as a new protocol Application (see section 5.5.4).

5.2.2 Review by Designated Committee Member(s) (Designated Member Review)

Some review activities of the IACUC may be carried out by one or more Designated Reviewer(s) without a formal meeting of the full IACUC. A description of any item proposed for Designated Member Review will be provided to each IACUC member prior to the review. Full text versions of the item will be provided to any IACUC member on request. Any IACUC member may request full committee review or participation as a Designated Member Reviewer by informing the Chair within three working days of notification. If there is no request for full committee review, the Chair will designate one or more qualified members to review the item. The Designated Member Reviewer(s) will include all members requesting to participate.

In special circumstances, the IACUC chair can adjust the timeline by which members are required to respond requesting full committee review. In such cases, the Chair must provide adequate time and opportunity for all IACUC members to review the protocol information prior to assigning the Designated Member Reviewers.

Designated Member Reviews may take place at any time, and are used in the following capacities:

- **Revised Application Review** – After initial application review by full committee, the IACUC may assign Designated Member Reviewer(s) to review revisions after the committee votes to categorize an Application as “Revision Required to Secure Approval” (see section 5.5.1). Such Designated Member Reviews subsequent to Full Committee Review can only be done when all IACUC members were in attendance at the meeting in which it was voted upon. If all members were not present, then written notice from absent members must be procured prior to the meeting acknowledging their willingness to permit Designated Member Review subsequent to Full Committee Review.
- **Review of Significant Modification to an Approved Protocol** – Requests for small changes (generally substitution of an alternative procedure, drug, strain etc) that are *Significant Modifications* as defined in section 5.5.2 will be sent to all IACUC members. IACUC members will have three working days from the date of notification that the request has been posted to review the modifications. Any IACUC member who wants to request full committee review (see section 5.2.1) or to be a designated reviewer must inform the Chair within this time period. If there is no request for full committee review, the Chair will designate one or more reviewer(s). Minor administrative modifications to open protocols will be considered by the Chair or his/her designee without notification of the full committee (see section 5.5.2).
- **Initial Review of Protocol**—In limited cases an initial review of a protocol can be done by Designated Member Review. A description of any item proposed for Designated Member Review will be provided to each IACUC member prior to the review. Full text versions of the item will be provided to any IACUC member on request. Any IACUC member may request full committee review or participation as a Designated Member Reviewer by informing the Chair within three working days of notification. If there is no request for full committee review, the Chair will designate one or more qualified members to review the item. The Designated Member Reviewer(s) will include all members requesting to participate. Initial reviews done by Designated Member Review should be utilized on a very limited basis and only for categories B and C of animal use (see section 5.3).
- **Continuing Review of Open Protocol** – After continuing annual review of an open protocol, designated reviewers may be assigned to review revisions to Continuing Reviews for which the committee has requested Additional Information Required to Secure Approval (see section 5.5.3).

Designated Reviewers have authority to approve, require revision to secure approval, or request full committee review of an item. The reviewer(s) may consult with additional individuals as part of the review process. The item must be approved by all Designated Reviewers in order to receive IACUC approval; if any Designated Reviewer does not agree to approve, the item will receive full committee review at the next IACUC meeting. A proposal under Designated Member Review cannot be disapproved. Only the full committee can disapprove projects. Designated Reviewers other than the Chair must notify the Chair of their decisions in writing (e-mail and/or hard copy).

5.3 Categories of Animal Use

IACUC categorizes animal use based on the purpose of the animal use and the extent of pain, discomfort or distress anticipated for the animals. The categories parallel USDA designations:

- **Category B** – Breeding that involves no procedures or functional deficits that may cause more than momentary slight pain, discomfort or distress.
- **Category C** – Research or teaching that involves no procedures or functional deficits that may cause more than momentary slight pain, discomfort or distress.
- **Category D** – Research, teaching or breeding that has the potential to cause more than momentary slight pain, discomfort or distress that will be alleviated with appropriate anesthesia, analgesia or tranquilizers and/or that involves chronic maintenance of animals with a minor to moderate functional deficit.
- **Category E** – Research, teaching or breeding involving more than momentary pain, discomfort or distress that cannot or will not be alleviated through the administration of appropriate anesthetics, analgesics, or tranquilizers; and/or that involves chronic maintenance of animals with a severe functional deficit.

5.4 Review Criteria

Federal requirements state that the IACUC review proposals for animal use must be based on the following criteria:

- **Potential Value of the Study** – Activities involving live animals are designed and performed with the reasonable expectation that such use of animals will contribute to the enhancement of human or animal health, the advancement of knowledge or the good of society (*PHS Policy*).
- **Selection of Animal Species** – The animals selected are of an appropriate species and the number of animals requested is the minimum number needed to obtain valid results (*PHS Policy*).

- **Minimization of Pain and Distress:**
 - Procedures with animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design [9 CFR 2.31(d) (1) (i) and *PHS Policy*, Section IV.C.1.a].
 - Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia or anesthesia, unless the Principal Investigator justifies, in writing, the scientific reasons that the procedure must be performed without such treatments [9 CFR 2.31(d) (1) (iv) (A) and *PHS Policy*, Section IV.C.1.b].
 - The Principal Investigator has consulted with the Attending Veterinarian or his/her designee in planning procedures that may cause more than momentary or slight pain or distress to the animals [9 CFR 2.31(d) (1) (iv) (B)].
 - Procedures that cause more than momentary or slight pain and/or distress to the animals will not include the use of paralytics without anesthesia [9 CFR 2.31(d) (1) (iv) (C)].
 - Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be humanely euthanized at the end of the procedure, or if appropriate, during the procedure [9 CFR 2.31(d) (1) (v) and *PHS Policy*, Section IV.C.1.c].
- **Alternatives** – The Principal Investigator has considered alternatives to procedures that may cause more than momentary or slight pain and has provided a written narrative description of the methods and sources used to determine that alternatives are not available [9 CFR 2.31(d) (1) (ii)].
- **Duplication** – The Principal Investigator has provided written assurance that proposed activities involving animals does not unnecessarily duplicate previous experiments [9 CFR 2.31(d) (1) (iii)].
- **Living Conditions and Housing** – Animal living conditions and housing are appropriate for the species and contribute to the health and comfort of the animals [9 CFR 2.31(d) (1) (vi) and *PHS Policy*, Section IV.C.1.d].
- **Personnel** – Personnel conducting procedures will be appropriately qualified and trained in those procedures [9 CFR 2.31(d) (1) (viii) and *PHS Policy*, Section IV.C.1.f].
- **Surgery:**
 - Activities that involve surgery include appropriate provision for pre- and post-

operative care of the animals in accordance with established veterinary medical and nursing practices [9 CFR 2.31(d) (1) (ix)].

- No animal will be used in more than one major operative procedure from which it is allowed to recover unless it is:
 - Justified for scientific reasons in writing by the Principal Investigator, or
 - Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the Attending Veterinarian [9 CFR 2.31(d) (1) (x)].

- **Euthanasia** – Methods of euthanasia must be consistent with the most recent Report of the *American Veterinary Medical Association Guidelines on Euthanasia*, unless a deviation is justified for scientific reasons in writing by the Principal Investigator [9 CFR 2.31(d) (1) (xi) and PHS Policy, Section IV.C.1.g].

5.5 Review Process

Two primary forms are used by IACUC for reviewing animal use, as follows:

- **Protocol Application for Animal Use Form** (the Application) – The Application must be used for new projects, significant revisions to existing protocols, and protocol renewals.
- **Animal Protocol Continuing Review Form** (Continuing Review form) – The Continuing Review form must be used to submit information for continuing IACUC review of previously approved projects, which occurs at least annually for each approved protocol.

The Application and the Continuing Review form are provided in Appendices A and B, respectively. The documents are available on the IACUC website at www.drake.edu/academics/iacuc.

5.5.1 New Protocol Application

Submitting the Application – An Application (Appendix A) must be completed for any new project. The original signed Application and an electronic version must be submitted to the IACUC email account (iacuc@drake.edu) by one week prior to the meeting in which IACUC review is requested. All sections of the Application must be completed. All correspondence regarding the Application should include the protocol title.

Requirements for Application Review – The Application must be completed in full as described in the Instructions and signed by the Principal Investigator (see section 1.1 for qualifications of the Principal Investigator). All personnel listed on the Application must be certified for animal use (see section 4.2). The IACUC will not approve any Application that does not meet these criteria.

Processing the Application – Upon receipt of the Application:

- The Application is given an IACUC number;
- The proposal is placed on the agenda for consideration at the next IACUC meeting;
- The Application is made available to all members of the IACUC, either electronically or on paper, at least one week prior to the meeting at which the Application will be reviewed;
- The Chair, or his or her designee, in consultation with the IACUC members, may request that the Principal Investigator make changes in the Application between the time of submission and the time of the meeting to improve the likelihood of approval. If a revised Application is submitted before the meeting, it is made available to all members of the IACUC, either electronically or on paper, prior to the meeting;
- The Principal Investigator may be asked to discuss the Application at the meeting at which the Application will be considered. Principal Investigators may also request to speak at the meeting.

Reviewing the Application – Applications are considered for approval during regularly scheduled meetings of the full IACUC. A quorum of the IACUC must be present when initially reviewing any Application. During the meeting, the IACUC membership decides the action to be taken on the Application. Reviewed Applications will be assigned to one of the following five categories, based on a majority vote of the IACUC members present:

- **Approved** – The Application is approved as presented with no revisions required. The Chair will provide the Principal Investigator with a signed IACUC approval letter. For activities funded by an external agency, the Principal Investigator bears the responsibility of forwarding the IACUC approval information to the agency.

- **Revision Required to Secure Approval**– the Application is not approved because revisions are required to secure approval. If no member requests full committee review of the revised Application, the Chair designates one or more members to review the revision (see section 5.2.2, *Review by Designated Committee Member(s)*). The Chair or a Designated Reviewer will notify the Principal Investigator in writing of the required modifications. After a revised version of the Application and an accompanying memo describing the revisions have been received by the IACUC, the modified Application is reviewed by the Designated Reviewer(s) unless Full Committee Review has been requested. The Designated Reviewer(s) has the authority to approve, require further revisions of, or request Full Committee Review of the revised application. If the revised Application is approved by the Designated Reviewer(s), the Chair will provide the Principal Investigator with a signed IACUC approval letter. If the Principal Investigator cannot revise the Application to the satisfaction of the Designated Reviewer(s), approval will not be granted and the Chair will notify the Principal Investigator in writing of the reasons for the decision. The Principal Investigator may respond with further clarification or revision, or may request Full Committee Review of the revised application. If Full Committee Review has been requested, the modified application is considered at the next scheduled committee meeting.
- **Tabled** – The IACUC requires substantial additional information and/or has significant concerns about the Application, such that Full Committee Review of a revised Application is required. The Chair or his/her designee will notify the Principal Investigator in writing of the decision and will arrange to discuss the Application with the investigator. Before the IACUC review can continue, the Principal Investigator must revise and resubmit the Application, clearly identifying changes. In addition, the Principal Investigator must provide a separate cover letter to the IACUC specifically responding to each item listed in the notice of the decision to table the Application. Review of the revised Application may result in any of the outcomes described in this section.
- **Disapproved** – The Application is not approved. The Chair will notify the Principal Investigator in writing if the Application is disapproved, providing the basis for the IACUC decision. If an Application is disapproved, the Principal Investigator has the right of appeal to the IACUC for a period of 14 days. The IACUC may, at its discretion, obtain external review of the Application by a PHS-approved IACUC of an equivalent institution and/or by expert consultants in the field of that research. The Drake University IACUC, however, shall be the final authority in determining the acceptability of the Application. If no satisfactory resolution is reached, the principal investigator may submit a written appeal to the Institutional Official requesting assistance. The Institutional Official will attempt to mediate a solution to the situation. Neither the Institutional Official nor any other administrative official, however, can override a decision by the IACUC.

- **Decline to Review** – Where the Application has significant deficiencies in information, or where the Principal Investigator has failed to follow the Instructions for completing the Application, or in other similar situations, the IACUC will return the Application to the Principal Investigator with an indication of why the Application was not reviewed. In those situations, the Principal Investigator is encouraged to discuss the Application with the IACUC Chair or his/her designee to receive assistance in correcting the deficiencies. The completed Application should be resubmitted one week prior to the next scheduled IACUC meeting for review.

Applications classified as *Revision Required* or *Tabled* must be revised within six months of receipt of the letter of notification, or the Application will be considered withdrawn. Protocols are valid from the date of Approval for a maximum of three years and are subject to Continuing Review on at least an annual basis.

5.5.2 Amendments to an Approved Protocol

Approved protocols grant permission to conduct only those activities listed in the protocol, conducted in the manner described, by the individuals listed, with no more than the number of animals indicated in the protocol. Any changes in procedures, personnel, endpoints, care or use of additional animals require submission of an amendment to IACUC and approval before the changes are implemented.

Review of protocol amendments may result in approval, a request for more information or disapproval of the request. Approval of an amendment does not alter the expiration date of a protocol. The IACUC recognizes two general classes of amendment to open protocols:

- **Minor amendments** – Modifications that qualify as Minor Amendments include changes in the animal genetic background or strain; number of animals; animal source, animal care facility, housing unit, or field site; personnel (other than PI); disposition of animals/carcasses; and administration of treatment as it relates to timing, dose, route of administration and/or specific chemical composition. To make a Minor Amendment to an open protocol, an IACUC Protocol Minor Amendment Form must be completed and submitted to IACUC for review.

- **Major amendments** – Modifications not qualifying as Minor Amendments are considered to be Major Amendments. To make a Major Amendment to an open protocol, a memorandum that describes the modification and its rationale must be submitted to IACUC for review along with the original protocol with modifications inserted and clearly indicated. Prior to submitting a Major Amendment, Principal Investigators are encouraged to consult with the IACUC Chair to determine whether a Major Amendment or a *de novo* protocol submission is warranted.

Both major and minor amendments must be submitted by one week prior to the meeting in which IACUC review is requested.

5.5.3 Continuing Review

All protocols are reviewed by IACUC at least annually during scheduled monthly meetings. The purpose of this continuing review is to provide the IACUC with current information concerning the status of protocols. The IACUC sends the Continuing Review form (Appendix B) to the Principal Investigator at least six weeks prior to the protocol anniversary date. The Principal Investigator must complete the Continuing Review form and return it to the IACUC no later than 1 week prior to the next scheduled meeting. Upon receipt of a completed Continuing Review form by the IACUC, it will be distributed to each member of the IACUC at least one week prior to the meeting at which the protocol will be reviewed or for designated member review, if appropriate.

If the Principal Investigator fails to complete and return the Continuing Review form on time, the IACUC will not conduct Continuing Review of the protocol. If Continuing Review cannot be conducted for this reason, or if continued activity is not approved by the IACUC, the protocol will be placed on administrative hold by the IACUC, effective on the last day of the anniversary month, and no further activities can be undertaken with animals until the IACUC approves continued activity. Administrative hold status normally has a limit of one month. If Continuing Review cannot be conducted or continued activity cannot be approved before the end of the administrative hold period, the protocol will be closed.

The IACUC conducts Continuing Review at its regularly scheduled meeting during the anniversary month of the protocol and takes one of the following actions:

- **Approved** – The IACUC approves continued activity under the protocol, including any requests for modifications to the protocol. A letter of approval is sent to the investigator from the IACUC chair.
- **Approved without Modifications** – The IACUC approves continued activity under the current protocol, but does not approve the requested changes to the protocol. The Chair will notify the Principal Investigator in writing of the committee's concerns regarding the requested modifications. The Principal Investigator may then request protocol modification (see section 5.5.2).
- **Additional Information Required** – Insufficient or unclear information prevents the IACUC from conducting its Continuing Review. The Chair will notify the Principal Investigator in writing of the required clarification or elaboration. After the requested information has been received by the IACUC, Continuing Review will be conducted by the Designated Reviewer(s) (see section 5.2.3). The Designated Reviewer(s) has the authority to approve continued activity, require further clarification of the Continuing Review materials, or request Full Committee Review of the revised Continuing Review material. If the revised protocol is approved by the Designated Reviewer(s), the Chair and the Attending Veterinarian will sign the form and the IACUC Coordinator will send a copy of the signed form to the Principal Investigator for his/her records. If approval does not

occur by the end of the anniversary month, the protocol is placed on administrative hold.

- **Tabled** – The IACUC requires substantial additional information and/or has one or more significant concerns about the protocol, such that full committee review of protocol continuation is required. The Chair will notify the Principal Investigator in writing of the decision, indicating what additional information or action is required before continued activity under the protocol can be approved. The Principal Investigator must address all the IACUC concerns and provide all requested materials one week prior to the next scheduled IACUC meeting for the IACUC to proceed with Continuing Review. If approval does not occur by the end of the anniversary month, the protocol is placed on administrative hold.
- **Disapproved** – If the IACUC does not approve continuation of the protocol, the Chair will notify the Principal Investigator in writing of the IACUC decision, indicating what issues resulted in the disapproval of continued activity. If the Principal Investigator wishes to submit a modified protocol, it must be submitted as a *de novo* Application and will be evaluated (see section 5.5.1). If an Application with a modified protocol is submitted, the disapproved protocol will be put on administrative hold at the end of the anniversary month. If a modified protocol is not submitted, the disapproved protocol will be closed at the end of the anniversary month.

5.5.4 Renewal

Once a protocol reaches its expiration date it is closed and no further activities can be conducted with animals under that protocol. Therefore if work covered by an open protocol is expected to continue beyond its current expiration date, the Principal Investigator must submit a complete Application (Appendix A) to IACUC one week before the IACUC meeting prior to the month and year in which the protocol expires. The IACUC reviews the Application as an original new submission (see section 5.2.1). If the new protocol is approved before the original protocol expires, all animals on the expiring protocol will be transferred to the new protocol and covered activities can continue. If the new protocol is not approved before the original protocol expires, all activity under the protocol must cease when the protocol closes.

5.6 External Protocols

When all animal housing and use by Drake University personnel is conducted at another institution, IACUC may recognize the animal care and compliance oversight provided by that institution's IACUC or equivalent body. If the participation of Drake University personnel in the project is in a capacity other than as the Principal Investigator, and if the supporting grant(s) are not held by University personnel, IACUC will accept oversight by the other institution without formal verification. If Drake University personnel are participating in the capacity of Principal Investigator or hold

supporting grants, then IACUC will require either verified oversight by the other institution or will oversee activities directly.

The IACUC may recognize the oversight provided by other institutions. If the investigator requires IACUC to verify the grant and protocol for federal funding agencies, then the following must be on file with Drake University:

- A current memorandum of understanding between Drake University and the other institution;
- The protocol approved by the institution;
- The letter of approval from the institution's IACUC.

For PHS-approved or foreign institutions, IACUC must review the institution's policies and procedures in order to determine whether Drake University will accept the oversight of animal activities provided by the institution. The IACUC will not accept oversight by U.S. institutions not PHS-approved.

5.7 Comparison of Grant Proposals to Protocols

Drake University is required by the *PHS Policy* to verify that the IACUC has reviewed any procedure in a PHS grant proposal that involves the care and use of animals. In order for Drake University to provide the required verification, the grant proposal must be compared with one or more IACUC-approved animal use protocols.

At the time of grant proposal submission, the Office of Sponsored Programs will request that the Principal Investigator identify the IACUC-approved animal use protocol(s) that contain the procedures in the grant proposal. The title of the protocol(s) does not have to match that of the grant proposal; however all research that involves animals must be included in the approved IACUC protocol(s). The Office of Sponsored Programs will submit the grant proposal and the protocol numbers(s) to the IACUC Chair or the Chair's designee, who compares the description provided in Section F "Vertebrate Animals" (or its equivalent) of the grant proposal to the approved IACUC protocol(s) for consistency in:

- overall scope of the animal work;
- proposed animal models (including species and strain);
- estimated number of animals; and
- procedures performed on live animals.

If Section F "Vertebrate Animals" (or its equivalent) of the grant proposal and the approved IACUC protocol(s) are consistent, the IACUC Chair or the Chair's designee will inform the Office of Sponsored Programs, who will communicate the verification to the federal granting agency. If the grant proposal and protocol(s) are not consistent, the

Principal Investigator must resolve the discrepancy.

6.0 Reporting and Record Keeping by Project Personnel

All personnel working with animals are required to report any unapproved activities or any unexpected events that may compromise animal welfare (see Section 8). In addition, certain procedures have specific record-keeping requirements that must be followed by project personnel. Projects with external funding may also have record keeping requirements in addition to those noted here.

6.1 Animal Incident Reporting

During the course of an IACUC approved research activity, an unanticipated or atypical event (including death of the animal) may occur. An unanticipated event is a serious event that impacts animal welfare but is not listed as part of the IACUC approved protocol. An atypical event is an event that does not normally occur as a result of the IACUC approved research activity. An Animal Incident Report must be completed within 72 hours of the event and submitted to the Animal Vivarian. A copy of the report is forwarded to the IACUC Chair for further review by the IACUC. Failure to report an animal incident within 72 hours may result in corrective action by the IACUC.

6.2 Surgery Record Keeping

All surgeries on non-rodent mammals require detailed Standard Operating Procedures on file with IACUC in the approved protocol. The health records and protocol are kept with the animal at all times along with records of pre-operative, operative and post-operative care. These forms must be complete and available to all project personnel, the Animal Vivarian, and the Attending Veterinarian so the investigator can be quickly contacted and appropriate treatment decisions can be made. Animal incident reports are required for all unexpected and serious complications including, but not limited to death.

Surgery and recovery in rodents should be documented according to the requirements including post-procedure care and health alert cards.

7.0 Semiannual Reviews and Post-Approval Monitoring

Twice each year the IACUC reviews the Drake University IACUC Policies and Procedures for animal care and use programs and inspects all Drake University facilities where animals are housed and/or used. The IACUC uses *The Guide* and the AWA regulations as the principal reference documents in conducting these reviews.

7.1 Types of Semiannual Review

7.1.1 Review of the IACUC Policies and Procedures

The IACUC is required to semiannually evaluate the Drake University IACUC Policies and Procedures for animal care and use programs. This semiannual evaluation includes the following:

- IACUC membership and functions, including protocol review practices;
- IACUC records and reporting requirements;
- Veterinary care, to include:
 - Preventive medicine, animal procurement, and animal transportation,
 - Surgery,
 - Pain, distress, analgesia, and anesthesia,
 - Euthanasia,
 - Drug storage and control;
- Personnel qualifications and training;
- Occupational health and safety of personnel;
- Disaster Plan.

7.1.2 Review and Inspection of Animal Facilities

As part of its semiannual review, the IACUC will inspect all facilities where animals are kept longer than twelve hours and areas in which surgical manipulations are performed. Other areas, such as laboratories in which only routine injections, dosing, and weighing occur, will be monitored by random site visits and evaluations as necessary to ensure compliance. The IACUC maintains an updated list of all facilities to be inspected during its semiannual review. This semiannual review includes the following:

- Animal housing and support areas,
- Cage wash,
- Aseptic surgery,
- Procedure areas, non-survival surgeries, laboratories, and rodent surgeries.

7.2 Semiannual Review Subcommittee and Reports

At least two members of the IACUC shall conduct the semiannual reviews. No IACUC member wishing to participate in any review shall be excluded. The IACUC may invite ad hoc consultants to assist in the reviews.

Upon completion of the reviews, the IACUC Chair shall prepare a written memorandum to be reviewed by the committee and made part of the semiannual report for OLAW. The report shall describe Drake University's adherence to *The Guide* and the AWA and shall state the reasons for any deficiencies. Deficiencies identified during the reviews are categorized as either minor or significant. A significant deficiency is defined, by USDA regulations and the PHS Policy, as something that is or may be a significant threat to animal health or safety. The report shall include a plan and schedule with dates for correction of each program or facility deficiency. All individuals to be involved in the corrections shall be consulted to ensure that the plan is realistic. An IACUC member along with the compliance officer shall follow up to assure that all deficiencies have been resolved by the dates of correction.

The report must be reviewed and signed by a majority of the IACUC members and shall include minority views. The IACUC shall submit the approved report to the Institutional Official and shall maintain a copy in its files. The report shall be made available to USDA, OLAW and any federal funding agencies upon request.

Any failure to adhere to the plan and schedule identified in the report for correcting deficiencies that results in a significant deficiency remaining uncorrected, shall be reported in writing by the IACUC, through the Institutional Official, within 15 business days to APHIS. If the uncorrected deficiency is related to a federally funded activity, the relevant funding agency shall also be informed.

7.3 Monitoring of Corrective Action Plans

The IACUC shall provide a copy of the final semiannual report to the Academic Compliance office. The compliance office shall monitor compliance with required corrective actions, as identified in the final semiannual report, and shall submit a written report to the IACUC. If any deficiencies are not remedied within the time period set forth in the final semiannual report, the IACUC shall take appropriate corrective action.

7.4 Protocol Post-Approval Monitoring

Post-approval monitoring of protocols is permitted to provide assurance to regulatory agencies and to the IACUC that animal experiments are performed in accordance with

approved protocols. The Animal Vivarian can perform post-approval monitoring on behalf of the IACUC. The Animal Vivarian confirms consistent and accurate performance of the IACUC-approved protocols, standard operating procedures and practices.

Post-approval monitoring may be performed as a “For Cause” investigation or routinely as a “Not for Cause” review.

The Animal Vivarian conducts “For Cause” Investigations at the request of the IACUC for a variety of reasons including:

- Receipt of an internal complaint (i.e. anonymous report) or internal concern of possible protocol violation or regulatory noncompliance;
- Receipt of an external complaint (the FDA, Sponsor, OLAW, or USDA) of potential protocol violation or regulatory noncompliance; or
- Investigator history of poor adherence to Drake University policies/procedures or regulatory requirements.

The “Not for Cause” or routine post-approval monitoring may include:

- Review of IACUC records and activities to ensure that the IACUC policies and procedures are consistent with regulatory requirements and federal assurances;
- Review of risk areas identified during periodic risk assessments of research at Drake University;
- Protocols randomly selected for on-site review.

In post-approval monitoring:

- All active and approved protocols and modifications are available for review;
- All allegations of misuse, neglect or inappropriate protocol performance will be investigated;
- In general, the monitoring reviews will be scheduled with the Principal Investigator or other laboratory personnel in advance. Follow-up audits for the purpose of confirming PI reported resolutions may be unscheduled;
- “For Cause” monitoring may be conducted at any time, with or without advance notice (i.e., unannounced) to the Principal Investigator;
- During a monitoring visit, the Animal Vivarian will compare procedures conducted in the laboratory with those listed in the approved protocol;
- The Animal Vivarian will provide a description of any discrepancies between the procedures performed in the lab and those listed in the protocol to the Principal Investigator;

- The Animal Vivarian will provide information to the IACUC by means of a written report. The report may include identification of:
 - Unapproved personnel who are performing procedures in the protocol,
 - Outdated cage cards, incorrect cage cards, or improperly labeled cage card,
 - Location of the procedure that does not match the location specified in the protocol,
 - Anesthetics/analgesics: unapproved regimen or route of administration, expired date, improper use,
 - Minor unapproved modifications to approved procedures that are performed,
 - Other procedural deviations that can be corrected by submission of a minor change request, and
 - Incidents of animal distress that were not anticipated;

- The Animal Vivarian will discuss monitoring/auditing results with the Principal Investigator to confirm the observations for accuracy, and to assure a complete understanding of issues;
- The Animal Vivarian shall refer issues that pose an immediate threat to animal welfare to the Academic Compliance office, the Attending Veterinarian, and the IACUC;
- The Animal Vivarian will send a final written report of the monitoring results to the research compliance officer, Principal Investigator, and the IACUC;
- As the Animal Vivarian determines necessary, he/she may recommend further training/ retraining or modifications, and may perform a follow-up monitoring/audit visit to check for compliance and to assure the welfare of the animals and the integrity of the IACUC protocol process.

8.0 Review of Noncompliance

The IACUC investigates concerns involving the care and use of animals raised by complaints or reports of noncompliance received from the public or from research personnel or employees [9 CFR 2.31(c)(4)]. The University is required to report results of some investigations to OLAW and the USDA.

8.1 Identification of Compliance Issues

Anyone who has a concern or question about animal care and use at Drake University, including protocol noncompliance or animal treatment, is expected to contact the IACUC Chair or to call 271-3472 to report anonymously. The Attending Veterinarian, animal care staff and individual IACUC members must also report any suspected incidence of noncompliance. Reports are delivered to the IACUC Chair for investigation (see section 8.2). Strict confidentiality will be maintained to the extent possible and allowable by law. Drake University prohibits retaliation against any employee who makes a good faith report of known or suspected noncompliance in the care and use of animals at Drake University.

Concerns include situations or activities in which animals are in immediate jeopardy and those in which violations of the Federal Animal Welfare Regulations or the Assurance are alleged but animals are not in apparent danger. They may also be past violations of the IACUC Policies and Procedures or protocol noncompliance.

8.2 Investigation of Animal Care and Use Concerns

8.2.1 Initial Evaluation and Actions

The response of the IACUC to a concern about animal use is driven by the urgency of the situation. Conditions that jeopardize the health or well-being of animals are evaluated immediately. The Attending Veterinarian is authorized to halt procedures if he or she has reason to believe that animal welfare is being compromised until the IACUC can be convened to consider the matter formally. Situations that involve potential criminal activity or human safety are reported promptly to Drake University's Security or human resources officials. Allegations concerning less urgent policy or procedural matters are handled as promptly as practicable.

An emergency meeting of the IACUC may be necessary to ensure prompt consideration. Upon receipt of a concern, the IACUC Chair or the Chair's designee(s) will convene a meeting of the IACUC to determine whether the concern requires further investigation and immediate action, further investigation but no immediate action, or no action. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately. If immediate action is warranted to protect animal or human welfare, the IACUC notifies the Institutional Official or the Institutional

Official's designee(s). Any suspension of activity is reported to regulatory agencies (Section 8.6).

8.2.2 Investigation

If further investigation is required, the Chair or a subcommittee appointed by the Chair conducts the investigation and reports its findings to the IACUC by an assigned completion date. To avoid actual or perceived conflicts of interest in the investigation process, no person with an unresolved personal, professional or financial conflict of interest with the affected investigator or personnel is involved in the investigation.

The investigation may involve:

- interviewing complainants, any persons against whom allegations were directed, and pertinent program officials;
- observing the animals and their environment;
- reviewing pertinent records, (e.g., animal health records, protocol).

The report to the IACUC summarizes:

- the concern(s),
- the results of interviews,
- the condition of animals and their environment,
- the results of document reviews.

The report must also contain:

- any supporting documentation such as correspondence, reports, and animal records,
- conclusions regarding the substance of the concerns;
- recommended actions.

8.2.3 Outcomes and Final Actions

Upon receipt and evaluation of the report, the IACUC may request further information or find that:

- there was no evidence to support the concern or complaint,
- the concern or complaint was not sustained, but
 - related aspects of the animal care and use program require further review, *or*
 - other institutional programs may require review, *or*
- the concern or complaint is valid.

Actions of the IACUC may include:

- notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.);
- implementing measures to prevent recurrence;
- notifying the Institutional Official;
- notifying funding or regulatory agencies.

8.3 Noncompliance with IACUC Polices

Failure to comply with IACUC policies or to adhere to the procedures of an approved protocol constitutes noncompliance. Examples of noncompliance are performing unauthorized surgery, unauthorized persons participating in a research project, or injecting drugs that the IACUC has not approved.

The IACUC's first goal when non-compliance is found is to restore compliance. In determining its response to a finding of non-compliance, the IACUC may consider:

- self-reporting by the Principal Investigator or staff,
- proactive corrective action(s) taken in response,
- the extent to which the incident(s) represent a continuing, or repeated violation and the length of time between incidents of noncompliance,
- the extent to which harm to an animal resulted from the incident(s).

The response of the IACUC may include:

- counseling,
- mandating specific training aimed at preventing future incidents,
- monitoring by the IACUC or IACUC-appointed individuals of activities that involve animals.

8.4 Consequences of Noncompliance

If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. If the IACUC finds that sanctions are appropriate, they may include;

- requiring the Principal Investigator to present plans for corrective action to the IACUC;
- issuing letters of reprimand;
- notification to the Principal Investigator's Departmental chair;
- a letter to the Principal Investigator from the Institutional Official outlining the problem and requesting a detailed plan of corrective action;
- suspension of protocol and or loss of animal use privileges;

- permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals;
- recommending to the Institutional Official that institutional sanctions be imposed. (e.g., reassignment, termination of employment).

8.4.1 Suspension of a Protocol

The IACUC may suspend activities on a protocol if it finds violations of the Institutional Policy, PHS Policy, the Assurance, and/or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the affirmative vote of a majority of the quorum present. Further, the IACUC must consult with the Institutional Official regarding the reasons for the suspension. The Institutional Official is required to take appropriate corrective action and report the action to regulatory agencies (Section 8.6).

The Attending Veterinarian has authority to immediately suspend IACUC approval if he or she has reason to believe that animal welfare is being compromised. The Attending Veterinarian immediately notifies the affected Principal Investigator and the IACUC Chair in writing. The circumstances that led to suspension shall be investigated as quickly as possible and the IACUC Chair shall call an emergency meeting of the IACUC to review the suspension (see section 8.2).

8.5 Programmatic Deficiencies and Corrective Actions

The IACUC semiannual evaluations are tools for institutional self-identification and correction of facility and program deficiencies. Program deficiencies include:

- failure to correct situations identified as significant deficiencies in a timely manner,
- shortcomings in the programs of veterinary care, occupational health, training, or with the IACUC,
- conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals.

Programmatic deficiencies must be categorized as acceptable, minor, or significant. The corrective action for a significant deficiency must include a reasonable plan to correct the issues as well as a date by which the issue will be corrected. Significant programmatic deficiencies must be reported to the applicable regulatory agencies if the deficiency jeopardizes the health and welfare of the animals, or if Drake University is unable to make the correction by the specified date.

8.6 Reporting Requirements

The IACUC, through the Institutional Official or the Institutional Official's designee, shall promptly report to OLAW and the USDA, as appropriate, circumstances and actions taken with respect to:

- any serious or continuing noncompliance with PHS Policy;
- any serious deviation from the provisions of the Guide; or
- any suspension of an activity by the IACUC.

In addition, the IACUC, through the Institutional Official or the Institutional Official's designee, must report within 15 days any failure to correct a significant deficiency to the USDA and any federal agency funding the activity in which the significant deficiency was found.

Examples of reportable incidents include:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC-approved protocols;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval;
- conduct of animal-related activities beyond the expiration date established by the IACUC;
- conduct of official IACUC business requiring a quorum in the absence of a quorum;
- conduct of official IACUC business during a period of time that the IACUC is improperly constituted;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the Guide unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained;
- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);

- failure to ensure death of animals after euthanasia procedures;
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments);
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the PHS Policy, Animal Welfare Act, the Guide, or the University's Animal Welfare Assurance.

8.6.1 Agency-Specific Reporting Requirements

Office of Laboratory Animal Welfare (OLAW)

The Institutional Animal Care and Use Committee (IACUC), through the Institutional Official or the Institutional Official's designee(s), must contact the office of the Director of Compliance at OLAW immediately after:

- suspension of any activity by the IACUC;
- a finding of serious or continuing noncompliance with the PHS Policy;
- a finding of significant deviation from the provisions of the Guide.

After review of any allegation of non-compliance by the IACUC and the Institutional Official or the Institutional Official's designee(s), a formal written report will be filed with OLAW within 3 months of the event stating a full explanation of circumstances, a description of corrective actions taken, any minority views filed by the IACUC, and the status of the research program.

United States Department of Agriculture (USDA)

The IACUC, through the Institutional Official or the Institutional Official's designee(s), must contact the Western Regional Director of Animal Care immediately in the following instances:

- suspension of any activity by the IACUC;
- failure to adhere to a plan to correct a significant deficiency.

Federal Funding Agencies

The IACUC, through the Institutional Official or the Institutional Official's designee(s), must contact any Federal agency funding an activity involving the use of animals immediately

- if the activity is suspended by the IACUC;
- the institution fails to adhere to a plan to correct a significant deficiency that affects the activity.

8.6.2 Non-reportable Incidents

Examples of incidents that are not normally required to be reported are:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules).

9.0 Institutional Reporting and Record Keeping

9.1 Reporting Requirements

9.1.1 USDA Registration and Public Health Service Assurance

The IACUC is responsible for completing the USDA Registration and PHS Assurance. The USDA Registration is renewed every three years. The PHS Assurance is renewed every five years. The USDA Registration and PHS Assurance are signed by the Institutional Official and submitted to the appropriate agency by the IACUC.

9.1.2 Annual Reports

USDA/APHIS – The IACUC is required to submit an Annual Report to APHIS. The IACUC shall prepare the Annual Report for signature by the Institutional Official. The Annual Report shall outline Drake University’s compliance with the AWA, the location of all facilities where animals are housed or used, and specific animal information as required by the AWA.

PHS/OLAW – At least once every 12 months the IACUC, through the Institutional Official, shall submit a written report, to include any minority views, to OLAW. The report shall include the following:

- Changes to Drake University’s program or facilities that would place it in a different category than specified in our Assurance;
- Changes in the IACUC membership;
- Changes in the description of the Drake University IACUC Policies and Procedures for animal care and use programs as outlined in the Assurance;
- Dates that the IACUC conducted its semiannual evaluations and submitted its reports to the Institutional Official.

If there are no changes, the report shall state that there are no changes and shall inform OLAW of the dates of the semiannual evaluations and submission of semiannual reports to the Institutional Official.

9.1.3 Semiannual Reports

Upon completion of semiannual reviews (see section 5.1), the IACUC shall submit written semiannual reports (see section 5.2) to the Institutional Official.

9.1.4 Other Reporting Requirements

The IACUC shall ensure reports are made when required by findings of noncompliance as set forth in Section 8.5 above.

9.2 Record Keeping Requirements

The IACUC shall maintain Applications and Continuing Review forms submitted for review; minutes of meetings, including records of attendance; activities of the IACUC and deliberations, records of proposed activities, and proposed significant changes, including whether the IACUC approval was given or withheld; records of semiannual reports and recommendations; and Drake University's Assurance, USDA Registration and annual reports to government agencies. These records shall be retained as follows:

- **Five-Year Retention** – The IACUC shall retain the Assurance for at least five years or until such time as a new Assurance is approved, whichever is longer.
- **Three-Year Retention** – The IACUC shall retain the following records for at least three years:
 - Records of semiannual IACUC reports and recommendations,
 - Records of animals,
 - Records of any accrediting body determinations, if applicable,
 - Annual reports,
 - USDA Registration.
- **Other** – The IACUC shall retain records relating to proposed activities and significant changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and three years after the end of the activity. Such records include, but are not limited to, records of Applications, Continuing Review forms, minutes of IACUC meetings, and records of investigations of noncompliance related to an approved protocol.

10.0 Animal Occupational Health and Safety Program

In accordance with the *Guide*, an occupational health and safety program must be part of the animal care and use program of Drake University. The IACUC is responsible for overseeing the occupational health and safety program. The training provided for investigators on at <http://aalaslearninglibrary.org/> includes some guidance to identify potential hazards, assess risks associated with those hazards and to eliminate or otherwise manage those potential risks for individuals who use or have exposure to animals in research or teaching activities at Drake University.

Additional training necessary for safe work or research that is provided by an investigator, veterinarian or animal vivarian should be documented. For example, if a lab provides specific training on the use of needles or what to do in the case of a bite or scratch, the date of this training should be recorded with the names of those present. A copy of this document should be sent to the research compliance office (Old Main 319). An additional copy can be retained by the PI in his/her records.

11.0 Animal Facility Disaster Plan

The detailed Disaster Plan for Facilities is posted on the Drake IACUC website at <https://www.drake.edu/iacuc/>.