

Drake University
Institutional Animal Care and Use Committee

INVESTIGATORS' MANUAL FOR THE CARE AND USE
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APPENDIX B

Protocol Continuing Review Form

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

APPENDIX C

Drake University Sample Semiannual Program and Facility Review

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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 (livph

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 birds of the order *Columbiformes*.

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

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

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

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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

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

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

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

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

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

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 InvestC re

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

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

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

Principal Investigator must resolve the discrepancy.

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,

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

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:

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

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

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

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.

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/>.