The University of Maryland at College Park
Institutional Animal Care and Use Committee

Handbook of Policies and Procedures

1 This document was prepared with the assistance of the University of Texas at Austin.
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Section 1: Introduction

1.0 Purpose and Scope of the Handbook

It is the responsibility of The University of Maryland at College Park to provide orientation, appropriate materials, adequate resources, and training to enable faculty, staff, and IACUC members to carry out their duties and responsibilities as required by the Guide for the Care and Use of Laboratory Animals (the Guide), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), and the Animal Welfare Act and Animal Welfare Regulations (AWRs).

Local institutional policies and procedures are part of the training and education program. Researchers and IACUC members may need assistance to understand the differences between the federal policies and requirements. It is the Institution’s responsibility to inform and teach researchers and IACUC members of their responsibilities, provide training relative to their respective roles, and ensure that resources are available to them to perform their duties. The office responsible for providing information and training resources is the Office of Research Compliance.

1.1 Mission Statement

The University of Maryland Institutional Animal Care and Use Committee (IACUC) is responsible for the review and approval of all proposed uses of live vertebrate animals in teaching and research. IACUC activities are mandated by the Animal Welfare Act and Public Health Service Policy.

No vertebrate animals may be used under campus auspices without prior approval of the IACUC.

The IACUC and the University expect all researchers using invertebrate species to handle them appropriately and humanely according to their species needs. However, no protocol is required by the IACUC or federal regulations.

The IACUC adheres to the belief that the development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. In particular, the IACUC observes the principles espoused by the Institute of Laboratory Animal Resources Guide for the Care and Use of Laboratory Animals:

- Procedures should be designed and performed on the basis of relevance to human or animal health, advancement of knowledge, and/or the good of society.
• The appropriate species, quality, and number of animals should be used.
• Discomfort, distress, and pain should be avoided or minimized in concert with sound science.
• Appropriate sedation, analgesia, or anesthesia should be used.
• Humane and experimental end points should be established.
• Appropriate animal husbandry should be directed and performed by qualified persons.
• Experimentation on living animals should only be conducted by or under the close supervision of qualified and experienced persons.

Currently, the IACUC only has direct oversight over vertebrate animals in teaching and research. However, it is assumed that invertebrate species will be handled with the same degree of care and concern.

1.2 Office of Laboratory Animal Welfare (OLAW)

The Office of Laboratory Animal Welfare (OLAW) implements PHS Policy. While OLAW is located organizationally at the National Institutes of Health (NIH) in Bethesda, Maryland, OLAW’s responsibility for laboratory animal welfare extends beyond NIH to all PHS-supported activities involving animals. OLAW issues guidance regarding PHS Policy, and co-sponsors animal welfare workshops to educate institutions and individuals regarding policy requirements.

Specific OLAW responsibilities include:

• Implementation of PHS Policy;
• Interpretation of the PHS Policy;
• Negotiation of Animal Welfare Assurances;
• Evaluation of compliance with the PHS Policy; and
• Education of institutions and investigators receiving PHS support.

1.2.1.1 Animal Welfare Assurance

Before PHS will award a grant or contract that involves the use of animals, the recipient institution must have on file with OLAW an approved Animal Welfare Assurance (Assurance). The Assurance is the cornerstone of the relationship between the institution and the PHS.

The University of Maryland at College Park is registered under Assurance number: A3270-01
Included in the Assurance are:

- The designation of the Institutional Official responsible for compliance;
- An organizational chart showing the key components of the animal care program and their responsibilities;
- A commitment that the institution will comply with the PHS Policy, with the Guide, with AWA and AWR; and
- A description of the institution’s program for animal care and use.

The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the Public Health Service (PHS). PHS agencies include:

- Agency for Healthcare Research and Quality;
- Agency for Toxic Substances and Disease Registry;
- Centers for Disease Control and Prevention;
- Food and Drug Administration;
- Health Resources and Services Administration;
- Indian Health Service;
- National Institutes of Health;
- Office of Public Health and Safety;
- Office of the Secretary;
- Program Support Center;
- Substance Abuse and Mental Health Services Administration; and
- Office of the Assistant Secretary for Preparedness and Response.

1.3 United States Department of Agriculture (USDA)

In 1966, Congress passed the Laboratory Animal Welfare Act (PL 89-544) and the United States Department of Agriculture (USDA) was named the responsible agency for the enforcement of the Animal Welfare Act (AWA) to protect certain animals from inhumane treatment and neglect. Congress passed the AWA in 1966 and strengthened the law through amendments in 1970, 1976, 1985, and 1990. The USDA’s Animal and Plant Health Inspection Service (APHIS) administers the AWA, its standards, and its regulations.

The University of Maryland at College Park is a registered research facility with the USDA certificate number: **51-R-025**

1.3.1. Inclusions Relevant to the Institution

The AWA (title 7, Chapter 54, Section 2132(g)) defines the term “animal” to mean any live or dead dog, cat, monkey (non-human primate mammal), guinea pig, hamster, rabbit, or other warm-blooded animal that is being used,
or intended for use in research, testing, experimentation, or exhibition purposes.

1.3.2 Exemptions Relevant to the Institution

The AWA (Title 7, Chapter 54, Section 2132(g)) excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, horses not used for research purposes, and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

Pets owned by private citizens are not regulated under the Act.

1.3.3 Research Facilities

In addition to providing the required standard of veterinary care and animal husbandry, regulated research facilities must provide dogs with the opportunity for exercise and promote the psychological well-being of primates used in laboratories. Researchers must also give regulated animals anesthesia or pain-relieving medication to minimize the pain or distress caused by research if the experiment allows. The AWA also forbids the unnecessary duplication of a specific experiment using regulated animals.

Research facilities must establish an Institutional Animal Care and Use Committee (IACUC) to oversee the use of animals in experiments. The IACUC is responsible for ensuring that the facility remains in compliance with the AWA and for providing documentation of all areas of compliance to the USDA/APHIS. The AWA does not permit APHIS to interfere with research procedures or experimentation. To ensure that all licensed and registered facilities continue to comply with the AWA, APHIS inspectors at least once annually.

If an inspection reveals deficiencies in meeting the AWA standards and regulations, the inspector instructs the facility to correct the problems within a given timeframe. If deficiencies remain uncorrected at the unannounced follow-up inspection, APHIS documents the facility’s deficiencies and considers possible legal action.

APHIS also conducts reviews and investigates alleged violations. Some cases are resolved with Official Notices of Warning or agency stipulation letters, which set civil penalties for the infractions. Civil penalties include cease-and-desist orders, fines, and license suspensions or revocations. If APHIS officials determine that an alleged AWA violation warrants additional action, APHIS submits all evidence to the USDA for further legal review.
In addition to conducting regular inspections, APHIS will perform inspections in response to public input about the conditions of regulated facilities. Concerned individuals are also encouraged to inform APHIS about facilities that should be licensed or registered.
Section 2: The Institutional Animal Care and Use Committee

2.0 Authority

Institutional Animal Care and Use Committees (IACUCs) derive their authority from the law. The Health Research Extension Act of 1985 and the Animal Welfare Act mandate the existence of IACUCs. The laws require the Chief Executive Officer (CEO) of an organization to appoint the IACUC, whose responsibilities are delineated in federal policy and regulations. The Office of Laboratory Animal (OLAW) considers the CEO to be the highest operating official of the organization. The President of the University of Maryland at College Park delegates authority through the Institutional Official (IO) to appoint the membership of the IACUC.

Once appointed, the IACUC reports to a senior administrator known as the Institutional Official (IO). The Vice President for Research is the appointed IO at the University of Maryland at College Park. The IO is given the administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements.

The Vice President for Research has delegated responsibilities for oversight of the IACUC to the Assistant Vice President for Research and Compliance (AVPR) who also directly oversees the Office of Research Compliance which supports all IACUC activities and functions.

The IACUC’s mandate to perform semiannual program evaluations as a means of overseeing the animal care and use program puts the IACUC in an advisory role to the AVPR and IO. In its semiannual reports the IACUC advises the AVPR and IO of the status of the Institution’s compliance, establishes plans and schedules for correcting deficiencies necessary to maintain or achieve compliance, and makes recommendations to the AVPR and IO regarding any aspect of the Institution’s animal program, facilities, or personnel training.

The IACUC’s authority to review and approve protocols is independent of the AVPR and the IO, neither of whom may overrule an IACUC decision to withhold approval of a protocol. If the IACUC approves a protocol, however, the Institution is not required or obligated to conduct the research activity. The Institution may also subject protocols to additional institutional review (e.g. departmental, Biosafety committee, etc.).

2.1 Committee Composition

The IACUC is composed of regular voting members, alternate voting members, and non-voting members. The IACUC may use, as necessary, non-voting members and
consultants during review discussions. Some IACUC members fulfill specific regulatory requirements (e.g. veterinarian with program responsibility, an individual not affiliated with the University), others have unique roles by virtue of their positions (e.g. Chair, Veterinarian).

There are no specific prohibitions regarding individuals filling more than one role on the IACUC, but OLAW strongly recommends against the same person serving in multiple roles, because the responsibilities and authorities vested in each of the positions are distinct and often require different skills and may circumvent intended checks and balances. Also of importance is the perception of conflict of interest which can lead to allegations of improprieties from various sources.

Required categories of membership, all of whom are voting members, include:

**Veterinarian.** PHS Policy and AWRs mandate the appointment of a veterinarian with direct or delegated program responsibility to the IACUC. The IO may appoint more than one veterinarian to the IACUC, but the veterinarian with direct or delegated program responsibility must be designated as such. The veterinarian with program responsibility, e.g. Attending Veterinarian, must have training or experience in laboratory animal science and medicine or in the care of the species being used.

**Chair.** The Chair is appointed to a term determined by the IO and is a faculty member of the University with research experience.

**Nonaffiliated.** The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, can have an affiliation with the University of Maryland at College Park. These members have equal voting status to every other committee member and are provided the opportunity to participate in all IACUC functions.

**Scientist.** PHS Policy requires that an IACUC include a practicing scientist with experience in research involving animals.

**Nonscientist.** PHS Policy requires that the IACUC include a member whose primary concerns are in a nonscientific area. Examples include, but are not limited to, ethicist, lawyer, member of the clergy, librarian, etc.

The University of Maryland at College Park includes persons with expertise in the disciplines involved in institutional research and teaching programs for service on the IACUC. In addition to the required categories of membership, the University includes other members of the campus community with specific areas pertinent to protocol review and program oversight.
There is no requirement that any particular member or category of members be present at all IACUC meetings. The institution, however, must have a properly constituted IACUC in order for the IACUC to conduct official business.

Alternate members may be appointed to the IACUC as long as they are appointed by the IO, and there is a specific one-to-one designation of IACUC members and alternates. An IACUC member and his/her alternate may not count towards a quorum at the same time or act in an official member capacity at the same time. Alternates receive training identical to all full members.

The University of Maryland at College Park meets the compositional requirements set forth in PHS Policy and the AWR.

2.2 Conflict of Interest

Both the AWRs and PHS Policy state that no IACUC member “may participate in the IACUC review or approval of an activity in which that member has a conflicting interest, (e.g. is personally involved in the activity) except to provide information requested by the IACUC.”

An investigator or IACUC member is said to have a conflict of interest in the situations including, but not limited to, the following conditions:

- Is a Principal Investigator, Co-Investigator, or Contributing Scientist on the protocol (IACUC members only).
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
- Has identified him or herself for any other reason as having a conflict of interest.

Other possible examples of conflict of interest include cases where:

- A member is involved in a potential competing research program;
- Access to funding or intellectual information may provide an unfair competitive advantage;
- A member’s personal biases may interfere with his or her impartial judgment.

If the investigator submitting the protocol believes that an IACUC member has a potential conflict, it is within their rights to request that the member be excluded from the review. The Chair (or in his/her absence, the Co-Chair) will present the declared conflict to the committee and the IACUC will determine whether a conflict exists.
Any member that declares a conflict of interest with a protocol under discussion will recuse themselves during the IACUC’s discussion of the protocol and for any voting that occurs. The member may be asked to return to answer questions or provide additional information at any stage of the process.

2.3 Confidentiality

During the process of initial or continuing review of an activity (including, but not limited to, any annual reviews or protocol amendment), material provided to the IACUC and the Office of Research Compliance (administrative office that supports the IACUC) shall be considered privileged information and the IACUC will assure the confidentiality of the data contained therein.

2.4 Quorum Requirements

Most IACUC activities require a quorum: full committee review of a research project (Policy IV.C.2. and AWR 2.31(d)(2)) and suspension of an activity (Policy IV.C.6. and AWR 2.31(d)(6)).

The University of Maryland at College Park defines a “quorum” as half of the regular IACUC voting members plus one (i.e. a 12 member IACUC would have a quorum of 7).

A protocol is approved only if a quorum is present, and if more than 50% of the quorum votes in favor of protocol approval. The number of votes required for a quorum vote is not altered by abstentions or members recused from the active discussion.

2.5 Functions of the IACUC

The Institutional Animal Care and Use Committee (IACUC) will:

1. Review at least once every six months the University’s program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are described in Section 7.1.
2. Inspect at least once every six months all of the University’s facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are described in Section 7.2.
3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are described in Section 7.3.
4. Review concerns involving the care and use of animals at the University. The IACUC procedures for reviewing concerns are described in Section 8.
5. Make written recommendations to the Institutional Official regarding any aspect of the Institution’s animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are described in Section 2.8.

6. In accord with PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals. The IACUC procedures for protocol review are described in Section 3.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research or educational projects are described in Section 3.9.

8. Notify investigators and the University in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the University of its decision regarding protocol review are described in Section 3.6.4.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are described in Section 4.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are described in Section 8.4.2.

2.6 Liability

Under PHS Policy, the primary responsibility for meeting applicable federal and state rules rests with the research facility or PHS awardee institution. The Institutional Official (IO) is the individual held responsible on behalf of the research facility for ensuring compliance. Failure to comply with PHS Policy could result in OLAW's withdrawal of approval of the institution’s Animal Welfare Assurance, thereby making the institution ineligible to receive Federal funds for activities involving animals. Failure to comply with the Animal Welfare Act could result in the USDA’s withdrawal of Certification and assessment of monetary fines.

2.7 Use of Electronic Mail (Email) for Official Correspondence

Electronic mail (Email), like postal and intercampus mail, is a mechanism for official University communication. The IACUC will exercise the right to send email communications to laboratory animal users in addition to intercampus mail. The IACUC expects that correspondence, from any source, will be received and read in a timely manner.
This policy applies to all faculty, staff, students, or any other person listed on an animal study protocol (ASP) submitted to the IACUC for review and approval. Official communications can occur through the IACUC listserv, or to specific individuals.

Email is also used for limited function in the IACUC process.

2.8 Making Recommendations to the Institutional Official

The IACUC will make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

- Recommendations regarding any aspect of the University's animal program, facilities, or personnel training are formulated at convened meetings of the IACUC.

- Recommendations are prepared in writing by the IACUC Program Coordinator, the Attending Veterinarian, the IACUC Chair (or in his/her absence, by the Vice-Chair), and/or any IACUC member. A copy of these recommendations are reviewed and approved at a convened meeting of the IACUC. Any minority views are noted and included in the final report.

- The IACUC Chair or his/her designee submits recommendations, including minority views that are approved by the IACUC to the IO.
Section 3: IACUC Animal Study Protocols

3.0 Protocol Review

The IACUC is responsible for overseeing and evaluating all aspects of animal care and use, and is charged with reviewing proposals that involve animals to ensure that the criteria established in PHS policy and Animal Welfare Regulations (AWRs) are implemented. In its review of proposals, the IACUC’s primary goal is to facilitate compliance with applicable laws, regulations, and policies consistent with the performance of appropriate and productive scientific endeavors.

3.1 General Scope of Review

The following activities involving animals are required to undergo review by the IACUC prior to initiation:

- Activities conducted by University faculty, staff, or students;
- Activities performed on University premises or under University auspices;
- Activities performed with or involving the use of facilities or equipment belonging to the University;
- Activities satisfying a requirement imposed by the University for a degree program or completion, a course of study, or an employment requirement.

3.2 Specific Types of Activities

Review is required even if the activity does not seem to qualify as “true research”. The IACUC will be the determining agency of when review is or is not required.

Research
Many of the animals covered in IACUC review are used in research, including medical, biological, behavioral, and agricultural research. Most of these animals are acquired and housed by the University of Maryland at College Park but may include free-ranging wildlife where appropriate.

Teaching / Extension Activities
The use of animals in educational settings is subject to IACUC review. Examples include using animals to teach agricultural techniques, animal husbandry, and other procedures associated with animal research.

Research Conducted by ‘Affiliated Faculty’
Research conducted by ‘affiliated faculty’ – those who hold adjunct or related appointments – is subject to the University’s guidelines for animal use and
must be submitted for IACUC review.

**Research Projects with University Faculty, Staff, or Students at Other Institutions**

In many instances, research will require that faculty, staff, or students conduct projects in cooperation with Institutions or Agencies outside the University. IACUC review, done at the University of Maryland at College Park, is required for all University associated individuals doing animal work on or off-campus. Review by another institution or facility's IACUC is insufficient.

**Research in Foreign Countries**

Research conducted by University affiliates in foreign countries falls under the University’s purview and guidelines. Regardless of the setting, the standards for ethical and responsible use of animals in research will not be relaxed even if different customs prevail.

**Use of Primate Tissue**

The IACUC requires a protocol for any research or teaching activities conducted with unfixed primate tissue.

All animal-based research conducted in foreign countries is subject to review. This involves the use of animals in foreign research institutions or fieldwork involving either domestic or wild animals.

### 3.3 Exemptions

The following are exempt from IACUC review:

- Activities involving animals that perform tasks, participate in club activities, or appear in exhibits (ie, AgDay, Camel ride, Dump for Dollars);
- Use of tissue, organs or other parts of dead animals if received as such (this does not include unfixed primate tissue which must be covered by a research protocol); and
- Noninvasive observation of wild animals in their natural habitat.

### 3.4 Who can be a Principal Investigator?

All animal research must be conducted under the direction of a faculty or staff member employed at the University of Maryland at College Park. Generally, faculty and some staff are considered sufficiently knowledgeable to supervise and/or conduct research. The IACUC may, at its discretion, determine that a faculty member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience.
All research conducted by graduate, undergraduate, or post-doctoral students must be conducted under the direct supervision and oversight of a faculty or staff member as defined above. In all cases, the faculty or staff member must be designated as the Principal Investigator and bears full responsibility for all work and training of individuals performing animal work under the protocol including any intentional or unintentional breaches of compliance that occur on the protocol.

Individuals that do not meet the above criteria may, by demonstrating sufficient cause and expertise, petition the IACUC for permission to submit an application for approval of an IACUC protocol. Such an agreement will be detailed in a contract between the individual and the University and will require the individual to comply with all relevant IACUC and University policies for the conduct of research involving the use of animals.

### 3.5 Protocol Review Criteria

In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with PHS Policy, AWRs, and the applicable US Government Principles. Since the PHS Policy further requires that the provisions of the *Guide* apply, there are many other aspects of research that an IACUC should review, such as food and water deprivation, use of noxious stimuli, and physical restraint. The *Guide* provides useful guidance on these and other practices. If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal it may bring in outside expert consultants to provide information. Such consultants will not have a conflict of interest with the research activity and may not vote on any matters pertaining to the protocol. In all cases, the onus should be on the investigator to justify and explain his or her proposed experiments to the satisfaction of the IACUC.

### 3.6 Protocol Review Procedures

The IACUC has the responsibility to review all University of Maryland activities relative to the use of all vertebrate agricultural and laboratory animals in teaching and research. The IACUC utilizes both the Full Committee review and Designated review processes. The IACUC procedures for protocol review are as follows: The Animal Study Protocol form is completed by the investigator and forwarded to the IACUC office. Upon receipt by the IACUC office, the application for protocol review is numbered and catalogued.

#### 3.6.1 Full Committee Review

All protocols for the coming meeting are placed in Word or pdf format in a secure electronic system (Blackboard) which is maintained by the office. Two (2) committee members are designated by the Chair to review each protocol.
in detail. Paper copies are provided to each reviewer and all members of the IACUC have access to the electronic system. Each reviewer is asked to prepare a review of their assigned protocols for the meeting. The Attending Veterinarian also reviews every protocol submitted. Reviews that are sent to the IACUC office are provided to the entire committee to assist in discussion of the protocols. At the convened meeting of a quorum of the IACUC, each protocol is summarized by the committee reviewers. Following discussions, the committee may approve, disapprove or require modifications in the submitted protocol (to secure approval). Any of these actions must be made with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an application or proposal in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

3.6.2 Designated Review

Most Animal Study Protocols (ASP) are reviewed in a convened meeting of the full IACUC. Designated Review (DR) of an Animal Study Protocol is an exception to this policy. Designated Review is conducted by a subset of the IACUC members and occurs outside a convened meeting of the committee. However, any member of the committee at any time may request that a protocol, revisions, or amendments be returned to Full Committee Review (FCR).

The following is the UMCP IACUC policy for when and how Designated Review is permitted. The process for designated review is equally applicable to the review of proposed significant changes to ongoing protocols. For all DR situations, the full IACUC has voted and approved this Policy which stands as prior written approval to conduct business in the following manner, and to allow a unanimous vote of the quorum to make decisions on behalf of the IACUC. Again, any member may request FCR of any protocol or addenda at any time during the process.

1. Designated Review of an Animal Study Protocol may be used in three situations: a) The full quorum of the IACUC reviewed the ASP and voted acceptance pending responses to questions or modifications to the protocol. The modifications sent by the PI may be reviewed by DR. b) A legitimate reason exists for a review to be conducted outside of a regularly scheduled IACUC meeting. c) UMCP Protocols that involve off-campus research approved by that institution’s IACUC.

2. Procedure for DR following full-committee review (1.a., above): Prior to FCR, ASPs are distributed to all committee members and at least two primary reviewers are identified to provide an in-depth evaluation. If questions or modifications to the ASP are identified during the full-
committee review, at least two members are identified to review the PI’s response to the committee’s request. Often the Chair and the Attending Veterinarian perform this second review, but other members may be selected including the original primary reviewers.

3. The second situation (1.b., above) occurs when the Chair or the Attending Veterinarian feel that there are circumstances that warrant a review of an ASP prior to the next convened meeting. It is the decision of the IACUC Chair whether the circumstances justify this review. The PI’s time constraint is generally not considered sufficient justification to warrant DR. If the Chair is in agreement, the ASP is sent to all committee members. If any member wishes full-committee review, then the ASP must be reviewed at a convened meeting with a quorum present. A committee member not requesting full-committee review within 5 business days is equivalent to approval of the DR process. If all (not just a quorum) of the voting members reply before the end of five business days, and there are no requests for FCR, the Chair may initiate designated review by referring the protocol to at least two designated reviewers. If the work involves animals in pain category II or III, the PI must also consult a veterinarian familiar with the use of animals in research. If revisions to the ASP are requested by the designated reviewers, the same reviewers must review each subsequent revision. ASPs are not considered approved unless all designated reviewers, the Attending Veterinarian and the Chair agree.

4. The third situation (1.c., above): The Chair of the UMCP IACUC and the Attending Veterinarian may conduct a Designated Review of ASPs that involve a UMCP PI, or graduate student advised by a UMCP PI, and for which the animal work will be done off-campus and has been approved by another institution’s IACUC.

3.6.3 Notification of Review Outcome

The IACUC Office notifies all Principal Investigators within one (1) week of the IACUC meeting. All communication between the IACUC and the PI falls into one of the following categories (detailed further in Section 3.8):

- Approved;
- Approved pending required modifications;
- Withhold approval; or
- Tabled for the next IACUC meeting.

3.7 Required Principal Investigator Certifications

Principal investigators are required to sign and attest to the following certifications for each protocol they submit:
1. I acknowledge responsibility for the procedures and care of animals used in this protocol. I will conduct all work in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals, USDA regulations (9 CFR Parts 1, 2, 3), the Federal Animal Welfare Act (7 USC 2131 et. Seq.), the Guide for the Care and Use of Laboratory Animals, and policies set forth by the University of Maryland IACUC.

2. I have determined that the research proposed is not unnecessarily duplicative.

3. I confirm that all individuals on this protocol are participating in an appropriate Occupational Health & Safety Program. Participation in an Occupational Health Program is mandatory for those with direct animal contact). Labs should also have DES Chemical Hygiene Plan.

4. I authorize individuals listed on this application to conduct procedures involving animals and I accept responsibility for their oversight in the conduct of this proposal.

5. I confirm that all individuals listed on this protocol as working with animals have completed the Animal User training or will be required to do so before being permitted to begin work with animals. Further, I certify that those individuals are properly trained, or will receive such training prior to working with animals, in all areas relevant to their assigned work with animals.

6. For animals held in a UMCP operated facility, I understand that in cases of necessary medical treatment, UMCP University veterinarians are authorized to provide the treatment required to sustain life, or if that is not possible, to prevent distress and pain by humane euthanasia.

7. I recognize that the veterinary staff will contact me as soon as possible using the emergency contact information that I provide in this application, but I understand that such contact may not always be possible prior to providing treatment or performing euthanasia.

8. I will notify the IACUC regarding any unexpected study results that negatively impact the welfare of the animals, including but not limited to those that require veterinary care or treatment not described in the approved protocol.

9. For animals held in a UMCP operated facility or used on the UMCP campus, I will notify a University veterinarian and the IACUC when unanticipated pain or distress, unexpected morbidity, or unanticipated mortality occurs with animals approved for use under this protocol.

10. I will obtain approval from the IACUC before initiating any change in the study design or procedures by submitting a request for minor or significant change as
appropriate. I understand that work performed without IACUC approval cannot be published with certification of IACUC approval and may result in federally-required reporting of non-compliance.

11. For all USDA Category D (anesthesia / analgesia provided to relieve potential pain) and USDA Category E (pain not relieved by anesthesia / analgesia) animal use procedures, I certify that I have reviewed the pertinent scientific literature and the sources and/or databases noted in this application and found no scientifically acceptable alternative to any of those procedures that would result in less pain or distress.

3.8 Range of IACUC Actions

Upon review of protocols, the IACUC may take one of several different actions depending upon the findings of the committee: approval, modifications required in (to secure approval), and withhold approval. An IACUC may also defer or table review of a protocol. The PHS Policy and AWRs require the IACUC to notify investigators and the institution in writing of its decision to approve or withhold approval, or require modifications in (to secure approval) of a protocol. If approval is withheld the IACUC must provide the reasons for its decision and give the investigator an opportunity to respond.

Approval
When the IACUC has determined that all review criteria, based on the PHS Policy and AWRs, have been adequately addressed by the investigator, the IACUC may approve the project, thus granting the investigator permission to perform the experiments or procedures as described. The IACUC-approved proposal may be subject to further appropriate review and approval by institutional officials due to financial, policy, facility, or other institutional or administrative considerations. Those officials, however, may not approve an activity if it has not been approved by the IACUC.

Modifications required (to secure approval)
The IACUC may require modifications to the protocol before granting approval. If the IACUC determines that a protocol is approvable contingent upon receipt of a very specific modification (e.g., receipt of assurance that the procedure will be conducted in a fume hood), or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details that any member, such as the Chair, could verify prior to granting approval.

If a study is unusually complex or involves untried or controversial procedures the IACUC may wish to impose restrictions, (e.g., approval for the use of a limited number of animals as a pilot study with a written report of interim results, or close monitoring by veterinary or other qualified
personnel). If such modifications represent significant departures, the IACUC can ask the investigator to revise the protocol to reflect the modifications imposed by the IACUC.

If the protocol is missing substantive information necessary for the IACUC to make a judgment, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be revised and resubmitted. If the IACUC wishes to shift to the designated member reviewer mode for the approval of the modified protocol, that shift should be explicitly noted in the meeting minutes and the requirements for designated review must be met.

**Withhold approval**

When the IACUC determines that a proposal has not adequately addressed all of the requirements of the PHS Policy and AWRs, as applicable, or the described activities represent inappropriate or unethical use of animals, the Committee may withhold approval. A designated reviewer may not withhold approval; this action may only be taken if the review is conducted using the full committee method of review.

As indicated above, a higher institutional authority may not administratively overrule an IACUC decision to withhold approval of a proposal.

**Defer or table review**

If the protocol requires significant clarification in order for the IACUC to make a judgment, Committee members with certain expertise are not present, the IACUC wishes to seek external consultation, or any of a number of other reasons prevent the IACUC from conducting its review, then the IACUC may wish to defer or table review until a future FCR.

### 3.9 Review of Modifications to Approved Protocols

The IACUC determines whether changes are significant or minor under the guidelines of USDA and PHS. However, the determination of a major vs. minor change is done by the IACUC.

#### 3.9.1 Significant Changes

All significant changes to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur (PHS Policy IV.C.1 and AWR 2.31(d)(1)). The University interprets significant changes to mean those that have any potential impact on the health and well-being of experimental animals. Examples of significant changes include, but are not limited to, changes:

- In the objectives of a study;
• From non-survival to survival surgery, or vice versa;
• Any change in invasiveness;
• Any change in level of pain;
• In species or number of animals needed;
• In Principal Investigator;
• In anesthetic agents or analgesics;
• In the method of euthanasia; or
• In the duration, frequency, or number of procedures performed on an animal.

Proposed significant changes require IACUC review and approval prior to initiation.

3.9.2 Minor Changes

The University interprets minor changes to mean those that do not have the potential to impact the health and well-being of experimental animals. Examples of minor changes include, but are not limited to, changes:

• In the funding source;
• In personnel (other than the PI); and
• Additional tissue collection after planned euthanasia.

3.10 Minimization of Pain and Distress

In design of the research, training or educational activities, it is the responsibility of the PI to consider and include procedures that minimize animal pain or distress. As required by the PHS Policy and the AWRs, and reiterated in the Guide, the IACUC is mandated to critically evaluate research protocols to ensure that pain and distress are minimized in laboratory animals and assure that appropriate steps will be taken to enhance animal well-being. The AWRs stipulate that the IACUC determine that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources used to determine that alternatives were not available. The Guide states that the IACUC should ensure the protocol addresses:

• Appropriate sedation, analgesia, and anesthesia;
• Criteria for timely intervention, removal of animals from study, or euthanasia if painful or stressful outcomes are anticipated; and
• Details of post-procedural care.

The protocol must provide adequate information for the IACUC to assess the potential animal pain and/or distress resulting from the study and the effectiveness of the pain- and distress-relieving agents proposed for use. Criteria for re-dosing the
animal should also be established. The AV must be consulted for any procedure that has the potential to cause more than momentary pain or distress.

Examples of procedures which the Guide suggests may have the potential to cause pain or distress, include:
- physical restraint,
- survival surgeries,
- food or water restriction,
- death as an endpoint,
- noxious stimuli,
- tumor burdens,
- intra-cardiac or orbital sinus blood sampling, and
- abnormal environmental conditions.

3.10.1 Assessing Pain and Distress

Numerous references indicate that both laboratory animals and humans receive and process noxious stimuli using similar mechanisms. An animal’s response to pain is often adaptive to reduce movement to minimize re-injury and aid recuperation. This response, however, may lead to physiological and behavioral changes which impact negatively on both the animal’s well-being and the research results.

Fundamental to the relief of pain is the ability to recognize its clinical signs in various species of animals. Due to the inability of animals to verbalize, it is essential that animal care staff and researchers receive adequate training on how to recognize clinical signs of pain and distress. It is often useful to start with a general set of observations for assessing pain and distress such as change in body weight, physical appearance/posture or changes in unprovoked and provoked behavior. The assessment system should then be modified on a case-by-case basis using specific changes that may be anticipated in a particular study.

3.10.2 Alleviation of Pain and Distress

Accepted best practices for dealing with the possibility of unrelieved pain and distress should be considered and incorporated into protocols unless there is a sound scientific rationale for deviation from those practices. The investigator must also provide an assurance that unrelieved pain will continue for only the minimum period of time necessary to attain the study objectives.

Protocol methodology should be considered that decreases the potential for pain or distress. In addition to thorough searches of the literature, this can be done through the careful use of pilot studies to determine earlier endpoints.
or less invasive alternatives. Pharmacologic treatment of pain or distress should be given as consistent with the type of pain/distress and the needs of the research question. The veterinarian must be consulted for all such protocols and should provide guidance to investigators and the IACUC. Non-pharmacologic treatments should also be employed. This may include special housing considerations, dietary and other environmental enrichments, adjustments and careful supportive care.

It is the responsibility of the investigator to show s/he has considered all the options for minimizing pain and distress that do not compromise the scientific validity of the experiment. The IACUC’s deliberations regarding the management of potential pain and distress in a protocol will be documented. Personnel should be trained in pain and distress management. The IACUC should ensure that there is a mechanism in place for prompt reporting of sick animals to the veterinary staff.

3.11 UMCP IACUC Policies

The UMCP IACUC issues all internal University policies regarding animal care and use. These documents are listed on the IACUC website:

http://www.umresearch.umd.edu/IACUC
Section 4: Monitoring of Approved Protocols

4 Continuing Review: The Annual Review

Animal Welfare Regulations require an annual review of protocols. PHS Policy requires the IACUC to conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years.

At the University of Maryland at College Park, regardless of species used, the IACUC requires an annual report on the status of each protocol, with one exception detailed below. In doing so, the Investigator verifies that completed activities were conducted in accordance with the approved protocol.

When the Annual Review form is received by the IACUC Office the protocol is considered active and experiments can be conducted while the Annual Review is under review.

The only exception to the Annual Review requirement is those protocols designated (X) by the IACUC office. The (X) designation is for work conducted in its entirety at another institution and that has initial approval and is under the direct oversight of the other institution. The University of Maryland at College Park provides only indirect oversight, all annual reviews are maintained at the original institution. However, these protocols are required to undergo the three year de novo review in order to maintain approval status.

4.0.1 Procedures for Conducting Annual Reviews

Sixty (60) days and thirty (30) days before the first and second anniversary of the protocol approval, the PI is sent an email notification requesting the status of the protocol (active or inactive) and the questions detailed above. The PI must complete the Annual Review form and return it to the IACUC Office by the first and second anniversary of the protocol approval. Review of the Annual Review form is detailed above. If a PI fails to submit an Annual Review form the following action is taken:

1. The Chair (or in his/her absence the Co-Chair) will notify the PI, the Attending Veterinarian, and the Assistant Vice President for Research and Compliance that all work under the animal protocol must cease until further notice.
2. The PI must promptly provide, in writing, a statement that he or she will not use any animals under the protocol for teaching or
research until the IACUC has reviewed and approved the annual review. If a PI fails to promptly provide such a verification statement and continues animal work, then the University may report such an incident as described in Section 8.5.

3. When the PI has successfully submitted the annual review and been approved, animal work may continue when notified by the IACUC.

4. If the PI fails to successfully renew the protocol within 30 days of the protocol anniversary date, the protocol will be considered to be permanently expired and the PI will be required to submit a new protocol in order to restart work. In addition, the IACUC may consider suspending (as described in Section 8.4.2) or terminating the PI's animal use privileges.

If a protocol is allowed to lapse while associated vertebrate animals are still being housed on campus their disposition will be determined by the IACUC Chair depending on the species involved and the level of transgression. Possible outcomes include:

- Temporary holding of animals pending a resolution of the issue;
- Transferring animals to another PI and research project; or
- Euthanized.

**4.0.2 The Purpose and Substance of Continuing Review**

The purpose of continuing review is primarily threefold:

1. To inform the IACUC of the current status of the project;
2. To ensure continued compliance with PHS, USDA and institutional requirements; and
3. To provide for re-evaluation of the animal activities at appropriate intervals.

Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IACUC's conduct appropriate and meaningful reviews of ongoing animal protocols in the same responsible manner that initial reviews are done. This means that the IACUC will not "rubber stamp" a previously approved protocol during continuing review just because it has undergone a thorough initial review. In a society where use of animals in research, testing and teaching is viewed with increasing concern, high standards of oversight must be maintained. Within the framework of federal regulations and policies, however, there is need for institutions to develop review procedures that are reasonable, meaningful and efficient, and that do not burden the IACUC or investigators with unnecessary requirements that do not contribute directly to the welfare of
the animals or provide significant information relevant to the role of the IACUC.

4.0.3 Ethical Cost-Benefit Analysis

Animal activities are most frequently justified from an ethical cost-benefit perspective. This means that any animal pain, morbidity and mortality must be outweighed or at least balanced, by the potential benefits of the project in terms of its relevance to human or animal health, advancement of knowledge or the good of society. Ethical cost-benefit assessment should be a major focus during initial and continuing review by the IACUC. This assessment should not, however, be misconstrued as the equivalent of an NIH study section review of scientific merit. Instead, it represents a threshold level of review that documents that the use of animals continues to be justified. Without such assessment, there is lack of accountability, which negates the purpose of continuing review, particularly for projects not funded by the PHS or other funding agencies with rigorous peer review.

The obvious question that arises is why an ethical cost-benefit relationship would change over time. After a protocol is initially approved by the IACUC it is possible that new information may have become available, which allows application of one of the “three R’s” (reduction, refinement, replacement). For example, new in vitro techniques or statistical methods may be discovered that could reduce the number of animals required. Or an investigator may find that a lesser degree of morbidity can be used as an experimental end point. Conversely, in some situations, it may be necessary for scientific reasons to increase the number of animals or to allow animals to reach a more advanced stage of morbidity than originally specified in the protocol. In either case, the ethical cost-benefit ratio will be altered and the IACUC should, therefore, re-evaluate this new relationship. Proposed changes in the protocol can be considered during continuing review and approved as warranted. Admittedly, there are considerations related to scientific continuity and grant requirements that may dictate whether changes in a protocol are possible. Nonetheless, it is incumbent on investigators and the IACUC alike to determine during continuing review whether the 3Rs can be applied further to the protocol.

4.1 The Third-Year Resubmission: de novo Review

The PHS Policy requires that a complete IACUC review of PHS-supported protocols be conducted at least once every three years. This triennial review is interpreted by OLAW as a requirement for de novo review, meaning that the criteria and procedures for review specified in IV.C. of the PHS Policy must be applied not less than once every three years.

The three-year period begins on the actual date of IACUC approval; the IACUC may
not administratively extend approval beyond the three years. Since protocol approval period cannot be extended, investigators must be cognizant of the protocol approval period. To aid investigators, the IACUC shall attempt to provide adequate warning of pending protocol expiration via email reminders prior to expiration. However, the reminder system is not fail-safe. It is the responsibility of the investigator to submit the third-year resubmission by the appropriate deadline date for a scheduled Full Committee Review (FCR) prior to protocol expiration. The IACUC requires a Third Year Resubmission be submitted as a new proposal, using the most recent version of the application.

4.1.1 Procedures for Conducting Triennial Review

If the PI wishes to continue work he or she must submit a new Animal Study Protocol and return it to the IACUC Office. The de novo review is detailed above. If a PI fails to submit an new Animal Study Protocol, yet continues work the following action is taken:

1. The Chair (or in his/her absence the Co-Chair) will notify the PI, the Attending Veterinarian, and the Assistant Vice President for Research and Compliance that all work under the animal protocol must cease until further notice.
2. The Chair, in consultation with the IO, will report the incident to OLAW as a violation of PHS Policy.
3. The Chair will begin an investigation into the incident. Once the investigation is completed the IACUC Office will provide the results of the investigation to the IACUC for final decision on the actions to be taken. The IACUC may consider suspending (as described in Section 8) or terminating the PI’s animal use privileges.
4. The results of the investigation and any follow-up are then reported back to OLAW.

If a protocol is allowed to lapse while associated vertebrate animals are still being housed on campus their disposition will be determined by the IACUC Chair depending on the species involved and the level of transgression. Possible outcomes include:

- Temporary holding of animals pending a resolution of the issue;
- Transferring animals to another PI and research project; or
- Euthanized.

4.2 Comparison of Protocols to Grants

Public Health Service (PHS) agencies will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites
are operating in accordance with an approved Animal Welfare Assurance and have provided verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy. Additionally, PHS agencies will not make an award for research involving live vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with the Policy and has filed the necessary assurance with OLAW.

Regardless of when the review occurs, the investigator should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IACUC. Therefore, a copy of the of the funded or unfunded grant proposal application may be requested by the IACUC and reviewed by designated member(s) to confirm that all research outlined in the grant is included in the approved IACUC protocol.

4.3 Post-Approval Monitoring

As stated by the Guide, post-approval monitoring is a duty of the IACUC and should continue throughout the life of the protocol. The IACUC uses several methods to ensure that protocols are in compliance with the stated goals and experiments designated in the protocol, these are;

- Semi-annual inspections of animal facilities and laboratory spaces;
- Continuing protocol review through annual reviews;
- Veterinary or IACUC observation of surgical procedures; and
- Daily observation by animal care staff.
Section 5: Training in the Humane Care and Use of Laboratory Animals

5.0 Statement on Training

All staff working with laboratory animals must be appropriately qualified to do so in order to ensure the humane treatment of animals. Training is a classic performance standard where the emphasis is on the outcome (i.e., all personnel are qualified to do their jobs). Although the PHS Policy and Animal Welfare Regulations (AWRs) do not specify a particular program or the frequency with which a program should be offered, the requirement for competence is mandatory.

The AWRs, in Sec. 2.32 (a) and (b), specify:

“It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility’s responsibilities....”

The PHS Policy, Section IV.C.1.f. places responsibility specifically with the IACUC to ensure that personnel conducting procedures on research animals are appropriately qualified and trained in those procedures.

Personnel’s training in the care and use of research animals is also an important aspect of the alternatives concept (replacement, reduction and refinement). Training in the recognition and alleviation of animal pain, distress, and abnormalities addresses refinement. Similarly, training in the conduct of animal procedures prepares staff to work without causing unnecessary harm to the animal. Technical proficiency also invokes reduction by avoiding wasted animal lives through failed procedures.

5.1 Who Should Receive Training?

All personnel must receive training if they interact directly with or work in the vicinity of animals. Training made available is specific to the animal species involved and to the kind of procedures to be performed or animal-related interactions.

For training purposes, staff can be grouped as:

- Direct animal users
- Indirect animal users
• Other (e.g. maintenance or support staff)

Training is also available to temporary staff, such as students, visiting scientists, or other individuals who would benefit from official training. PIs are responsible for identifying these people and assuring that appropriate training is accomplished.

5.2 Training Requirements for University Laboratory Animal Users

The IACUC requires that all personnel that conduct research and teaching that involves handling, manipulating, or performing procedures on live vertebrate animals, whether in the laboratory or the field, complete this training.

The initial IACUC training is a three-fold process:

1. Completing the PI/Animal User training course scheduled through the office of the Attending Veterinarian. This training includes both required animal user training and the mandatory occupational health training.
2. Enrolling in the Occupational Health and Safety Program administered by the Occupational Health Office at the Health Center.
3. Hands-on or specific research training given by the PI. This training is specific to the research or teaching being conducted and may vary from individual to individual within a lab. However, the lab is required to maintain training records on all animal users within the lab including what procedures they have been trained on, by whom, and the date of training. The PI assumes full responsibility for assuring that all individuals are competent in the procedures needed to conduct research or teaching activities.

Refresher training for all animal users and Principal Investigators (PIs) is required every three (3) years. Refresher training consists of the following two items:

1. Completing an on-line training course offered by AALAS Learning Library titled “Working with the IACUC – non-VA version”.
2. Re-enrolling, or keeping enrollment up-to-date, in the Occupational Health and Safety Program.

5.3 Education and Training for IACUC Members

5.3.1 New Member Orientation

New IACUC member orientation consists a didactic training course offered by the Attending Veterinarian, receipt of documents such as a copy of the Guide and other reference documents, and specific procedural related training as provided by the Chair and/or IACUC Office.

The objectives of providing this information are the following;
• To introduce members to the role of the IACUC and its evolution;
• To provide the basic information necessary for IACUC members to discharge their responsibilities; and
• To provide a forum for response to, and discussion of, members’ concerns and questions.

5.3.2 Continuing Education

Continuing education for IACUC members usually occurs at every IACUC meeting. The objectives of providing ongoing training for IACUC members is to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practices, and institutional policies. It also provides a regular forum for the IACUC to discuss concerns or questions brought forth by the faculty, staff, and members of the community.

All members will also complete the 3-year on-line refresher course offered by the AALAS learning library. Specific modules are assigned by the IACUC Office.
Section 6: Occupational Health Program

6.0 Statement of Purpose

The purpose of the Animal Handler Health and Safety Program (AHHSP) is to protect the health of personnel and laboratory animals by providing:

1. Health and safety information related to the use and care of animals.
2. Occupationally indicated immunizations.
3. Clinical care for individuals with animal related injuries and illnesses.
4. Appropriate personal protective equipment

6.1 Responsible Offices for Oversight

University Health Center (UHC)
   Urgent Care: (301) 314-9144
   Occupational Health: (301) 314-8172
   http://www.health.umd.edu/

Department of Environmental Safety (DES)
   (301) 405-3960
   http://www.des.umd.edu/

Institutional Animal Care and Use Office (IACUC)
   Amanda Underwood, IACUC Manager
   (301) 405-5037
   http://www.umresearch.umd.edu/IACUC/

Department of Laboratory Animal Resources (DLAR)
   Dr. Doug Powell, University Attending Veterinarian
   (301) 405-4921
   http://www.umresearch.umd.edu/IACUC/carf.htm

6.2 Who is required to enroll?

1. Enrollment in the AHHSP is required prior to working with any species of vertebrate animals.

2. Direct animal contact is defined as touching live animals, unpreserved animal tissues or body fluids, dirty animal cages, dirty cage accessories, animal waste or carcasses.
3. Enrollment is required for the following groups when direct animal contact is anticipated:
   A. Faculty
   B. Animal caretakers
   C. Animal care or research technicians
   D. Graduate students and post doctoral fellow in teaching and research labs
   E. Undergraduate students working in research labs
   F. Student employees
   G. Facility Management employees (Pest Control) Animal facility employees

4. Indirect animal contact is defined as entering areas where animals are used or housed, but without handling or touching the animals.

5. Enrollment in the AHHSP is not required for individuals with indirect animal contact working in areas such as laboratories, maintenance, housekeeping, security, and any animal environment. Academic departments that use animals, Facilities Management, and the UMD Police Department will be provided the AHHSP. Facility supervisors will provide training as outlined in the AHHSP to individuals assigned to designated animal zones.

6. Enrollment in the AHHSP is not required for students in course curricula that require the use of vertebrate animals. Course instructors will provide training as outlined in the AHHSP.

7. Visiting scholars and volunteers who handle vertebrate animals are required to enroll in the AHHSP if they handle animals for more than 3 months during their visit or work with bats for any amount of time. They are not required to participate in the AHHSP if they already participate in an analogous program at their home institution.

8. Organizers of University sanctioned events (e.g., Ag Day) will provide training as outlined in the AHHSP to all volunteer workers. Appropriate hand washing stations and signage to alert visitors of potential hazards will be provided.

6.3 Length of Enrollment

Enrollment is valid for three (3) years after which point the individual must submit an update to the Occupational Health and Safety Office.

6.4 Full Occupational Health and Safety Policy

Is available at the IACUC website www.umresearch.umd.edu/IACUC
Section 7: Semi-annual Program Review and Facility Inspections

7.0 Semi-annual Reviews

The PHS Policy and Animal Welfare Regulations (AWRs) stipulate that the IACUC must review the program for humane care and use of animals at least once every six months, using the Guide as the basis for evaluation. Federal requirements also state that the IACUC must inspect all institutional animal facilities at least once every six months.

7.1 Program Review

The animal care and use program review includes an evaluation of institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC recordkeeping and reporting procedures. It also includes a review of the adequacy and appropriateness of the veterinary medical care program, the training program for personnel, and the occupational health and safety program.

The IACUC will review at least once every six months the University’s program for humane care and use of animals, using the Guide as a basis of evaluation. All members, especially non-affiliated and non-scientist members, are encouraged to take part in inspections.

7.2 Facility Inspection

The IACUC uses the Guide for the Care and Use of Laboratory Animals and the Guide for the Care and Use of Agricultural Animals in Research and Teaching to evaluate all animal facilities on campus. The IACUC procedures for conducting semi-annual program reviews are as follows:

1. The IACUC conducts facility inspections once every six months, generally held in April and October. These inspections are conducted by at least two voting members of the IACUC.
2. Findings from the facility inspection, including a schedule for correction of deficiencies, are compiled and prepared for IACUC review and discussion at a regularly convened IACUC meeting in conjunction with the Program Review. The IACUC Manager requests additional comments and minority views from all members present.

7.3 Laboratory Inspections

Under USDA and OLAW guidance, the IACUC also inspects all facilities where
surgical manipulations, animal holding, and euthanasia take place in PI laboratories.

1. Laboratory inspections are held once annually except for those labs where survival surgery takes place, which are inspected twice a year in conjunction with the facility inspection schedule. These inspections may be conducted by members of the IACUC or by individuals designated as representatives of the IACUC.

7.4 Documentation

A written report of the semi-annual program review and facility inspection is prepared. The AWRs require the report to be signed by a majority of the IACUC members at a convened meeting. The report describes the institution's adherence to the AWRs, PHS Policy, and the Guide, and identifies specifically any deviations from these documents.

The report will indicate whether or not any minority views were filed, and minority views will be included in the final document. A copy of the report is sent to the IO and is kept on file for a minimum of three years in the Office of Research Compliance. The University retains all inspection reports and provides them to federal agencies as required, including any minority opinions.
Section 8: Animal Welfare Concerns and Non-Compliance Situations

8.0 Evaluation of Animal Care and Use Concerns

To help ensure that laboratory animals receive humane care, use or treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC must review and, if warranted, address any animal-related concerns raised by the public or institutional employees. Procedures must be established to ensure that concerns are communicated to the IACUC. The Committee must review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions.

8.1 Methods for Reporting

To facilitate communication, there are a number of options available to communicate concerns about animal care and use at the University of Maryland at College Park, or to report instances of suspected non-compliance with laws, rules, regulations and policies. The names and phone numbers of contact persons including the Attending Veterinarian, the IACUC Manager, the Director of the Office of Research Compliance, and the Institutional Official should be posted in or near the entrance to animal facilities and are listed on the IACUC website, readily available to institutional employees. This information is also provided to participants in the PI/Animal User class including the email address that allows confidential complaints to be made (iacuc@umd.edu).

Although written concerns are more convenient to handle, complainants may not be willing to submit them in this manner. In such cases, the individuals who receive concerns should document them fully to ensure that the issues are clear and to prevent misunderstandings.

Requests for anonymity should be honored to the greatest extent possible. This includes protecting the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The policy of the University is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

8.2 Procedures for the Investigation of Animal Care and Use Concerns

8.2.1 Initial Evaluation and Actions

The IACUC requests that any concern be brought to the committee’s
attention. Concerns may include situations or activities ranging from those in which animals are reported to be in immediate, actual or perceived jeopardy to those in which violations of the AWRs or institutional Animal Welfare Assurance are alleged to be occurring but animals are not in apparent danger. They may focus on allegations of past policy and procedure violations or protocol non-compliance.

The course of action taken by the IACUC should be driven by the potential significance of the alleged situation. For example, conditions that reportedly jeopardize the health or well-being of animals should be evaluated immediately. To cope promptly with such situations, the IACUC Chair is authorized to halt procedures which they believe do not comply with institutional policies until the IACUC’s investigation committee can be convened to consider the matter formally. Similarly, situations that may involve potential criminal activity or human safety should be reported promptly to the institution’s law enforcement or occupational health and safety officials. Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be deferred merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

8.2.2 The IACUC Investigation

Upon receipt of a concern, the IACUC Chair will conduct the initial fact-finding investigation to determine the extent and details of the complaint. Once those facts are gathered the IACUC Chair will assign a subcommittee to conduct a complete investigation. The Chair may assign current or former IACUC committee members as he or she sees fit. The subcommittee will review the complaint and conduct further investigation. The subcommittee will report initial findings to the Chair regarding what follow-up may need to occur, this may include reporting the issue to the Institutional Official and federal agencies. If immediate action appears warranted because animal or human welfare may be compromised, the IACUC will notify the IO immediately and proceed accordingly. 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 to protect animal or human welfare. In accordance with the AWRs, if an activity is suspended, the IO shall report that action to APHIS and any federal agency funding that activity. If the PHS supports the activity in any way, the IACUC, through the IO, must promptly notify OLAW.

8.2.3 Final Investigation

When the subcommittee investigation is complete it will report back to the IACUC. It is important to avoid actual or perceived conflicts of interest in this process.
The IACUC should charge the designated person or group with its requirements for information gathering and impose a completion date. The assigned completion date will depend on the IACUC’s determination of whether immediate remedial action may be required. The nature of the information required will vary depending on the circumstances, but often involves:

- Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
- Observing the animals and their environment; and
- Reviewing any pertinent records, (e.g., animal health records, protocol, and other documents).

The subcommittee will provide a report to the IACUC, which summarizes:

- The concern(s),
- The results of interview(s),
- The condition of animals and their environment, and
- The results of records and other document reviews.

The report should also contain:

- Any supporting documentation such as correspondence, reports, and animal records,
- Conclusions regarding the substance of the concerns vis-à-vis requirements of the AWRs, the PHS Policy, the Guide, and institutional policies and procedures, and
- Recommended actions, if appropriate

### 8.2.4 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 was valid.

### 8.3 Non-compliance with IACUC Protocol, Policies, Procedures, or Decisions

Protocol non-compliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include performing unauthorized surgery, unauthorized persons participating in a research project, or injecting drugs that the
IACUC has not approved. When faced with protocol noncompliance, the IACUC’s first step, if possible, should be to find a way to bring the protocol into compliance.

If allegations of animal mistreatment or protocol non-compliance are verified, the IACUC can apply sanctions. If, in the opinion of the IACUC, sanctions are not appropriate, they need not be applied. A clearly minor and unintentional misinterpretation of an IACUC policy that has created no problem for an animal is an example of where a verified allegation of protocol non-compliance might lead to an explanation, not a sanction.

8.4 Consequences of Non-Compliance

Subsequent actions of the IACUC may include:

- Implementing measures to prevent recurrence;
- Notifying the IO and the AV of its actions;
- Notifying funding or regulatory agencies, as required; and/or
- 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.).

8.4.1 Institutional Sanctions

Examples of institutional sanctions that have been devised include:

- counseling;
- issuing letters of reprimand;
- mandating specific training aimed at preventing future incidents;
- monitoring by the IACUC or IACUC-appointed individuals of research, testing, or training that involving animals;
- temporary revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;
- permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals; and recommending to the IO that institutional (e.g., reassignment, termination of employment) sanctions be imposed.

8.4.2 Suspension of Animal Activities

The IACUC is empowered to suspend a project if it finds violations of University policy, PHS Policy, the Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and a vote for suspension by 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 and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly.

8.5 Reporting Requirements

Failure by research personnel to follow Federal and/or University regulations, guidelines, policies and/or procedures may require reporting to the appropriate institutional, local, state and/or Federal agencies. Violations may include, but not limited to

- Serious or continuing non-compliance with the PHS Policy;
- Serious deviations from the Guide; and
- IACUC suspensions.

8.5.1 Principal Investigator Reporting

The Principal Investigator and protocol personnel must report any serious or continuing non-compliance with an IACUC protocol, policies, procedures, decisions, or deviations from the Guide. The report should be on University/departmental letterhead, addressed to the IACUC Chairperson, and emailed (preferred) to the Chair and the IACUC Manager. The self-report of non-compliance should include the following information:

- relevant grant or contract number(s);
- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by PI to address the situation; and
- description of short- or long-term corrective plans and implementation schedule(s).

8.5.2 IACUC and IO Reporting

The IACUC, through the IO, will submit an annual report to OLAW by January 31 of each year. The University’s reporting period is January 1 – December 31. The report will include:

- Any change in the accreditation status of the University (e.g. if the University obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the University’s program for animal care and use as described in the Assurance, or any change in the
IACUC membership. If there are no changes to report, the University will provide written notification that there are no changes.

- Notification of the dates that the IACUC conducted its semiannual evaluations of the University’s program and facilities (including satellite facilities) and submitted the evaluations to the IO.

The IACUC, through the IO, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- Any serious or continuing non-compliance with PHS Policy.
- Any serious deviations from the provisions of the Guide.
- Any suspension of an activity by the IACUC.

All investigations by subcommittees and/or the IACUC will be reported internally at the completion of the investigation to the following individuals, as appropriate:

- Principal Investigator (PI)
- PI’s Department Chair
- PI’s College Dean
- Chair, IACUC
- Co-Chair, IACUC
- Director, Office of Research Compliance
- Attending Veterinarian
- Director, ORAA (if project is externally funded)
- Vice President for Research

8.5.3 Response to External Requests for Information

In accordance with applicable policies, guidelines and regulations, upon request, the University will make available to the public all IACUC meeting minutes and any documents submitted to or received from funding agencies with the latter are required to make available to the public. Redaction of proprietary and private information is allowed but “must be done so judiciously and consistently for all requested documents.” In addition, the IACUC will adhere to requirements for providing copies of documents as specified in the Maryland Public Information Act.
Section 9: Recordkeeping

9.0 Maintaining IACUC Records

The institution is responsible for maintaining:

- The Assurance approved by OLAW;
- Minutes of IACUC meetings;
- Records of IACUC activities and deliberations;
- Minority IACUC views;
- Documentation of protocols reviewed by the IACUC, and proposed significant changes to protocols;
- IACUC semi-annual program evaluations and facility inspections, including deficiencies identified and plans for correction; and
- Accrediting body determinations.

All record are kept for minimum of three (3) years, with the exception of records that relate directly to protocols, which must be kept for the duration of the activity and for an additional three (3) years after completion of the activity.

Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the Guide and with commonly accepted professional standards.

9.1 Meeting Minutes

Review of proposals by the IACUC invokes a deliberative process, and the PHS Policy and AWRs require that the institution maintain “minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations” (PHS Policy IV. E; 9 CFR Part 2 Subpart C 2.35 (a)(1)). The IACUC has some latitude in the degree of detail in these minutes.

Recorded minutes from IACUC Full Committee Reviews are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the Committee such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or non-compliance would be recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IACUC from members who have served on the Committee and observed the procedures being proposed, served as reviewers for protocols involving similar procedures (where their questions were answered), or participated in past IACUC discussions about the procedures.
Minutes of each FCR are recorded in writing and include records of attendance, a summary of the issues discussed and the resolution of issues, and the results of IACUC votes on protocols.

- **Records of attendance**

  Although members may arrive late or leave during a meeting, generally a member is marked as either present or absent. An exception would be when the IACUC member leaves the meeting room during discussion of a protocol on which that member is a participant. If the temporary absence of a member drops the number of members present below the quorum no official actions may take place and this will be noted in the minutes.

- **Activities of the Committee**

  Activities of the Committee include, but not limited to, corrections or approval of previous minutes; presentation of program, policy, facility and compliance reports; and decisions on policies, protocols, and amendments.

- **Deliberations of the Committee**

  A deliberation of the Committee refers to the discussion and reasons leading to particular IACUC decisions. Minutes should include as a minimum a summary of the key points discussed prior to a committee decision.

Completed minutes are distributed to all IACUC members. Minutes are discussed at a subsequent convened meeting of the IACUC (e.g., FCR) and the Committee votes on approval. All records are maintained with the Office of Research Compliance and are accessible by the Institutional Official whenever he or she requires.

### 9.2 Protocols

The PHS Policy and the AWRs require that animal applications and proposed significant changes be retained for the duration of the animal activity and for an additional three years after the end of the activity. Proposals submitted to the IACUC must be kept for three years even if approval was not granted or animals were not used. The records must show whether or not IACUC approval was given.

### 9.3 Other Records

Both the PHS Policy and the AWRs require that the University retain the semiannual Program Review and Facility Inspections Report and any recommendations of the IACUC. PHS Policy also requires that the OLAW Assurance and reports of accrediting agencies (e.g., AAALAC) be kept on file. USDA requires additional records on dogs and cats acquired, transported, sold, or euthanized by the research facility. Animal health records are not usually maintained by the IACUC but are kept in the animal
facility or in research laboratories. All these records must be kept for at least three years; and must be accessible to OLAW, USDA/APHIS, and funding agencies for inspection or copying.