Ohio University Institutional Animal Care and Use Committee Policy Manual

I. Regulatory

Ohio University maintains an institutional animal care and use program with U.S. Department of Agriculture (USDA) Animal Welfare Act (AWA) regulations and the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) regulations governing the use of vertebrate animals.

The program operates under the National Institutes of Health (NIH) Animal Welfare Assurance number A3610-01. The current approval is effective from July 7, 2017 through July 31, 2021. The program also follows the requirements of the United States Department of Agriculture (USDA) Animal Welfare Act for applicable species. The Ohio University USDA registration certificate number is 31-R-0082. The current registration is effective through August 30, 2020. Ohio University is fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, int.) The facilities have been accredited since 2000.

A. United States Department of Agriculture (USDA)

The U.S. Department of Agriculture (USDA), through its division of the Animal and Plant Health Inspection Service (APHIS) (http://www.aphis.usda.gov/ac/), administers the 1996 Animal Welfare Act (AWA) (http://www.aphis.usda.gov/ac/awapdf.pdf) and its amendments, codified at 7 USC §2131 et. seq. and CFR Title 9. 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 certain species being used, or intended for use for research, teaching, testing and experimentation. Exemptions are present for some use of animals.

The AWA requires the establishment of an Institutional Animal Care and Use Committee (IACUC) to review all activities using animals to ensure their humane use in research activities and to conduct semiannual assessments of the institution's animal care and use program, including inspections of all animal study areas and facilities. Ohio University is subject to random inspections by the USDA and files an annual report with USDA concerning its animal care and use program.

B. Public Health Service (PHS), National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (*Policy*) was created to implement the provisions of the Health Research Extension Act of 1985. The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) (http://grants1.nih.gov/grants/olaw/olaw.htm) administers the Policy.

The Policy applies to institutions conducting U.S. Public Health Service-supported projects involving live vertebrate animals. The *Policy* requires that the institution establish an Institutional Animal Care and Use Committee. The IACUC, using the *Guide for the Care and Use of Laboratory Animals* (*Guide*), is responsible for reviewing the use of animals and conducting semiannual assessments of the institution's animal care and use program, including inspections of all animal study areas and facilities.

II. Lines of Authority and Responsibility

The lines of authority and responsibility for administering the program and ensuring compliance are as follows.

A. Institutional Official

The Vice President for Research serves as the Institutional Official (IO) with authority to legally commit Ohio University to meet federal regulatory guidelines. This authority is delegated from the President of Ohio University. The IO is responsible for appointment of members to the Institutional Animal Care and Use Committee (IACUC). The IO is the signatory authority for the Ohio University Assurance.

B. Attending Veterinarian

The attending veterinarian (AV) is a part time (consultant) position reporting to the Institutional Official. The AV is a voting member of the IACUC and has authority to implement the regulatory requirements of the Public Health Service and Animal Welfare Act. The Attending Veterinarian provides routine veterinary care and preventive medical care, as well as on-call emergency care and consultation. The Attending Veterinarian is available to make recommendations concerning preventive health programs for animals, disease treatment, analgesia, post-operative recovery, euthanasia, and general animal welfare. When the Attending Veterinarian is not available veterinarians from his private practice serve as back up.

C. Director of the Office of Research Compliance

The Director of the Office of Research Compliance reports directly to the Vice President for Research. This position staffs the IACUC and is responsible for administration of the IACUC records and maintaining federal records and reports. The Office of Research Compliance also provides monitoring of approved animal use protocols.

III. Institutional Animal Care and Use Committee (IACUC)

The IACUC is established pursuant to the Animal Welfare Act and the PHS Policy and reports to the Institutional Official. All animal use for teaching, testing or research, conducted by faculty, staff or students at or under the auspices or financial support of Ohio University, including the regional campuses, must be reviewed and approved by the IACUC.

For research projects that occur elsewhere, but involve Ohio University faculty, staff or students, the investigator must submit to the Ohio University IACUC the approval from that institution. The Ohio University IACUC may choose to defer to the IACUC at the site where the work will be occurring if an approval is in place and the institution has the appropriate current PHS assurance and USDA registration (if applicable).

The IACUC makes written recommendations to the Vice President for Research, the Institutional Official, regarding any aspects of the institution's Animal Care and Use Program or training of personnel with regard to animal care and use.

A. IACUC Committee Membership

The Institutional Official appoints the members of the IACUC, typically for renewable, three-year terms. The IACUC consists of not less than five members of varying professional and personal backgrounds, including at least one veterinarian, one non-scientist, one practicing scientist, and at least one person who is not affiliated with Ohio University in any way other than as a member of the IACUC (community member). The community member may be either a scientist or non-scientist. No more than three members shall be from the same department within Ohio University.

Alternate IACUC members may be appointed by the Institutional Official. There is a one to one designation of alternates to assure that the IACUC will be duly constituted according to regulatory requirements. Alternates are encouraged to attend IACUC meetings and participate in all IACUC activities. Alternates may contribute to the quorum and vote only if the regular member for whom he or she serves as alternate is absent. Alternates are expected to vote according to their conscience and not represent the position of the regular member.

Representatives from the University Library and Environmental Health and Safety serve as non-voting appointments to the IACUC.

A tenured Ohio University faculty member chairs the IACUC; they may not be the Director of Animal Resources or the Attending Veterinarian. The IACUC may, from time to time, consult with other professionals (i.e., biostatisticians, legal counsel, etc.) in fulfilling its responsibilities.

Support staff for the IACUC is provided by the Office of Research Compliance.

B. IACUC Member Expectations

Members are expected to complete the orientation requirements for service on the committee, attend meetings regularly, participate in semiannual facility inspections and program reviews, and provide feedback on protocol reviews prior to the convened IACUC meetings. Members who fail to attend a majority of IACUC meetings in a twelve month period may be removed from membership.

C. Conflicts of Interest

To assure integrity of the program, IACUC members are responsible for disclosing any potential or perceived conflicts of interest that may exist for any business discussed by the IACUC. Common conflicts of interest include being an investigator on a study under review, having a financial interest in a study under review, being a family member of an investigator with a study under review, etc. Members with conflicts are expected to disclose these prior to discussion and recuse themselves from deliberations and voting. They may not serve as a part of the quorum for the study for which they recuse themselves.

D. IACUC Review Procedures

The IACUC reviews and has the authority to approve, require modifications in order to secure approval, or disapprove all research activities involving animal subjects as covered by this program. The IACUC has authority to require progress reports from investigators and to oversee the conduct of the study.

Research involving animal subjects, as covered by this program, and which has been approved by the IACUC may be subject to further review and approval or disapproval by the Institutional Officials. The Institutional Officials may not, however, approve research if it has not been approved by the IACUC.

E. General Processes

Investigators are notified in writing of the IACUC's decisions on protocol reviews.

IACUC members with a conflict of interest related to a protocol under review may not contribute to the quorum and may not vote on the protocol in question. The IACUC member is asked to leave the meeting during the discussion of the protocol.

Written documentation of the convened committee's deliberations is kept in the minutes. Issues raised with the protocol during pre-review, or as part of a designated member review, are also kept in the individual protocol file.

No initiation of animal activities or submission of an IACUC approval date to NIH as part of a grant application may be made without final approval of the IACUC protocol covering activities within the grant.

The IACUC has determined that protocols meeting the criteria in Section IV.A., may automatically be routed to designated member reviewers by the chair, without notification of the rest of the IACUC. The IACUC will be informed of which protocols have been assigned to designated member review under these criteria, on the agenda of each month's meeting.

IV. IACUC Review

The Ohio University IACUC reviews all protocols with the same process, including those for teaching. Protocols with species covered by the United States Department of Agriculture are reviewed yearly; other protocols are reviewed every three years. Protocols are reviewed with the same process regardless of funding source. All protocols with the potential for pain and distress are reviewed by the Attending Veterinarian, who also provides oversight for these protocols.

A. Criteria for Designated Member Review Versus Full Committee Review

The IACUC has determined that protocols meeting the following criteria may automatically be routed to designated member reviewers by the chair, without notification of the rest of the IACUC. The IACUC will be informed of which protocols have been assigned to designated member review under these criteria, on the agenda of each month's meeting.

1. Addenda to currently approved protocols that include:
    a. Changes in non-PI, non-surgical staff
    b. Procedure site changes
    c. Animal number changes that do not exceed 10% of the original requested number
    d. Changes in procedures that do not impact animal welfare
    e. Changes in strains, breeds of animals

2. Protocol submissions for approval that are:
    a. Commercial antibody production/use
    b. Noninvasive field studies
    c. Noninvasive use of animals for film/media/art

The IACUC has determined that new protocols must be initially reviewed in a convened meeting of the IACUC if they include the following criteria:

1. Unrelieved pain and distress
2. Death as an endpoint
3. Multiple survival surgeries

Once reviewed in a convened meeting the final approval may be by designated member review. Addenda and renewals, once the initial approval has been made, may be reviewed by designated member review.

- Protocols, renewals or addenda are submitted to the Office of Research Compliance.
    - New protocols are assigned an identification number by the IACUC Administrator.

- Assignment to review status
    - Protocols or addenda meeting the criteria for automatic designated member review may be assigned to designated member reviewers by the chair without notification of the rest of the IACUC members.
        - All IACUC members will receive notice of what has undergone designated member review each month, on the monthly meeting agenda.
    - Protocols containing elements that require review in a convened IACUC meeting are routed to all IACUC members for review and assigned to a meeting agenda.
        - If the protocol is assigned to a convened IACUC meeting, all IACUC members are asked to return pre-review questions or concerns to the IACUC administrator for distribution to the Investigator prior to the convened IACUC meeting.
    - Protocols not meeting the criterion for automatic designated member review and that do not contain elements requiring review in a convened IACUC meeting may be assigned to designated member review, if the chair requests this and no IACUC members object.
        - All IACUC members are then notified that the protocol or addenda has been assigned to designated member review and are given a minimum of 72 hours to call for full review.
        - The chair assigns designated member reviewer(s) for the protocol.

B. Full Committee Review Process

If the protocol, renewal or addendum is assigned for review at a convened IACUC meeting, the IACUC members are asked to conduct a pre-review and return issues to the IACUC administrator for distribution to the Primary Investigator (PI).

If the chair identifies a need for an external consultant they are sent the protocol, renewal or addendum.

The Attending Veterinarian and other IACUC members review the protocol for completeness and compliance with information requirements. Issues and requests for clarifications are returned by the IACUC members to the IACUC administrator, who compiles the issues and sends them to the PI.

PI responses, clarifications and/or revised protocols are sent to the IACUC members prior to the convened IACUC meeting, or distributed at the IACUC meeting.

The protocol is discussed at a convened IACUC meeting containing a quorum of the IACUC. A majority of a quorum of the IACUC votes to determine the final disposition of the protocol, renewal or addendum. The IACUC may vote to:

1. Table the protocol to a future meeting if significant issues remain, or if the

IACUC lacks sufficient information to determine approval.
2. To approve the protocol.
3. To approve the protocol and request that administrative changes (spelling, formatting, grammar, minor revisions not affecting animal welfare, or approval decisions) are made prior to placing in the protocol file.
4. To withhold approval. If the IACUC decides to withhold approval, a written notification of the reasons for the decision will be provided to the Institutional Official and the PI. The PI is given the opportunity to respond in person or in writing.

The IACUC may opt to ask that the chair assign the protocol to designated member review if they determine the issues do not warrant tabling, but require revisions prior to approval. If any IACUC member at the convened meeting requests that a protocol remains under full committee review it will be tabled to the next convened IACUC meeting. The IACUC has adopted a policy that members who are not at the meeting agree to allow the protocol to move to designated member review without further notification.

C. Designated Member Review Process

One or more designated member reviewer(s) are appointed by the IACUC Chair.

The IACUC is notified of the assignment to designated member review and is provided a minimum of 72 hours to request that the protocol, addendum or renewal be reviewed in a convened IACUC meeting.

Designated reviewer(s) either contact the PI directly to discuss the protocol, addendum or renewal, or forward issues and requests for clarifications to the IACUC administrator, who compiles and sends them to the PI.

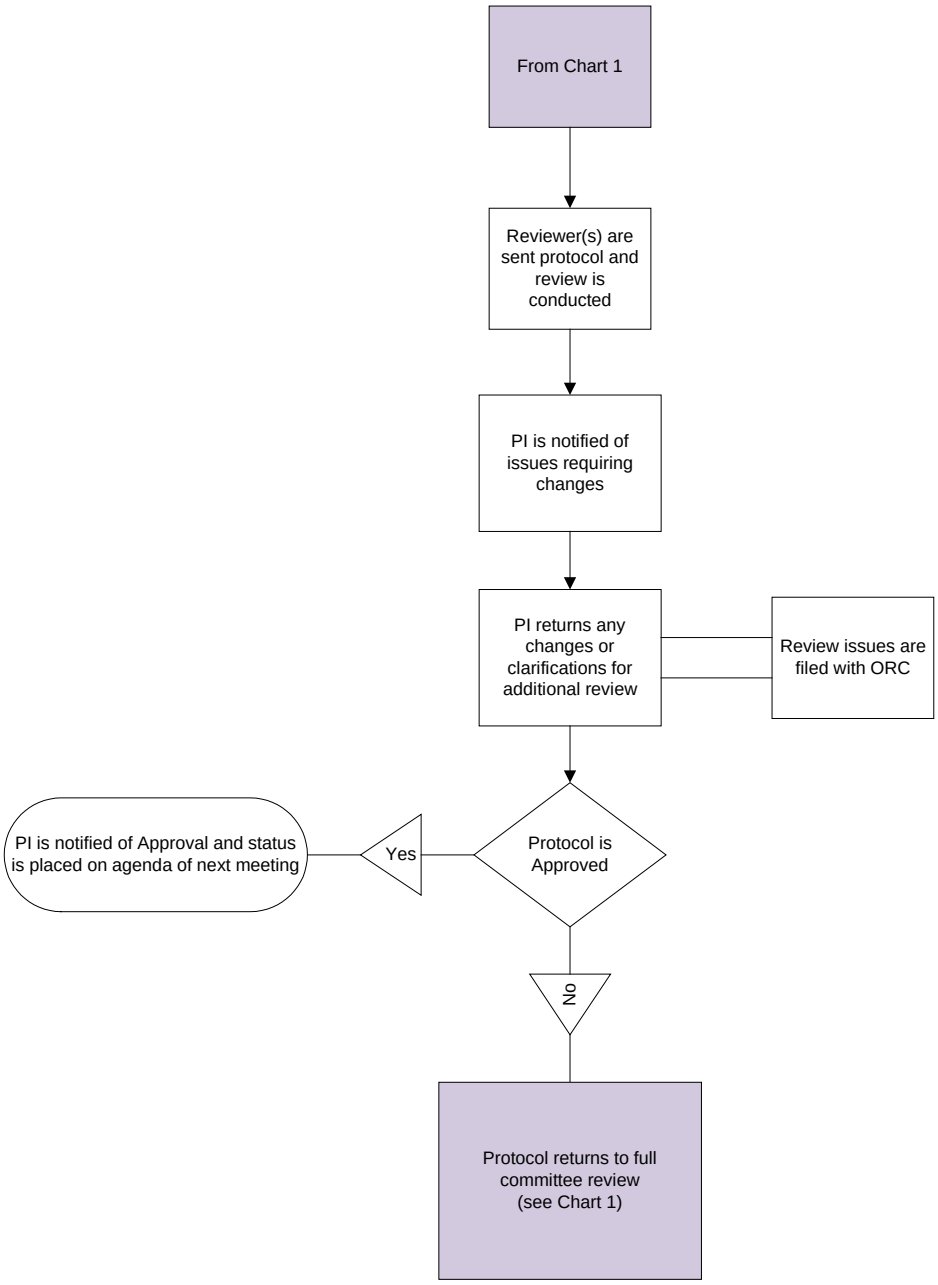
Once the PI has returned any needed changes or clarifications to the designated member reviewer(s), the designated member reviewer(s) either approve the protocol, renewal or addendum, or call for full committee review if issues remain unresolved.

Documentation of the IACUC review and approval are kept in the protocol file. Once the designated reviewer(s) have documented approval, the IACUC administrator processes an approval letter and notifies the PI of the approval.

If the protocol, renewal or addendum is called to full committee review by any of the designated reviewers, it is placed on the agenda of the next meeting and IACUC members are notified.


CHART 1
Protocol Review Process
Protocol (new or renewal) submitted for review to Office of Research Compliance
Attending vet assures that protocols with potential for pain and distress have received input
Protocol is assigned a number and entered in database
Meets Auto DR criteria
Yes
Chair assigns Designated Reviewers
Move to Chart 2
No
No
Chair requests DR
Yes
Members are notified of DR status
Member calls for full review within 72 hours
No
Yes
Protocol is sent to all committee members
Pre-review is conducted
EHS reviews for safety concerns Occupational reviews for health concerns
External consultant reviews if requested by chair
Attending Veterinarian reviews
Issues are compiled and sent to PI prior to meeting
Protocol is tabled to next convened meeting
Protocol reviewed in convened meeting
Additional Information needed to complete review
Committee requests Designated Review
Move to Chart 2
Approved
No
PI and IO are notified of decision to withhold approval and reasons for withholding approval
yes
PI is notified of approval

CHART 2
Designated Review Process



D. Continuing Protocol Review

A successful program for animal care and use must incorporate elements of oversight in order to assure that the proposed work is following guidelines and to monitor the effectiveness of the institutional training and review programs. Ohio University's oversight program includes conducting continuing review of previously approved activities at appropriate intervals, not less than once per year for USDA protocols, and not less than once every three years for other protocols. All renewals are considered to be *de novo* reviews.

V. Oversight of Research Activities

A. Semiannual Evaluations of the Animal Care and Use Program and Facilities

The Office of Research Compliance (ORC) facilitates the semiannual program and facilities evaluations that are mandated by federal regulations. The ORC assists in scheduling inspections of laboratories and housing areas. The ORC distributes the current policies and forms and website materials for IACUC review, and ORC receives and compiles member comments. When necessary ORC edits and updates these documents.

1. Review of the Animal Care and Use Program

Twice each year (every 6-months) the IACUC reviews the Animal Care and Use Program and inspects all facilities where animals are housed and/or used. The IACUC utilizes the *Guide* and the Animal Welfare Act regulations as the principle documents in conducting these reviews.

A subcommittee of the IACUC, composed of at least two members, conducts these reviews and inspections. All IACUC members are encouraged to participate, and no IACUC member wishing to participate in any review or inspection shall be excluded. The subcommittee may invite *ad hoc* consultants to assist in the reviews and inspections. This semiannual evaluation includes the following:

- IACUC membership and functions, including protocol review practices;
- IACUC records and reporting requirements;
- Veterinary care, including preventive medicine, animal procurement, transportation, surgery, pain, distress, analgesia and anesthesia, euthanasia, and drug storage and control;
- Personnel qualifications and training; and
- Occupational health and safety of personnel.

2. Review and Inspection of Animal Facilities

The USDA regulations require inspection of the centrally designated or managed animal resource facilities as well as any other animal containment facilities in which animals are

kept for more than twelve hours. PHS Policy requires inspection of all surgical facilities and areas in which animals are maintained longer than 24 hours. Thus, the IACUC inspects all facilities where animals are kept for more than twelve hours. Locations where animals were formerly housed, but are not currently being used will not be inspected. The IACUC maintains an updated list of all facilities to be inspected during its semiannual reviews.

VI. Federally Required Reports

A. USDA Registration and PHS Assurance

The Office of Research Compliance is responsible for completing the USDA Registration and PHS Assurance. Input will be sought from the IACUC, Attending Veterinarian, facility oversight committee, Office of Legal Affairs, and others as necessary to complete these documents. The Registration and Assurance are signed by the Institutional Official/VPR and submitted to the appropriate agency by the Office of Research Compliance.

B. Annual and Semiannual Reports

1. USDA – Animal Welfare Act

The Office of Research Compliance shall prepare and submit the Annual Report to USDA/Animal and Plant Health Inspection Service (APHIS) for signature by the Institutional Official/VPR. The Annual Report shall specify the animals used or under control of the research facility, the location of all facilities where animals are housed/used and specific animal information as required by the AWA, covering the previous federal fiscal year (October 1 through September 30).

2. PHS, NIH Office of Laboratory Animal Welfare

In accordance with our assurance, at least once every 12 months the IACUC, through the Institutional Official, shall submit a report, including any minority views, to the Office of Laboratory Animal Welfare (OLAW), a unit of the Public Health Service. The report shall include the following:

Changes to Ohio University's program or facilities that would place it in a different category than specified in our Assurance.

Changes in IACUC membership and dates that the IACUC conducted its semiannual evaluations and submitted its reports to the Institutional Official.

Changes in the description of Ohio University's program for animal care and use as outlined in the Assurance.

If there are no changes, the report shall so state.

3. Semiannual Reports to the Institutional Official

Upon completion of the semiannual Animal Care and Use Program and facilities reviews, the Office of Research Compliance will assist in preparation of a written report, with subcommittee input, to be reviewed by the IACUC. The report shall describe Ohio University's adherence to the *Guide* and the Animal Welfare Act and deficiencies found, if any.

Deficiencies identified during the reviews are categorized as either minor or significant. A significant deficiency is defined by USDA Regulations and PHS Policy as something that is or may be a significant threat to animal health or safety. The report shall include a plan and schedule with dates for correction of each program or facility deficiency.

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

Any failure to adhere to the plan and corrective schedule resulting in a significant deficiency remaining uncorrected shall be reported, in writing, within 15 business days by the IACUC through the Institutional Official to the Animal and Plant Health Inspection Service (APHIS), if the project involves USDA covered species. If the activity is federally funded, the relevant agency shall also be informed.

4. Other Reporting Requirements

Any suspension of an activity involving animals shall be immediately reported by the Institutional Official (or, in their absence, by the Office of Research Compliance) to the Office of Laboratory Animal Welfare if federal funding is involved and, as appropriate, to APHIS and the federal agency funding the activity.

VII. Record Keeping

The Office of Research Compliance shall maintain all official institute records relating to the use of vertebrate animals. Such records include, but are not limited to, the institute's Assurance; USDA Registration; annual and semiannual reports to federal agencies and Institutional Official; minutes of IACUC meetings including attendance, deliberations, and determinations; records of proposed activities and proposed significant changes, including whether IACUC approval was given or withheld; protocol continuation applications and determinations; and records of investigations of noncompliance.

a. Copies of all research protocols reviewed.
b. Minutes of the IACUC meetings, which are in sufficient detail to show attendance, actions taken, votes (including votes for, against and abstained), the basis for

requiring any changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

c. Records pertaining to continuing review activities.
d. Copies of correspondence between investigators and the IACUC.
e. A current list of IACUC members including names, earned degrees, representative capacity, indications of experience, and any employment or relationship between each member and the institution.
f. Written procedures for the IACUC.

IACUC reports and documentation are retained for at least 3 years, with records relating to research retained for at least 3 years after completion of the research. Records are available for inspection and copying by authorized representatives of research agencies and other authorized persons at reasonable times during the normal work day and in a reasonable manner.

VIII. Investigator Eligibility Requirements

Primary Investigator refers to the individual who has the full and final responsibility for conduct of a study involving vertebrate animals. This assignment on an IACUC protocol form is for purposes of the IACUC approval only and does not imply any other purpose such as authorship or intellectual property rights.

Co-Investigator refers to individuals who share responsibility for the study but do not have the final oversight responsibility.

Primary Investigators must be faculty members or senior research scientists of Ohio University. Graduate and undergraduate students may be listed as Co-Investigators. Graduate student projects will list the advisor as Primary Investigator and the graduate student as Co-Investigator.

Primary Investigators and Co-Investigators must complete the CITI training modules before approval can be issued.

Personnel who perform surgery, anesthesia or euthanasia must be listed as Co-Investigators. Personnel who have only occasional contact with live animals but are involved with the protocol are listed as "other personnel with animal contact." The Primary Investigator must assure that other personnel are appropriately trained through the CITI program or by themselves. In accordance with Ohio University's PHS Assurance, all persons handling live animals and/or listed on an IACUC protocol are required to complete the Collaborative Institutional Training Initiative (CITI) online animal user course, which is entitled "Investigator's, Staff and Students" in the Working with the IACUC curriculum, prior to engaging in animal use. Once the initial course is completed and passed, each person handling live animals is required to complete the refresher course, which is located on the CITI site once every three years.

It is recommended that all persons using animals also complete the species and procedure specific courses available on CITI that are relevant to their work. In addition, these persons should be given sufficient training by the primary investigator to successfully accomplish the work assigned with live animals. This training must be documented by the PI and a copy made available upon request of the IACUC.

Exceptions to the general eligibility requirement to be listed as Primary Investigator may be requested from the Vice President for Research. This request must be in writing and the approval, along with the request for the exception, forwarded with the IACUC protocol application.

IX. Protocol Review Criteria

Federal requirements state that the IACUC must review proposals for vertebrate animal use on the basis of the following:

1. Potential Value of the Study

Activities involving live vertebrate animals are designed and performed with the reasonable expectation that such use of animals will contribute to the enhancement of human or animal health, the advancement of knowledge, or the good of society.

2. Selection of Vertebrate Animal Species

The vertebrate animals selected should be of an appropriate species and quality with the minimum number required to obtain valid results.

3. Justification of Animal Numbers

A proposal to conduct an activity involving animals must contain the following: (a) Identification of the species and the approximate number of animals to be used; and (b) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

4. Minimization of Pain/Distress

Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design. 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 PI justifies, in writing, the scientific reasons for the procedure. The PI shall consult with the Attending Veterinarian or his/her designee in planning the use of animals. Paralytics are not used without anesthesia. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly put to sleep (euthanized) at the end of the procedure, or if appropriate, during the procedure.

5. Alternatives

The PI shall consider alternatives to procedures that may cause more than momentary or slight pain and provide a written narrative description of the methods and sources used to determine that alternatives were not available.

6. Duplication

The PI shall provide written assurance that activities do not unnecessarily duplicate previous experiments.

7. Living Conditions/Housing

Living conditions of animals are appropriate for their species and contribute to their health and comfort.

8. Personnel

Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

9. Surgery

Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. No animal will be used in more than one major operative procedure from which it is allowed to recover unless this use is justified for scientific reasons in writing by the PI, or is required as a routine veterinary procedure, or to protect the health or well-being of the animal, as determined by the Attending Veterinarian.

10. Euthanasia

Methods of euthanasia are consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the PI.

X. IACUC Requirements Based on Location of Use

A. Use at Ohio University

All use of vertebrate species in teaching, testing and research (including training, experimentation, biological testing, breeding, etc.) at or under the auspices of Ohio University must be approved in advance of the use by the IACUC. This is true regardless of the funding source.

B. Use at another Institution with a PHS Assurance/USDA Registration

Where Ohio University researchers are engaged in animal work at another institution with a PHS assurance and, if applicable, a USDA registration, the review at Ohio University may be deferred to the site where the animal work is being conducted. In these cases the researcher must provide the Ohio University IACUC with a copy of the IACUC application and approval letter from that institution. The Ohio University IACUC reserves the right to request additional information or require modifications for substantive issues.

C. Use at a non-assured, non-USDA registered institution

Where Ohio University researchers are engaged in animal work off-campus at an institution without a PHS assurance and, if applicable, a USDA registration, the proposed work must be submitted to the Ohio University IACUC and receive approval prior to initiation of the study.

XI. Activities Conducted in the Field

All activities involving the study of vertebrate animals, including those studies conducted in the animals' natural habitats and without Investigator intervention, must be presented for the IACUC's review and approval prior to being undertaken. Federal guidance is provided below.

Field studies are defined by the US Department of Agriculture (USDA) as *"…any study conducted on free-living wild animals in their natural habitat, which does not involve invasive procedure, and which does not harm or materially alter the behavior of the animals under study."*

These studies require IACUC review even if the activity is purely observational. Generally, field study sites are not inspected by the Ohio University IACUC. When field sites require holding of animals for longer than 12 hours the site is considered during the semiannual review and facility inspection.

XII. Activities Involving the Study of Animals Owned by Private Facilities or Individuals

Activities conducted at a farm, zoo, petting zoo, wild Animal Park, or similar habitats by Ohio University personnel require prior IACUC review and approval, even if the activity is purely observational. The protocol should specify that the researchers do not own the animals or facilities and that the researcher has no direct control over the animal's habitat, care, feeding, husbandry, and so forth. The researcher must obtain a statement from the facility indicating that it is responsible for its animals and premises.

Ohio University acknowledges the Georgia Institute of Technology, Institutional Animal Care and Use Committee Policies and Procedures from March 2011, which was used as a template for this document.