

Institutional Animal Care and Use Committee (IACUC) Policy and Operating Procedures

A. Purpose

Kutztown University's College of Liberal Arts and Sciences requires that all research and teaching* involving non-human, vertebrate animals within the college be approved by the Institutional Animal Care and Use Committee (IACUC). The IACUC ensures that vertebrate research and teaching activities are conducted humanely and according to ethical standards. An ethical review and monitoring of the use of vertebrate animals in teaching and research is required by Federal Law under the Animal Welfare Act (USDA 2011) and the policies of the Public Health Service (OLAW 2002). Many scientific journals and granting agencies, such as PASSHE, NIH, and NSF, also require IACUC approval before research articles can be published or grant proposals will be reviewed. The operating procedures set forth in this policy will allow Kutztown University's IACUC to meet federal requirements for the review and monitoring of vertebrate research, training of personnel, and reporting of activities.

Vertebrate research that will be conducted at an outside organization and has been approved by the outside organization's IACUC does not need to be approved by Kutztown University's IACUC. However, the faculty member must notify the chair of Kutztown University's IACUC of this work and submit a copy of the outside IACUC's approval letter.

* Teaching activities involving vertebrate animals that are purely observational are not required to be reviewed by the IACUC. Observational studies are those that do not: involve the capture or holding of animals, manipulate the environment in any way, or alter the behavior or physiological state of the animal in any way.

B. IACUC Committee and Administrators

The Chief Executive Officer (CEO) of the university or their designee must appoint the members of the IACUC. The Provost has been designated by the President (the CEO) to appoint the committee members and the Institutional Official (IO). The Dean of the College of Liberal Arts and Sciences has been appointed as the IO. The IO is responsible for maintaining a functional animal care and use program at the university based on input from the IACUC. The IACUC must consist of a minimum of five members which represent the following categories:

1. Chair
2. Veterinarian
3. Scientist with experience in animal research
4. Non-scientist
5. Non-affiliated member with no association with the university

Members will be appointed for either two or three-year terms to ensure that there is no complete turnover of the committee in any particular year.

C. Meetings

The IACUC will meet for a minimum of two in-person meetings per year. A meeting is required to conduct any formal business, such as adoption of policies or procedures, approval of semi-annual reviews, and for a full committee protocol review (see Section E. Review of Research Proposals below). A quorum of greater than 50% of all voting members must be present at a meeting to conduct formal business.

D. Animal Use Protocols

Each primary investigator (i.e. researcher or instructor intending to work with vertebrate animals) must complete an Animal Use Protocol and submit it to the IACUC Chair. Only Kutztown University faculty members may act as primary investigators. All student projects must be supervised by a faculty member who is the primary investigator. The Animal Use Protocol should explain the objectives, justification, and methodology of the research project or class exercise in terms the general public or a non-scientist can understand. The Animal Use Protocol is the only document the IACUC will use to review the project. Thus, clear and accurate descriptions with no missing information will reduce the time needed to review the protocol. Note: any project that involves “Procedures that may cause more than momentary or slight pain or distress to the animals” (Animal Welfare Regulations, Section 2.31) must be discussed with the veterinarian in the planning process before a protocol may be submitted and considered for review. Also, primary investigators must notify the IACUC Chair immediately if there is any unanticipated large scale pain, distress, disease, or mortality in their animals.

E. Review of Research Protocols

The IACUC utilizes two types of review: full committee review or designated member review. A full committee review requires a quorum of the IACUC to meet in person to review a protocol, whereas a designated member review involves one or more IACUC members designated by the Chair to review a protocol. There is no set criterion that automatically requires a full committee review. Upon receipt of a protocol, the Chair will make the protocol available to all IACUC members for a period of three business days prior to any review. Each member has a right to request a full review during this initial time period for any protocol. If no member requests a full review after three business days, the protocol will be assigned as a designated member review. Any IACUC member with a potential conflict of interest must recuse themselves from serving as a reviewer of a protocol. In the case of a full committee review, the individual must leave the room while deliberations and voting occur. If the Chair has a conflict of interest, he or she will designate another member to serve as Acting Chair for that protocol and will not participate in the review process.

1. Full Committee Review. A quorum of the voting members of the IACUC will meet in person to discuss and review the protocol. The committee may approve the protocol with no modifications. More than 50% of the members present must vote in favor of the protocol to receive approval of the committee. The committee also may ask questions for clarification or require modifications prior to approval. The Chair or another member(s) may be designated by

the committee to determine if the responses or changes are appropriate and approval may be given without another meeting of the committee. The last option of the IACUC is to withhold approval of a protocol if it cannot be modified to meet ethical standards.

2. Designated Member Review. The Chair will assign one or more members to review a protocol. Reviewers may approve the protocol with no modifications, ask questions for clarification, require modifications prior to approval, or request a full committee review. A designated reviewer may not withhold approval of a protocol, but may simply request a full review.

F. Approved Protocols.

Each initial Animal Use Protocol that is approved will be valid for one year from the date on the letter granting IACUC approval. If the project is to continue after one year, a Renewal Animal Use Protocol must be submitted (see Section G. Renewal of Research Protocols, below).

G. Renewal of Research Protocols

After one year, an initial protocol may be renewed by completing a Renewal Animal Use Protocol and submitting it to the IACUC Chair. If any proposed modifications to the protocol are significant, the Chair will make the Renewal Animal Use Protocol available for review as outlined above in item E. Review of Research Protocols. Significant modifications include, but are not limited to, changes in study objectives, species or numbers of animals used, or experimental procedures. For Renewal Animal Use Protocols that have no changes or only include personnel changes, the IACUC chair will review and approve those changes. An initial protocol may be renewed twice. If the investigator chooses to continue a project beyond the first year, but fails to submit the renewal form before the date of expiration, the investigator is required to submit the project as a new Animal Use Protocol before the project may continue. The IACUC Chair will send a reminder to the principal investigator approximately one month prior to the protocol's date of expiration. A project continuing for more than three years must submit a new Animal Use Protocol at the end of the third year for the project to continue.

H. Amendments to Research Protocols

Any significant modifications to a project with an approved Animal Use Protocol prior to submission of Renewal Animal Use Protocol must be approved by the IACUC before they may be implemented. Significant modifications include, but are not limited to, changes in: study objectives, species or numbers of animals used, experimental procedures, or personnel involved in the study. Individuals must fill out an Amended Animal Use Protocol and submit it to the Chair. The Chair will make the Amended Animal Use Protocol available for review as outlined above in item E. Review of Research Protocols. For Amended Animal Use Protocols that only include personnel changes, the IACUC chair will review and approve those changes.

I. Training

All individuals listed on an Animal Use Protocol and all IACUC members must receive training in the ethical use of animals in research by completing the “Working with the IACUC: non-VA version” course through the American Association for Laboratory Animal Science’s (AALAS) online Learning Library (www.aalaslearninglibrary.org). Before starting the training, individuals must register for a free account. The online course will take approximately one to two hours to complete. This training must be renewed every three years for all individuals. To access training, go the AALAS Learning Library website and find the desired course under the “Libraries” menu tab. After completing the training, there will be a 25 question, multiple choice exam. A score of 80% or higher is required to pass. To document successful training, the final graded exam page stating a passing score must be printed. Add a statement to the page affirming that the undersigned completed training on a specific date and sign the page. The training documentation must be forwarded to the IACUC Chair as a hardcopy or scanned pdf document. No animal use protocol will be reviewed or approved until all members listed in the protocol have forwarded their training documentation to the IACUC Chair.

Each IACUC member also must receive training in IACUC administration and procedures by completing the “Essentials for IACUC Members” course through the AALAS online Learning Library. The online course will take approximately one to two hours to complete. This training must be renewed every three years for all individuals. The Veterinarian is recommended to complete a third online training course “Laboratory Animal Medicine” if he or she has not received prior training in this specific area. The procedure outlined above for accessing the training course and forwarding documentation to the IACUC Chair must also be followed for IACUC member training.

In addition, all individuals listed on an animal use protocol must complete Occupational Safety Training. Individuals working primarily in a lab setting must complete Laboratory Safety Training through Kutztown University’s Environmental Health and Safety (EHS) Desire2learn website. If individuals will be working with blood samples, they also must complete the Bloodborne Pathogens module on the EHS website. After completing the training, there will be a 20 question, multiple choice quiz. A score of 70% or higher is required to pass. Individuals working primarily in a field setting must complete the Occupational Field Work Training through Kutztown University’s Environmental Health and Safety (EHS) Desire2learn website. A score of 70% or higher is required to pass. For individuals working in both a lab and field setting, both the lab safety and field work safety training identified above must be completed. Additional training courses through the AALAS Learning Library and consultation with the Veterinarian may be required if projects involve handling of certain vertebrate species. Contact the IACUC Chair while planning a project that involves animal handling to determine what further training may be required. Follow the procedure outlined above for forwarding documentation of completed EHS training to the IACUC Chair.

Finally, primary investigators are responsible for demonstrating that they have sufficient experience working with the proposed animal species on the Animal Use Protocol and are required to providing training to other individuals listed on the Animal Use Protocol.

J. Suspension of Animal Use Activities

The IACUC has the authority to suspend any vertebrate animal research activity due to concerns about the health and welfare of animals involved. To suspend any research activity, the IACUC must utilize the following procedure. At a formal business meeting, the IACUC must review the activity in question to determine whether federal regulations are being followed. A majority of the quorum must vote for suspension. The IACUC must notify the IO that a suspension has been issued. The IO will review the suspension with the IACUC and take corrective action to bring the project into compliance. The IO must also notify the appropriate regulatory agencies (i.e. US Department of Agriculture and Public Health Service - PHS) and any funding agencies.

The IACUC also is required to investigate any reports of concerns regarding the use of vertebrate animals in research or teaching. When the IACUC receives a report expressing a concern, it must follow the procedures outlined in the Institutional Animal Care and Use Committee Guidebook (Pitts 2002) to investigate the reported problem. If the investigation reveals a problem that affects the health and welfare of animals, the IACUC will follow procedures outlined above to suspend animal use activity.

K. Semi-Annual Reviews

The IACUC will conduct a self-evaluation approximately every six months. The evaluation will involve an inspection of any vertebrate holding facilities and a review of the animal care and use program. The self-evaluation will be conducted by at least two IACUC members according to the Animal Welfare Act Regulations and Public Health Service Policies. A written report will be produced that describes how the animal care and use program adheres to federal regulations and notes in detail any departure from those regulations. The report must be reviewed by an in-person meeting of the IACUC. A quorum of IACUC members must approve and sign the report. Any dissenting minority views must be included with the report. The final approved self-evaluation report must be submitted to the IO and a copy of the report will be retained by the Chair.

L. Record Keeping

The IACUC is required to maintain documentation of its activities. The committee will elect a Secretary at its first meeting of each year. The Secretary will take minutes of each in-person meeting in sufficient detail to document the IACUC's activities to an outsider. The minutes should include attendance, details of committee actions, and the basics of any deliberations during protocol reviews. Copies of the minutes will be retained by the Chair. The Chair also will maintain records of individual training documentation for as long as individuals are active participants, of Animal Use Protocols and their renewals/amendments for a minimum of three years, and all Semi-annual Reviews.

Literature Cited

OLAW. 2002. Public Health Service Policy on Humane Care and Use of Laboratory Animals, revised. Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD. Accessed August 10, 2011.

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Pitts, M., Editor. 2002. Institutional Animal Care and Use Committee Guidebook. Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD.

USDA. 2011. Animal Welfare Act (United States Code 2009 Edition, Title 7 Chapter 54). United States Department of Agriculture, National Agricultural Library. Accessed August 10, 2011. (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>).

Revision Approved

March 6, 2014

Effective

March 7, 2014