

Institutional Animal Care and Use Committee (IACUC): Research Involving Animals

The IACUC exists to oversee the use of animals in research and teaching at Butler University and to ensure that all applicable federal, state, and local regulations governing the use of animals are met. The committee conforms to requirements established by the Public Health Service (PHS) and the National Research Council's (NRC's) *Guide for the Care and Use of Laboratory Animals* (www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth).

The IACUC is appointed by the Provost/Vice President for Academic Affairs or designee and comprises not fewer than five members, qualified through experience and expertise to assess the University's animal program, facilities, and procedures. The committee includes a doctor of veterinary medicine who is experienced in the care of laboratory animals, and a member who is not affiliated with the University in any way other than membership on the committee. If the Provost/Vice President for Academic Affairs delegates authority to appoint the IACUC, such delegation must be specific and in writing. The IACUC meets at least twice a year, with other meetings as needed.

The IACUC reviews all protocols involving vertebrate, non-human animals to ensure their ethical treatment. This includes animals that will be used in laboratory courses as well as in research. It also includes animals that will be used off campus by members of the Butler community. Everyone working with animals is required to review the Butler University Principles of Humane Care and Use of Laboratory Animals (<http://legacy.butler.edu/media/2548174/bu-principles-of-humane-use-of-laboratory-animals.pdf>) and sign verification that they are familiar with the information contained in that document.

All teaching and research activities involving the use of any vertebrate animals at Butler University must receive prior written approval of the IACUC. This includes, but is not limited to, animals owned by Butler University, wildlife animals whose behavior is altered by the proposed activities, and animals owned by other institutions or individuals.

Qualifications and Responsibilities of Researchers

A PI on research involving the use of animals must: 1) be a Butler University faculty member; 2) have an academic or professional degree in a discipline based upon animal experimentation, or have similar credentials by virtue of experience; 3) successfully complete Butler's training program, sign the statement of participation, and agree to comply with the principles of humane animal treatment contained therein; 4) successfully complete and submit with the protocol an Animal Use Qualifications Form to the research compliance officer at IACUC@butler.edu.

The PI must sign the Protocol for Animal Use, thereby certifying the accuracy of the information upon which the IACUC bases its decision to approve or withhold approval of the protocol, and must complete and sign the Animal Use Qualifications Form, listing the PI's experience and credentials to perform animal research, if one is not already on file. The PI is responsible for the proper and ethical conduct of the study as well as the humane treatment of the animals used;

additionally, it is the responsibility of the PI to ensure that all personnel handling animals (including technicians and students) are properly trained.

A student may conduct a project using vertebrate animals with supervision from a faculty member who meets the above requirements and agrees to act as the student's mentor and oversee the project as the PI. Students must complete and submit an Animal Use Qualifications Form to the research compliance officer at IACUC@butler.edu.

Required Training

Any Butler University employee (including PIs) or student who will have responsibility for the care and use of animals as an activity of his or her duties must undergo training prior to initiating that activity and annually thereafter. The training includes an online training course as well as training with the animal care staff. Certification from another institution may be considered but must be submitted and approved prior to animal use. Online training is through the Collaborative Institutional Training Initiative (CITI), available at www.citiprogram.org. Training is required every three years.

To complete the required education on the [CITI website](#):

- Select Butler University as the participating institution and create an account.
- On the page titled Select Curriculum (list of courses on animal care), complete the module Working with the IACUC as well as any other appropriate research module.
- The course may take a few hours to complete but can be done over a period of time. CITI will e-mail a record of completion to the Office of Sponsored Programs (OSP).

Investigators who have completed CITI education for another organization can add Butler to their profile. This will certify credit for previous courses to the extent that they overlap with Butler's requirements.

PIs must provide sufficient proof of qualifications for animal use to the consulting veterinarian (for invasive procedures) prior to beginning animal use. Any investigator lacking sufficient qualifications will be provided with appropriate training from the consulting veterinarian as needed.

In the case of a supervised employee and/or student, the animal care facility supervisor, the PI, or the appropriately trained designee trains the employee and/or student in specific requirements of the particular animal activity protocol.

In the case of students participating in the care and use of animals as part of a class or laboratory activity, the Butler PI directing the class or laboratory activity must be present at all times to directly supervise any interaction between the students and the animal(s) in question. The Butler PI must complete all appropriate CITI training, complete and submit a Protocol for Animal Use describing the class or laboratory activity, and submit an Animal Use Qualifications Form prior to student supervision. Students participating in the class or laboratory activity are exempt from completing the CITI online training and submitting an Animal Use Qualifications

Form. However, all students must be trained in appropriate animal care and use techniques by the supervising PI and the details of such training must be outlined in the protocol associated with the activity. Additionally, the PI is required to provide to the IACUC or regulatory authorities upon request written documentation signed by each participating student indicating that they received appropriate training for the activities performed.

Change of Species or Manipulation

Before any new species, new animal manipulation, or major change to a manipulation is introduced into a facility or animal activity, all employees and/or students caring for or handling the new species or carrying out the manipulation must be trained in the appropriate care and handling of the species and in the manipulation. The Office of Sponsored Programs procures and provides appropriate training materials, if available; otherwise, it will be the responsibility of the PI or animal care facility supervisor to obtain appropriate training and to ensure that support staff are adequately trained.

Continuing Education

It is the responsibility of each PI or animal care facility supervisor to acquire up-to-date information in the care and handling of research animals and to update support staff accordingly. The Office of Sponsored Programs serves as a resource for identifying such information as well as regulatory revisions.

Assurance of Training

Upon approval of a Protocol for Animal Use, the PI and any other personnel handling the animals will be required to sign the Animal Use Qualifications Form. Completion of the form assures the IACUC that the signatory has received required training prior to the initiation of the protocol and that the signatory will continually acquire up-to-date information relevant to the protocol as it becomes available.

Application and Protocol Guidelines

All teaching and research activities involving the use of any vertebrate animals at Butler University must receive prior written approval of the IACUC. This includes, but is not limited to, animals owned by Butler University, wildlife animals whose behavior is altered by the proposed activities, and animals owned by other institutions or individuals.

Projects using wildlife species are subject to review by the IACUC if they will alter species-specific behavior in any way. This includes, but is not limited to, any procedure in which the animal will be trapped, penned, or handled. Studies that involve only noninvasive observation of wildlife species and will not interfere with their normal behavior do not require a protocol. The PI must also consider the impact of the project on other wildlife populations that occupy the same area as the species under study.

Studies involving animals not owned by Butler University may also fall under the jurisdiction of the IACUC. If the animals are owned by another institution with an IACUC, the PI must submit a protocol to that institution's committee for approval. The approved protocol should then be forwarded to the Butler IACUC for approval.

Studies using animals owned by individuals will require protocol submission as well. Upon approval of the protocol, the PI must obtain written consent to use the animal from the animal's owner. In addition, the IACUC has the right to visit the home of the animal or other location of the project to ensure that all animal care and use regulations are being met.

Professional scientists must consider the effects of their activities on the organisms under study, on the validity of study results, and on the use of these organisms by other segments of society. The IACUC recognizes these relationships and supports the sound application of responsible methods for the conduct of animal research in all fields and laboratory investigations. This position reflects Butler's ethical and moral concerns regarding human interactions with each other and with other species, and recognizes the scientific benefits of investigations that are not compromised by the manner in which animals are handled or maintained.

[The Public Health Service \(PHS\) Policy on Humane Care and Use of Laboratory Animals](#) is intentionally broad in scope and does not prescribe specifics about the care and use of any species, assigning that task to the IACUC and allowing for professional judgment. Many of the principles embodied in the NRC's *Guide for the Care and Use of Laboratory Animals*, although not specifically addressing cold-blooded vertebrates, generally can be adapted to animal care and use programs for various kinds of amphibians, reptiles, and fishes. It is clear from the literature, however, that individual requirements for these three classes of vertebrates, which contain more than 28,000 species that have a diversity of requirements, cannot be addressed in a single set of guidelines. Consequently, the IACUC, while extending its regulatory purview to cold-blooded vertebrates, will seek input from faculty researchers and request a review of their research proposals involving cold-blooded vertebrates to ensure that suitable housing and care procedures are being used for these species.

Application and Review Process

The IACUC will consider for approval animal activities described in a properly completed and signed IACUC forms, available on the Office of Sponsored Programs website. A completed protocol must be submitted for each study or procedure to be performed. Completed, signed IACUC forms should be submitted to the Office of Sponsored Programs via email, IACUC@butler.edu, or in person to JH-144E.

Research Compliance Officer (RCO) will conduct the pre-review, including checking the CITI training completion. The application will not be sent to the committee until the CITI requirement is completed.

Designated Member Review

The IACUC uses the designated member review (DMR) process. The IACUC application will be sent to each IACUC Member electronically. Individual IACUC members are provided with the option to either request a full committee review or allow the protocol to be reviewed by a DMR. IACUC may consider the lack of member replies within the prescribed time period as no requests for full review. If any member of the IACUC requests full committee review (FCR), the protocol is reviewed at the next scheduled meeting.

If no request for FCR, the IACUC Chair will designate at least one (1) member of the IACUC qualified to conduct the DMR. The assigned reviewer(s) shall review the research projects and have the authority to approve, require modifications (to secure approval) or request FCR of assigned research projects.

The Designated Member Reviewer(s) (DMRs):

- may request additional information from the PI prior to approval;
- may require modifications in the protocol;
- may refer the protocol for full review; and/or
- may approve the protocol on behalf of the IACUC.

All designated reviewers assigned to review a protocol have to agree for approval to occur. If a member does not request FCR of a protocol, s/he may submit questions and/or comments for consideration by the DMR(s) during the review process to the Chair. The chair will notify the PI to address the questions/ comments. Once they are addressed, the Chair will notify the RCO to prepare the approval documents. The PI is provided with a written approval signed by the chair. Copies of the approval are sent and filed by the Office of Sponsored Programs to the PI, where they are archived and available to regulatory agency and appropriate animal care staff.

Full Committee Review

Member(s) notify the IACUC chair and RCO if they request a FCR. If FCR is requested, the protocol is then reviewed at the next IACUC meeting or a special meeting called for the review. This can be conducted either via convened meeting or teleconferencing. The RCO will set up the meeting.

If any member requests FCR, if appropriate, any questions or comments that had been submitted about the protocol will be forwarded to the PI by the Chair to provide an opportunity for him/her to provide answers or clarification prior to the convened meeting.

If full committee review (FCR) of the protocol is requested, approval of those research projects may be granted only after completion of the review at a convened meeting of a quorum of the IACUC and with the approval vote of the majority present.

If the quorum is satisfied, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR, or returned for FCR at a convened meeting.

Any member may submit questions and/or comments for consideration by the DMR(s) during the review process to the Chair. The chair will notify the PI to address the questions/ comments. Once they are addressed, the Chair will notify the RCO to prepare the approval documents. The PI is provided with a written approval signed by the chair. Copies of the approval are sent and filed by the Office of Sponsored Programs to the PI, where they are archived and available to where they are archived and available to regulatory agency and appropriate animal care staff.

Through DMR or FCR, protocol approval is granted for a period of three (3) years with instructions that the protocol must be reviewed by the IACUC on an annual basis to remain active, and any changes must be submitted, before the change is implemented, for review via the amendment process.

When a PI who is also a member of the IACUC submits a Protocol for Animal Use, he or she must abstain from the review process for that protocol.

Meetings

IACUC meetings are held at least twice a year. Other meetings are scheduled as necessary to fulfill the IACUC responsibilities. The agenda will include all the necessary items so IACUC business can be conducted efficiently and continuity is maintained. The Agenda will be prepared by the RCO.

IACUC “Quorum” is defined as a majority (>50%) of the voting members of the IACUC. Abstentions from voting (for reasons other than conflict of interest) do not alter the quorum and do not change the number of votes required for approval. Recusal of a member due to a conflict of interest does alter the quorum. When a PI who is also a member of the IACUC submits a Protocol for Animal Use, he or she must abstain from the review process for that protocol.

The meeting minutes should include an explanation of the major issues discussed by the IACUC and the outcomes of the discussions for each issue. A written transcript of the proceedings is not required. There should be enough information for an outsider to ascertain the nature of the discussion and the conclusions reached by the Committee. The minutes will be reviewed at the next meeting. When it is approved, it will be signed by the Chair (acting Chair) and the Office of Sponsored Programs representative.

Policies for the Use of Live Animals at Butler University

1. It is the policy of Butler University to comply with all applicable federal, state, and local laws and regulations governing the use of animals in research and teaching.
2. Animal studies will be conducted under the direction of a principal investigator who will be a member of the faculty and qualified to perform such studies.
3. It is the responsibility of the principal investigator and co-investigators to know and comply with all applicable federal, state, local, and Butler laws, regulations, and policies governing the use of live animals.
4. Principal investigators must obtain approval from the Butler University Institutional Animal Care and Use Committee (IACUC) prior to using any vertebrate animal for

research or teaching. Any deviations from the approved protocol must receive prior approval from the IACUC.

5. Adherence to the procedures identified in the animal use protocol is the responsibility of the principal investigator. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol. In addition, a noncompliance report indicating any principal investigator not in compliance with the policy outlined herein will be forwarded to the Provost for appropriate action.
6. All persons using animals will be appropriately trained. Training will include but will not be limited to reading the training manual provided by the IACUC and signing a statement of participation.
7. Studies using vertebrate animals will be performed only if suitable alternatives to the use of these animals is unavailable. The phylogenetically lowest species consistent with scientific validity will be employed in all studies and the principal investigator must provide written assurance that the studies do not unnecessarily duplicate previous experiments.
8. Numbers of animals used will be the minimum consistent with validity and reliability of the study. Methods such as videotaped procedures or computer-assisted simulations will be employed whenever possible to reduce the number of animals needed for student teaching laboratories.
9. Studies employing biologically hazardous materials must be approved by Butler's Institutional Biosafety Committee. Studies using radioisotopes must be approved by Butler's Radiological Control Committee.
10. No animal will be employed more than once in a major operative experiment from which it is allowed to recover unless:
 - a. it is scientifically necessary as a part of a protocol approved by the IACUC, or
 - b. it is required as a veterinary procedure to protect the health and well-being of animals as determined by the attending veterinarian.Any exception to this policy must be approved by the administrator of the Animal and Plant Health Inspection Service, US Department of Agriculture.
11. Living conditions of animals will be appropriate for their species in accordance with applicable federal, state, and local laws and regulations. Adequate food, water, airflow, temperature, space, and cleanliness are to be ensured.
12. Medical care for the animals will be available and provided as necessary by a qualified veterinarian.
13. Euthanasia will be performed by a qualified individual in an approved manner to produce rapid unconsciousness and subsequent death without evidence of pain or distress. The procedure will follow current American Veterinary Medical Association recommendations for acceptable methods of euthanasia.
14. Animal carcasses and tissues are considered to be biohazards by Butler's Department of Public Safety, Office of Environmental Programs. Disposal of these materials will be through the Environmental Programs Laboratory.
15. An occupational health program, including both a medical and an educational component, will be provided for all animal care personnel, and for faculty and students having substantial (an average of eight or more hours per week) animal contact. The level

and extent of the occupational health program needed for each individual will be determined by the species of animal and the nature and extent of the contact.

Animal Procurement

No vertebrate animals may be acquired without an approved protocol on file. In addition, all animal procurements must be pre-approved by the IACUC chair to ensure that there is space available to house the animals.

Safety Issues

Bite Reporting and Quarantine Program

The PI is responsible for ensuring that all persons using animals are aware of procedures to follow after being bitten by a laboratory animal, otherwise injured, or exposed to potentially hazardous animal fluids. The individual must immediately notify their immediate supervisor and follow the policy and procedures of the Bite Reporting and Quarantine Program and Butler University's Accident/Incident Reporting Policy. Complete information is available on the Office of Sponsored Programs website (see [Bite Reporting and Quarantine Program](#)).

Occupational Safety and Health Program

The Office of Sponsored Programs director is responsible for the overall implementation and maintenance of the Occupational Safety and Health Program (OSHP), and the animal care facility supervisor, PIs, and department heads are responsible for its implementation and maintenance. Complete information is available on the Office of Sponsored Programs website (see [Occupational Safety and Health Program](#)).

Additional Issues

Consequences of Noncompliance

Adherence to the procedures identified in the Protocol for Animal Use is the responsibility of the PI. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol.

Recordkeeping Requirements

The University maintains all IACUC records in the Office of Sponsored Programs. These include minutes of IACUC meetings; records of proposed activities involving animals and proposed significant changes in activities involving animals; and records of semiannual IACUC reports and recommendations. All records and reports shall be maintained for at least three years, and for an additional three years after the completion of a proposed activity or significant change in ongoing activities. Records are available for inspection and copying by authorized funding agency representatives and representatives of the USDA's Animal and Plant Health Inspection Service (APHIS). Additional policy details regarding release of information, investigations, and record-keeping practices are available from the Office of Sponsored Programs.

Facility Inspections and Program Review

The IACUC conducts inspections of animal facilities, rooms, areas, enclosures, vehicles, and satellite facilities every six months as detailed by Animal Welfare Act regulations and the PHS

Policy on Humane Care and Use of Laboratory Animals. These inspections evaluate all issues around animal care, conditions of facilities, training of personnel, and safety. Mechanisms are in place to address deficiencies, corrective actions, and agency reporting. Complete information is available from the Office of Sponsored Programs. Additionally, the IACUC conducts a full program review every six months; the review covers IACUC policies, procedures, and responsibility; training programs; occupational health; animal management practices; and veterinary medical care. Complete information is available from the Office of Sponsored Programs.