

Governors State University
POLICIES AND PROCEDURES PERTAINING TO RESEARCH
INVOLVING THE USE OF ANIMALS

I. OVERVIEW

Governors State University has the responsibility to maintain the highest possible quality of research and to provide for the humane care and treatment of animals used in research projects and teaching conducted at this institution, or under the direction of any employee or agent of this institution, whether funded or not, and regardless of the source of funding. In compliance with Public Health Service (PHS) regulations, GSU has established an Institutional Animal Care and Use Committee (IACUC), whose members are appointed by the President of the University to review all research involving animal subjects, and to set forth institutional policy regarding such research. The IACUC is directly responsible to the Institutional Official as designed by the President.

All activities involving the use of animals conducted by GSU faculty, staff, and/or students, or sponsored in part or in whole by GSU must be reviewed and approved by the IACUC and/or its agents. This includes teaching activities and research conducted in conjunction with undergraduate and graduate projects and theses. This institution is guided by the ethical principles regarding the humane treatment of animals used in research as set forth in the Animal Welfare Act. University policy specifies that (1) the proper management of laboratory animals is essential to the welfare of the animals; to the validity of research data, and to the health and safety of the animal care takers; and that (2) the University will comply with the state and federal regulations regarding animal welfare. The IACUC encourages and promotes constructive communication among the research administrators, division chairs, directors of

graduate studies, research investigators, and institutional officials, in order to maintain a high level of awareness regarding the safeguarding of the welfare of the animal subjects.

Correspondence concerning animal research and requests for additional information should be directed to the IACUC Institutional Officer c/o the Provost Office.

II. DEFINITIONS

GSU has adopted the following definitions included in the federal regulations to guide researchers and other interested parties in determining the necessity for review.

- A. **ANIMAL:** Any live, vertebrate animal used or intended for use in research, teaching, research training, experimentation, or biological testing or for related purposes.
- B. **ANIMAL FACILITY:** Any and all buildings, rooms, areas, enclosures or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated of managed area in which animals are housed for more than 24 hours.
- C. **ANIMAL WELFARE ACT:** Public Law 89-544, 1966 as amended. Implementing regulations are published in the *Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3*, and are administered by the U.S. Department of Agriculture.
- D. **ANIMAL WELFARE ASSUANCE OR ASSURANCE:** The documentation from an institution assuring institutional compliance with this policy.
- E. **GUIDE:** Guide for the Care and Use of Laboratory Animals, HHS, National Institutes of Health Publication No. 85-23, 2011 edition or succeeding revised editions.
- F. **INSTITUTIONAL OFFICIAL:** An Individual who signs, and has the authority to sign the institution's Animal Welfare Assurance, making a commitment on behalf of the institution that the requirements of this policy will be met. The President has designated the Provost of Governors State University as the Institutional Official.

- G. PUBLIC HEALTH SERVICE: The Public Health Service (PHS) includes the Alcohol, Drug Abuse, and Mental Health Administration; the Centers for Disease Control; The Food and Drug Administration; the Health Resources and Services Administration; the National Institutes of Health; and the Office of the Assistant Secretary for Health, Department of Health and Human Services.
- H. QUORUM: A Majority of the members of the Institutional Animal Care and Use Committee (IACUC).
- I. PRINCIPAL INVESTIGATOR: Any administrator, faculty, staff, or other individual affiliated with Governors State University who has the primary responsibility over a research activity. The Principal Investigator, in any student research project (whether conducted in conjunction with an undergraduate or graduate course, master's project, or master's thesis), is the faculty person with primary responsibility for overseeing the student's course, project, or thesis.
- J. RESEARCH INVESTIGATOR: Any administrator, faculty, staff, or other individual affiliated with Governors State University who is participating in a research activity in an investigative role and not as a research subject.

III. REVIEW PROCEDURES

It is the responsibility of the researcher to know and comply with the review procedures of the IACUC. Should the **researcher investigator** be a student matriculating at GSU, the student's academic or thesis advisor assumes primary responsibility for the proposed activity. The advisor is to familiarize the student with his/her obligation vis-à-vis the welfare of animal subjects research. The responsibilities of investigators using animals in research or teaching include obligations to:

- A. Become knowledgeable about and conduct all research and inquiry in accordance with approved policies governing the care and use of laboratory animals.
- B. Submit to the IACUC, prior to data collection, a fully completed "Application to Use Vertebrate Animals in Research and Teaching" accompanied by a copy of the methods section related to animal subjects from a grant application, if applicable.

- C. Maintain complete records of procedures undertaken during each animal experiment for a minimum of three years after its completion.
- D. Meet research protocol requirements in approved animal care unit facilities whenever possible. Where research protocols dictate unusual environmental, dietary or colony requirements that cannot be met in animal care unit facilities, be sure that the IACUC has approved the Protocol in advance of the proposed animal use activity.
- E. Maintain a scholarly, sensitive, respectful environment during all animal experimentation.
- F. Participate in continuing education and training programs designed to keep investigators abreast of the latest regulations and procedures in animal research.
- G. Immediately inform the departmental animal care administrator and/or the veterinarian on call of any problems which may arise with the health or care of the animals.

Division chairs, through appropriate procedures established within their respective programs, are responsible for reviewing teaching and research protocols for their educational and scientific merit. Research Investigators shall be responsible for insuring that all research involving animal subjects is submitted to the Office of the Provost for review by the IACUC in the form of a fully completed "Application to Use Vertebrate Animals in Research and Teaching"

For the section of the form calling for a description of the project, researchers should be sure to provide sufficient detail in nontechnical terms so that the IACUC may evaluate the proposed use of animal subjects. Assurance from the investigator, no matter how strong, will not substitute for a description of the procedure. Research protocols scheduled for review shall be distributed to all members of the IACUC prior to the meeting. Input from consultants or experts may be sought to assist the IACUC in its review of a protocol.

A majority of the membership of the IACUC constitutes a quorum and is required in order to convene a meeting for the review of research protocols. For an application to be

approved, it must receive the approval of a majority of those members present at the convened meeting. No member who has a conflicting interest in the project being reviewed may participate in its review, except to provide information requested by the IACUC.

Additional Responsibilities of the Investigator

Extension of Project Time Period: Ongoing projects must be reviewed at least annually, and the IACUC has the right to require more frequent monitoring if necessary. To obtain an extension of approval of a previously approved project without changes to the protocol, the researcher should submit a completed “Application for Continuation of Approval” to the IACUC. Approval must be obtained in writing from the IACUC chair before the researcher may continue data collection past one year from the date of the original approval.

Changes in the Research Protocol: The IACUC chair should be notified immediately of proposed changes in a research activity. Changes in research during the period for which IACUC approval has already been given require IACUC review and approval.

Reporting of Noncompliance: Research investigators and division chairs are responsible for reporting promptly to the IACUC any serious or continuing noncompliance with federal and/or university regulations.

Cooperative Research: Federal regulation of research involving the use of animals includes projects conducted at or in cooperation with another entity by GSU administrators, faculty, staff, or students. The GSU IACUC may accept, for the purpose of meeting the PHS requirements, the approval from another institution’s IACUC, provided that the said IACUC has on file an approved assurance of compliance with the Office of Laboratory Animal Welfare(OLAW). Such approval must be in writing, and acknowledge in writing GSU’s IACUC chair. For grant proposals, a copy of the agreement must be forwarded to the Office of Laboratory Animal Welfare.

IV. IACUC MEMBERSHIP AND FUNCTIONS

A. **MEMBERSHIP:** The chair and members of the IACUC are appointed by the President of the University upon the recommendation of the Institutional Official. It is the duty of the IACUC to periodically evaluate and report to the Institutional Official the status of the animal care and use program at GSU.

The membership of the IACUC shall meet the requirements of the federal and state laws and shall include members who are qualified through experience and/or expertise. The committee must have at least five members, including one doctor of Veterinary Medicine experienced in laboratory animal science and medicine; two practicing scientists experienced in animal research; one individual whose primary concerns are in a nonscientific area; and one individual who is neither affiliated with GSU nor the immediate family member of any person affiliated with GSU, but who has concern for animal welfare. Although the committee must have at least five members, one member can represent more than one of the required categories.

Members are appointed for a term of three years, beginning in September. In the event a member resigns, a replacement will be appointed for a new three-year term. At least two months prior to the resignation or completion of a term of one of the faculty members with animal expertise, the IACUC chair will notify the Institutional Official to solicit nominations for membership from the appropriate division and forward the name of the recommended candidate to the President.

B. **FUNCTIONS:** The functions and authority of the IACUC include:

- 1) Review annually the institution's program for humane care and use of animals following the *Guide*.
- 2) Inspect annually all of the institution's animal facilities, including satellite facilities, using the *Guide*.

- 3) Review concerns involving the care and use of animals at the institution.
- 4) Make written recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.
- 5) Review and approve, require modifications in (for approval) or withhold approval of animal use protocols as required by federal regulations.
- 6) Review and approve, require modifications in (for approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as required by federal regulations.
- 7) Notify investigators and the Provost's Office in writing of its decisions to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval as required by federal regulations.
- 8) Suspend immediately, pending an investigation, any research involving animal subjects that is suspected to violate any federal or state regulations, funding agency, or GSU policy. Suspension of an activity for minor deficiencies or non-emergency situations will result only after the following procedures have failed to effect compliance:
 - a. First, notification in writing to the investigator of the nature of the violation or noncompliance.
 - b. Second, written notice to the investigator's chair of the problem and no response to the committee, advising the chair of the implications of noncompliance.
 - c. Third, written notice of the continuing noncompliance to the Provost's Office with the committee's recommended action.

The IACUC, through the Institutional Official, must promptly report to the Office of Laboratory Animal Welfare a full explanation of the circumstances and actions taken with regard to:

d. Any serious or continuing noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals

e. Any serious deviation from the Guide.

f. Any suspension of an activity.

9) All formal committee action requires a majority of the quorum (simple majority of voting members)

10) The IACUC will operate in accordance with the Illinois Open Meetings Act, and therefore shall be open to the public except for the discussion of security, safety, personnel, and proprietary issues. Minutes of the open sessions of the IACUC meetings are to be available to the public after their approval.

11) Convened meetings of the IACUC shall occur once during each trimester.

V. MISCELLANEOUS

A. Procedures for Approval of Externally Funded Research

Researchers should obtain IACUC approval prior to submitting a proposal to an external granting agency to avoid possible delays in the review of the grant application. Some granting agencies require approval prior to or concurrent with the submission of the grant proposal to the agency. The IACUC chair is responsible for submitting a certification of approval or continuation of approval to the funding agency. In any event, no external funding will be distributed to the investigator prior to IACUC approval of the project.

B. Expedited Review of Research

Although its use is discouraged by the IACUC, an expedited review procedure maybe used to review a project that requires approval prior to the next regularly scheduled IACUC meeting. A copy of the Application to Use Vertebrate Animals in Research and Teaching will be sent to each member of the committee together with a review form to indicate approval as submitted, approval contingent on specified modifications, withholding of approval, or a request to review the procedures at a convened meeting. A request by any one member for a full meeting precludes approval by expedited review. Approval by expedited review of the application occurs when the Office of Sponsored Programs and Research has received signed review forms indicating approval from a majority of the members. The IACUC may use the expedited review procedure to review minor changes in previously approved research during the period for which approval was previously granted.

C. Appeal of IACUC Decisions

Appeals of IACUC decisions should be made in writing to the chair and/or the Provost. The Provost can review IACUC decisions, but cannot approve a project for which the committee withheld approval.

D. Record Keeping Requirements

The IACUC shall prepare and maintain adequate documentation of IACUC activities, including the following:

- 1) Copies of all applications for approval of research involving the use of animals, including applications for continuation of approval and approval of changes in the protocol.
- 2) Minutes of IACUC meetings which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the committee; the vote on those actions including the name of members abstaining or voting against an action; the basis for withholding approval of a project or requiring its modifications; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions.

- 3) Records of continuing review activities.
- 4) A list of the IACUC members
- 5) Copies of all correspondence between the IACUC and the researchers.

The IACUC shall provide for maintenance of records relating to a specific research activity for at least 3 years after termination of the last IACUC approval period. IACUC records shall be accessible for inspection and copying by authorized representatives of PHS at reasonable times and in a reasonable manner.

E. Occupational Health Program

All new personnel involved in handling animals are advised regarding zoonoses, personal hygiene, precautions for pregnant women, and other considerations by the principal investigator conducting the research project. Each investigator is required to inform the division chair and maintain records of individual work assignments, bite and/or other wounds and their treatment, unusual illnesses, and allergies. All personnel are instructed to notify the principal investigator of any suspected work-related illnesses and any suspected or potential health hazards.

F. Amendment of IACUC Policy

Amendment of the GSU policy on the care and use of animals in research may be recommended at any time by the IACUC. Proposed amendments shall be submitted to the full committee for review, and must be approved by a majority of a convened meeting. Approved proposed amendments shall then be forwarded to the Provost for review and final approval.