Institutional Animal Care and Use Committee

Handbook of Policies and Procedures

Version 3.0

3/1/2025

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Abbreviations and Acronyms

Abbreviations

Assurance	Animal Welfare Assurance letter with OLAW
Guide	Guide for the Care and Use of Laboratory Animals, 8th Edition (2011)
PHS Policy	Public Health Service Policy on Humane Care and Use of Laboratory Animals (2015)

Acronyms

APHIS	Animal and Plant Health Inspection Service (USDA)
AO	Authorizing Official
AWA	Animal Welfare Act
AWRs	Animal Welfare Regulations (USDA)
BOT	Board of Trustees
CAS	Complaint Assessment Subcommittee
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
DMR	Designated Member Review
FCR	Full Committee Review
GVSU	Grand Valley State University
IACUC	Institutional Animal Care and Use Committee
IACUPPS	Institutional Animal Care and Use Policies and Procedures Subcommittee
IO	Institutional Official
NIH	National Institutes of Health
ORCI	Office of Research Compliance and Integrity
OSP	Office of Sponsored Programs
OLAW	Office of Laboratory Animal Welfare (NIH)
PHS	Public Health Services
PI	Principal Investigator
RIO	Research Integrity Officer
SLT	Senior Leadership Team
USDA	United States Department of Agriculture

Section 1: IACUC Authority and Responsibilities

Policy 1.10: Ethical Standards and Practices for GVSU Activities Involving the Care and Use of Animals

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Policy

Grand Valley State University (GVSU) recognizes the importance of animals in research and educational activities and the scientific and ethical responsibility for their humane care and use. All individuals involved with the care and use of animals in research and educational activities at GVSU are responsible for ensuring the health and well-being of the animals.

The Institutional Animal Care and Use Committee (IACUC), with support from the Office of Research Compliance and Integrity (ORCI), is responsible for overseeing the provisions for the care and well-being of vertebrate animals used for research and educational purposes at the University. The IACUC and ORCI serve the public by ensuring compliance with all legal and ethical standards regarding the use of vertebrate animals in research and educational activities at GVSU.

Certain categories of animals are exempt from IACUC oversight: e.g. service animals, service animals in training, animals under the control of a law enforcement officer acting in the course of his or her duties, and animals kept in residence halls as approved by the Department of Housing and Residence Life, including animals kept by housing staff in residence. Refer to University Policy SLT 6.1 for the complete listing of exempt animals.

The primary ethical principles applied to research and educational activities involving animals that are covered by the IACUC are those set forth in the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (*Federal Register*, May 20, 1985, Vol. 50, No. 97 [FR Doc. 85-12059]).

Additionally, all individuals involved in the care and use of animals for GVSU research and/or educational activities are expected to adhere to the principles of *expertise* (competent to do the work) and *integrity* (uphold professional principles and standards). Additional ethical principles may be applied when appropriate. Training on the ethical principles and personnel responsibilities of individuals involved with the care and use of animals is provided by the ORCI.

Policy 1.20: Compliance with Applicable Laws and Regulations
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Policy

The IACUC and all associated entities will comply with Federal and State law and regulations, and University policy. In the case of variances between federal, state, local, laws and University policy, the more protective standard typically takes precedent.

Procedures and Regulatory Guidance

1. Office of Laboratory Animal Welfare (OLAW)
    a. The OLAW implements Public Health Services (PHS) Policy. While OLAW (https://olaw.nih.gov/home.htm) is located organizationally at the National Institutes of Health (NIH) in Bethesda, Maryland, OLAW's responsibility for laboratory animal welfare extends beyond NIH to all PHS-supported activities involving animals. Periodically, OLAW issues policy guidance, interpretation, or general notices regarding PHS Policy, and co-sponsors animal welfare workshops that are held in different locations across the country.

    b. Specific OLAW responsibilities include:
        i. Implementation of the PHS Policy

        ii. Interpretation of the PHS Policy

        iii. Negotiation of Animal Welfare Assurances

        iv. Evaluation of compliance with the PHS Policy; and Education of institutions and investigators receiving PHS support

2. Animal Welfare Assurance
    a. Before the PHS may award a grant or contract that involves the use of animals, the recipient institution and all performance sites involving or using animals must have on file with OLAW an approved Animal Welfare Assurance (Assurance). The Assurance is the cornerstone of a trust relationship between the institution and the PHS. Included in the Assurance are:

        i. The designation of the Institutional Official (IO) responsible for compliance

ii. A commitment that the institution will comply with the PHS Policy, with the *Guide*, and with the Animal Welfare Act and the Animal Welfare Regulations (AWRs)

iii. A description of the institution's program for animal care and use

b. The PHS Policy applies to the use of live, vertebrate animals in any activity supported or conducted by the PHS. PHS agencies include:

i. Agency for Healthcare Research and Quality

ii. Agency for Toxic Substances and Disease Registry

iii. Centers for Disease Control and Prevention

iv. Food and Drug Administration

v. Health Resources and Services Administration

vi. Indian Health Service

vii. National Institutes of Health

viii. Office of Public Health and Safety

ix. Office of the Secretary

x. Program Support Center

xi. Substance Abuse and Mental Health Services Administration

xii. Office of the Assistant Secretary for Preparedness and Response

c. GVSU has an Assurance on file with OLAW (Number A4449-01). The Assurance may be active or inactive depending on whether the University has any on-going PHS-funded animal research.

3. United States Department of Agriculture (USDA)

In 1966, Congress passed the Laboratory Animal Welfare Act (PL 89-544) and the USDA was named the responsible agency for the enforcement of the Animal Welfare Act (AWA) to protect certain animals from inhumane treatment and neglect. The USDA's Animal and Plant Health Inspection Service (APHIS) administers the AWA, its standards, and its regulations.

GVSU is a registered Class R Research Facility with the USDA (customer number 13477 under certificate number 34-R-0149).

4. Animal Welfare Act

The AWA requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. Individuals who operate facilities in these categories must provide their animals with adequate care and treatment in the areas of housing, handling, sanitation, nutrition, water, veterinary care, and protection from extreme weather and temperatures.

   a. Inclusions

   The AWA (Title 7, Chapter 54, Section 2132(g)) defines the term "animal" to mean any living or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal that is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

   b. Exemptions

   The AWA (Title 7, Chapter 54, Section 2132(g)) excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, horses not used for research purposes, and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry, used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. While these animals are excluded from the AWA, they still fall under the purview of the IACUC if they will be used for research or educational activities at GVSU.

   c. Research Facilities

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

      ii. Research facilities must establish an IACUC to oversee the use of animals in experiments. The IACUC is responsible for ensuring that the facility remains in compliance with the AWA and for providing documentation of all areas of compliance to the USDA/APHIS. The AWA also does not

permit APHIS to interfere with research procedures or experimentation. To ensure that all licensed and registered facilities continue to comply with the AWA, APHIS inspectors make unannounced inspections at least once annually.

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

iv. APHIS also conducts reviews and investigates alleged violations. Some cases are resolved with Official Notices of Warning or agency stipulation letters, which set civil penalties for the infractions. Civil penalties include cease-and-desist orders, fines, and license suspensions or revocations. If APHIS officials determine that an alleged AWA violation warrants additional action, APHIS submits all evidence to the USDA for further legal review.

v. In addition to conducting regular inspections, APHIS will perform inspections in response to public input about the conditions of regulated facilities. Concerned individuals also are encouraged to inform APHIS about facilities that should be licensed or registered.

Policy 1.30: Authority of the IACUC

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Policy

1. The IACUC derives its authority and requirements from federal law.

2. The IACUC reports to the IO. The IO is given the administrative and operational authority to commit institutional resources to ensure compliance with the PHS Policy and other requirements.

3. The IACUC's authority to review, approve, withhold approval, or suspend protocols is independent of the IO, who may not overrule an IACUC decision to withhold approval of a protocol.

4. If the IACUC approves a protocol, GVSU is not required or obligated to conduct the research activity. GVSU may also subject protocols to additional institutional review (e.g., unit head, Lab Safety committee, etc.).

5. The IACUC shall maintain appropriate confidentiality of IACUC submission materials (including, but not limited to, protocols, annual reviews, amendments, etc.), decisions, and discussions both inside and outside of IACUC meetings.

Procedures and Regulatory Guidance

1. IACUCs derive their authority from the law. The Health Research Extension Act of 1985 and the AWA mandate the existence of IACUC's. The laws require the Chief Executive Officer (CEO) of an organization to appoint the IACUC, whose responsibilities are delineated in the law and federal policy and regulations. The OLAW considers the CEO to be the highest operating official of the organization. The Provost of GVSU delegates authority through the IO to appoint the membership of the IACUC.

2. Liability
   Under PHS Policy, the primary responsibility for meeting applicable federal and state rules rests with the research facility or PHS awardee institution. The IO is the individual held responsible on behalf of the research facility for ensuring compliance. Failure to comply with PHS Policy could result in OLAW's withdrawal of approval of the GVSU's Assurance, thereby making the institution ineligible to receive federal funds for activities involving animals. Failure to comply with the AWA could result in the USDA's assessment of monetary fines and withdrawal of GVSU's Certificate of Registration.

3. Response to External Requests for Information
   The IACUC, through the Freedom of Information Act Coordinator in the Division of Legal, Compliance and Risk Management, will adhere to requirements for providing copies of documents to the public as specified in the Freedom of Information Act and the

Michigan Public Information Act. Redaction of proprietary and private information is allowed but must be done so judiciously and consistently for all requested documents.

Policy 1.40: Responsibilities of the IACUC
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Policy

1. The IACUC is responsible for performing the following functions:

    a. Review the University's program for humane care and use of animals at least once every six months, using the *Guide* as a basis for evaluation.

    b. Inspect all GVSU's facilities, including satellite facilities, used to house animals covered under IACUC protocols at least once every six months, using the *Guide* as a basis for evaluation.

    c. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit reports to the IO.

    d. Review concerns involving the care and use of animals at GVSU.

    e. Make written recommendations to the IO regarding any aspect of GVSU's animal program, facilities, or personnel training.

    f. In accord with PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals.

    g. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in PHS Policy IV.C.

    h. Notify investigators and the University in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4.

    i. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years.

    j. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6.

k. Evaluate animal-care related Standard Operating Procedures (SOPs) referenced in IACUC protocols and those instituted for use in the GVSU vivarium to ensure the SOPs are used in a manner that is consistent with federal, state, and local laws and regulations, and University policy overseeing animal care and use.

2. The Institutional Official is responsible for performing the following functions:

    a. Ensuring compliance with all applicable laws, regulations, and policies related to the GVSU animal care and use program.

    b. Giving proper administrative and operational authority to commit University resources to ensure compliance with the applicable laws, regulations, and policies.

    c. Appointing IACUC members and periodically reviewing the composition of the IACUC to ensure effectiveness and appropriate subject matter expertise.

    d. Overseeing the development of administrative procedures necessary to implement the animal care and use program and ensuring alignment of the program's goals with the University's mission.

    e. Performing all necessary reporting requirements—including the reporting of any noncompliance with laws, regulations, and policies—to the appropriate officials.

    f. Ensuring all personnel involved with the animal care and use program are appropriately qualified to perform their duties and that appropriate training is provided.

    g. Ensuring that IACUC records are appropriately maintained and securely stored.

Policy 1.50: IACUC Document Retention and Recordkeeping Requirements
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Policy

The ORCI will maintain all IACUC-related documents for a minimum of three years with the exception of records related directly to protocols, which must be kept for the duration of the activity and for an additional three years after completion of the activity.

Procedures and Regulatory Guidance

1. IACUC-related documents may include, but are not limited to, the following:

    a. Animal Welfare Assurance on file with OLAW

    b. Minutes of IACUC meetings

    c. Records of IACUC activities and deliberations

    d. Minority IACUC views

    e. Documentation of protocols reviewed by the IACUC and proposed changes to protocols

    f. IACUC semiannual program evaluations and facility inspections, including deficiencies identified and plans for correction

    g. OLAW annual reports

    h. USDA-related documents (i.e., registration, Annual Report of Research Facility, Program of Veterinary Care, etc.)

    i. Accrediting body determinations

    j. Animal adoption forms

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

3. Meeting Minutes
    a. Review of proposals by the IACUC invokes a deliberative process, and the PHS Policy and AWRs require that GVSU maintain “minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee

deliberations" (PHS Policy IV. E; 9 Code of Federal Regulations (CFR) Part 2 Subpart C 2.35 (a)(1)). The IACUC has some latitude in the degree of detail in these minutes.

b. Recorded minutes from IACUC full committee reviews are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the IACUC such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or noncompliance would be recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IACUC from members who have served on the IACUC and observed the procedures being proposed, served as reviewers for protocols involving similar procedures (where their questions were answered), or participated in past IACUC discussions about the procedures.

c. Minutes of each full committee review are recorded in writing and include records of attendance, activities of the IACUC, and a summary of the issues discussed and the resolution of issues:

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

    ii. <u>Activities of the IACUC</u>
    Activities of the IACUC include, but are not limited to, corrections or approval of previous minutes; presentation of program, policy, facility and compliance reports; and decisions on policies, protocols, and amendments. The minutes must reflect the IACUC votes on protocols.

    iii. <u>Deliberations of the IACUC</u>
    A deliberation of the IACUC refers to the discussion and reasons leading to particular IACUC decisions. Minutes should include as a minimum a summary of the key points discussed prior to a committee decision. Completed minutes are distributed to all IACUC members. Minutes are discussed at a subsequent convened meeting of the IACUC and the IACUC votes on approval. A copy of the approved meeting minutes is then provided to the IO. This informs the IO of all actions taken by the IACUC.

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

5. Other Records
   a. Both the PHS Policy and the AWRs require that institutions retain the semiannual program review and facility inspections reports and any recommendations of the IACUC.

   b. PHS Policy requires the OLAW Assurance and reports of accrediting agencies (e.g., Association for Assessment and Accreditation of Laboratory Animal Care) be kept on file.

   c. Depending upon the species, USDA requires records documenting the number of animals acquired, transported, sold, or euthanized by the research facility.

   d. Animal health records are not usually maintained by the IACUC but are kept in the animal facility or in research laboratories.

   e. All of these records must be accessible to OLAW, USDA/APHIS, and funding agencies for inspection or copying.

Policy 1.60: Institutional Animal Care and Use Policies and Procedures Subcommittee
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IACUC Approval Date: 03/18/2021
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Policy

1. The Institutional Animal Care and Use Policies and Procedures Subcommittee (IACUPPS) provides support for the IACUC and the GVSU research community by reviewing and developing IACUC policies and procedures.

2. The IACUPPS is comprised of four members, including the IACUC Chairperson (or an IACUC member designee), two other IACUC members, and a staff member from the GVSU ORCI.

3. IACUPPS member appointments are made by the IO, and are generally for one- or two-year terms, with appointments being renewable.

4. When requested by the subcommittee to complete special projects, the IO may choose to add an additional IACUC member to the IACUPPS on a temporary, short-term basis (i.e., less than 1 year).

Responsibilities of the IACUPPS

1. Periodically review the IACUC policies and procedures, including submission forms, documents, and guidelines.

2. Develop new or revised IACUC policies and procedures, forms, documents, and guidelines as appropriate.

3. Periodically review the information and instruction provided on the IACUC website and make recommendations for improvement.

4. Assist in identifying informational and/or knowledge lapses among IACUC members, investigators, research staff, and students. Support educational efforts in addressing deficits.

Policy 1.70: Review and Approval of IACUC Policies
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Policy

1. New policies and significant changes to existing policies must be reviewed and approved by both the IACUPPS and the IACUC.

2. Existing policies must be reviewed not less than once every 3 years by the IACUC, but more frequent review may occur as necessary.

Procedures and Regulatory Guidance

1. Significant vs. Minor Policy Changes
    a. Significant policy changes are those considered by the IACUPPS/IO/IACUC/ORCI to fundamentally change the interpretation of the policy and/or that add additional conditions to the policy. Significant policy changes recommended by the IO and/or the IACUC must be re-reviewed by the IACUPPS.

    b. Minor policy changes are those considered by the IACUPPS/IO/IACUC/ORCI to not change the fundamental interpretation of the policy. Such changes include, but are not limited to:
        i. Grammatical/typographical edits

        ii. Addition of clarifying statements to the policy that do not change the fundamental interpretation of the policy

        iii. Changes in the administrative procedures and/or regulatory references supporting the policy

2. New Policies or Significant Changes to Existing Policies
    a. IACUPPS Review and Approval
    Any new policies or significant changes to existing policies must be reviewed and approved by a majority vote of the IACUPPS.

    b. IO Review and Approval
    Following IACUPPS approval the IO may, at their discretion, review and approve the policy. The IO may approve as written or recommend changes to the policy.

        i. If the IO recommends major changes, the policy will be returned to the IACUPPS for further review and discussion, and the policy will require reapproval by the IACUPPS.

ii. If the IO approves the protocol with minor changes recommended, the policy will be updated to reflect the minor changes and forwarded to the IACUC for final review and approval.

iii. If the IO approves the protocol as written without further recommendations, or chooses not to review it, the policy will be forwarded to the IACUC for final review and approval.

c. IACUC Review and Approval

i. The IACUC will review the policies at a convened meeting with a quorum of members present.

ii. The IACUC may choose to take one of the following actions:
   1. Approve as written
   2. Approve with minor changes
   3. Table the policy for discussion at a future meeting
   4. Recommend significant changes and/or return the policy to the IACUPPS for further development.
   5. Disapprove the policy

iii. If the IACUC approves the policy as written or with additional minor changes, the policy will be considered final.

iv. If the IACUC recommends significant changes, the policy will be returned to the IACUPPS for further review and discussion, and the policy will require reapproval by the IACUPPS, the IO (at their discretion), and the IACUC.

v. All actions, with the exception of tabling, requires a majority vote.

3. Minor Changes to Existing Policies

a. IACUPPS Review and Approval

Minor changes to existing policies, with the exception of those described below in 3.b.ii and 3.d., must be approved by a majority vote of the IACUPPS.

b. IO Review and Approval

Following IACUPPS approval the IO may, at their discretion, review the policy. The IO may approve as written or recommend changes to the policy.

i. If the IO recommends major changes, the policy will be returned to the IACUPPS for further review and discussion, and the policy will require reapproval by the IACUPPS.

ii. If the IO approves the protocol with additional minor changes recommended, the policy will be updated to reflect the additional minor changes and will be considered final.

iii. If the IO approves the protocol as written without further recommendations, or chooses not to review it, the policy will be implemented as drafted.

c. IACUC Notification
The IACUC will be notified of any minor policy changes approved by the IACUPPS/IO at the next convened IACUC meeting.

d. Grammatical/typographical errors may be corrected by the ORCI at any time without IACUPPS review and approval.

4. Review of Existing Policies
   a. The IACUC will review existing policies at a convened meeting with a quorum of members present at least once every three years.

   b. The IACUC may choose to take one of the following actions:
      i. Approve as written
      ii. Approve with minor changes
      iii. Table the policy for discussion at a future meeting.
      iv. Recommend significant changes and/or return the policy to the IACUPPS for further development.
      v. Disapprove the policy.

Policy 1.80: Review and Approval of IACUC Standard Operating Procedures
Version: 1.1
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Policy

1. The IACUC is responsible for the evaluation of animal care-related Standard Operating Procedures (SOPs) referenced in IACUC protocols and those instituted for use in the GVSU vivarium.

2. New SOPs referenced in IACUC protocols and/or instituted for use in the GVSU vivarium must be approved by the IACUC.

3. Existing SOPs referenced in IACUC protocols and/or instituted for use in the GVSU vivarium must be reviewed not less than once every 3 years by the IACUC or a designated subcommittee of the IACUC, but more frequent review may occur as necessary. SOPs involving USDA-regulated species must be reviewed at least semi-annually by the IACUC or a designated subcommittee of the IACUC.

Procedures and Regulatory Guidance

1. Drafting SOPs
    a. Anyone in the GVSU Animal Care and Use community may draft an SOP. The Vivarium Supervisor is considered the "owner" of SOPs developed for the GVSU vivarium; for SOPs developed for facilities outside of the vivarium, the PI of the laboratory facility is considered the "owner".

    b. When developing a new SOP, users are encouraged to contact the ORCI for a template.

2. SOPs must be made available (either via hardcopy or electronically) to all researchers in the vivarium/laboratory where the SOP is to be used.

3. Review and Approval of non-GVSU vivarium SOPs (does not include GVSU vivarium SOPs)
    a. If a non-GVSU vivarium SOP will be referenced in an IACUC protocol, the PI must submit a copy of the SOP in the IACUC protocol application. The IACUC will review the SOP as part of the overall review process for the protocol, and may choose to approve the SOP as written, require changes/clarifications, or disapprove the SOP. (Disapproval of the SOP would require disapproval of the protocol per Policy 4.20: IACUC Protocol Submission and Review.)

    b. Following initial approval of the SOP, the IACUC will perform on-going review and approval of the SOP at a convened meeting for the duration of the protocol(s) referencing the SOP. These reviews will occur at the required intervals (e.g., at

least semi-annually for protocols involving USDA-covered species and at least every three years for all others) for the duration of the protocol(s) referencing the SOP.

c. If an SOP will not be referenced in an IACUC protocol, it does not require review and approval by the IACUC. However, the owner of the SOP should review the document at least once every three years and revise as needed to comply with the AWARs.

4. Review and Approval of GVSU Vivarium SOPs
   a. Newly drafted GVSU vivarium SOPs and requested modifications to previously approved GVSU vivarium SOPs must be reviewed and approved by both the Veterinarian and the IACUPPS. All IACUPPS members must unanimously approve the SOP. If changes are needed, the IACUPPS will work with the owner of the SOP and the Veterinarian to incorporate the changes.

   b. Following approval by the IACUPPS, the IO may, at their discretion, review the SOP. If the IO recommends changes, these recommendations will be reviewed by the IACUPPS, and if necessary, the IACUPPS will work with the owner and Veterinarian to incorporate the changes.

   c. New GVSU vivarium SOPs must further be reviewed and approved by the IACUC. The IACUC may choose to approve the SOP as written, require changes/clarifications, or disapprove the SOP. (Disapproval of the SOP would require disapproval of the protocol per Policy 4.20: IACUC Protocol Submission and Review.)

   d. Modifications of SOPs previously approved by the IACUC do not require additional review and approval from the IACUC.

   e. The IACUPPS will conduct a review of all previously approved vivarium SOPs at the required intervals (e.g., at least semi-annually for protocols involving USDA-covered species and at least every three years for all others). All IACUPPS members must unanimously approve the SOP. If changes are needed, the IACUPPS will work with the owner of the SOP and the Veterinarian to incorporate the changes. Review and approval of previously approved SOPs may occur via email.

   f. IACUC members will be notified of all modified SOPs and when existing SOPs have been reviewed by the IACUPPS. All IACUC members will have access to all approved GVSU vivarium SOPs.

5. PIs are not required to submit a copy of GVSU vivarium SOPs referenced in IACUC protocol applications.

Section 2: IACUC Operations

Policy 2.10: IACUC Board Composition

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IACUPPS Approval Date: 12/10/2021
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Policy

1. The IACUC will meet the minimum compositional requirements set forth in PHS policy and USDA regulations and policy.

2. The IACUC is composed of regular voting members and may include, as conditions warrant, alternate voting members.

3. The IACUC may use consultants during review discussions as necessary. There is a specific one-to-one designation of IACUC members and alternates. An IACUC member and their alternate may not count toward a quorum at the same time or act in an official member capacity at the same time.

4. Some IACUC members fulfill specific regulatory requirements (e.g., veterinarian with program responsibility, an individual nonaffiliated with the University); others have unique roles by virtue of their position (e.g., Chairperson, Veterinarian, etc.)

5. All IACUC members will be classified as either affiliated or non-affiliated and as either scientist, nonscientist, or veterinarian.

Procedures and Regulatory Guidance

1. IACUC Minimal Compositional Requirements

PHS Policy Policy IV.A.3.a., Policy IV.A.3.b	**USDA Regulations/Policy** 9 CFR 2.31 (a), 9 CFR 2.31 (b), Policy 15

• Appointed by the IO
• Minimum of five members:
  ○ One Doctor of Veterinary Medicine with training or expertise in laboratory animal science and medicine who has direct or delegated program authority and responsibility for activities involving animals at the institution.
  ○ One practicing scientist experienced in research involving animals.
	• Appointed by the IO
	• Minimum of three members:
	  ○ At least one Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine, and who has direct or delegated program responsibility for activities involving animals at the institution.
	  ○ One member not affiliated in any way with the institution and not a member of immediate family of

○ One member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, clergy, etc.). ○ One member not affiliated in any way with the institution and not a member of immediate family of a person who is affiliated with the institution. • The PHS Policy requires institutions to follow the *Guide*, which states that committee membership should include at least one public member to represent general community interests in proper care and use of animals, and that public members should not be current or former animal users	a person who is affiliated with the institution; person who represents the general community interests in the proper care and treatment of animals; and is not a laboratory animal user. ○ Not more than three members from the same administrative unit of the institution.

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

   b. Chairperson
   The Chairperson is appointed by the IO and is a faculty member of GVSU with research experience. In addition to serving as a member of the GVSU IACUC, the IACUC Chairperson shall:
      i. Direct the proceedings of convened meetings of the IACUC.
      ii. Hold regular meetings with the IACUC administrative support staff.
      iii. Write letters from the IACUC regarding IACUC decisions and actions.
      iv. Sign IACUC letters, as needed.
      v. When directed by the IACUC, make decisions about researcher/instructor responses to IACUC conditions for protocol approval.
      vi. Represent GVSU in interactions with personnel of federal and state agencies regarding the humane care and use of laboratory animals at GVSU.

vii. Represent the IACUC in discussions with researchers, instructors, and other GVSU and community stakeholders.

3. Determination of Affiliated vs. Unaffiliated
    a. Nonaffiliated Members
        i. The nonaffiliated member(s) represent general community interests in the proper care and use of animals.

        ii. Nonaffiliated members are individuals who are not affiliated with GVSU in any way other than as a member of the IACUC. Neither they, nor their immediate family, have a current affiliation with GVSU. Additionally, OLAW stipulates that nonaffiliated members are not to be a current or former animal user, and cannot have an immediate family member (parent, spouse, child, or sibling) affiliated with the institution. An individual whose only association with GVSU is that of health care patient, research participant, or former student may be considered unaffiliated if they meet all of the other required criteria to be an unaffiliated member.

        iii. These members have equal status (e.g., voting) to every other committee member and are provided the opportunity to participate in all aspects of IACUC functions.

        iv. Paying an unaffiliated member reasonable market value for the costs associated with participation as a member of the IACUC (e.g., transportation and parking costs) does not cause a member to become "otherwise affiliated" or cause a member to have a conflicting interest.

        v. An individual must be able to answer "No" to all of the following questions to be considered unaffiliated with GVSU:

            1. Are you (or any dependent member of your immediate family) a full or part-time employee, paid entity, or agent of GVSU?

            2. Are you a former employee of a GVSU institution who worked for GVSU within the past 5 years?

            3. Do you receive any funding or perquisites under the control of GVSU, except as compensation for IACUC?

            4. Are you (or any dependent member of your immediate family) a current student at GVSU?

            5. Do you serve GVSU in any other capacity (e.g. serving on other committees)?

6. Are you a current or former animal user on an IACUC-approved protocol?

b. Affiliated Member
A member is considered an affiliated member when they do not meet the conditions of a nonaffiliated member.

4. Determination of Scientist vs. Nonscientist
   a. Scientist
   For the purposes of determining IACUC member status, a scientist is a person who routinely utilizes the scientific method in the conduct of their discipline-related scholarship. Scientists may or may not have previous animal research experience; however, PHS Policy requires that the IACUC include at least one practicing scientist experienced in research involving animals.

   b. Nonscientist
   For the purposes of determining IACUC member status, a nonscientist is a person who does not routinely utilize the scientific method in the conduct of their discipline-related scholarship. Examples include, but are not limited to, ethicist, lawyer, member of the clergy, librarian, etc. PHS Policy requires that the IACUC include a member whose primary concerns are in a nonscientific area.

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

6. GVSU considers persons with expertise in the disciplines involved in institutional research and teaching programs for service on the IACUC. In addition to the required categories of membership, it is suggested that individuals with expertise in specific areas pertinent to protocol review and program oversight be considered (e.g. statisticians, occupational health experts, information resource specialists, animal health technicians, and scientific research staff).

Policy 2.20: IACUC Member Training and Continuing Education
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. New IACUC members must participate in a new member orientation prior to voting at an IACUC meeting.

2. The ORCI, in conjunction with the IACUC Chairperson, will provide IACUC members with continuing education opportunities related to their responsibilities as a committee member.

Procedures

1. New Member Orientation
    a. The objectives of New Member Orientation include the following:
        i. Introduce members to the role of the IACUC and its evolution
        ii. Provide the basic information necessary for IACUC members to perform their responsibilities
        iii. Provide a forum for response to, and discussion of, members' concerns and questions.
    b. New IACUC member orientation consists of the following:
        i. Description of the IACUC and its responsibilities and authority
        ii. Overview of U.S. government principles and federal regulations
        iii. Criteria for membership
        iv. Individual roles and responsibilities
        v. Overview of the protocol review process, including monitoring of approved protocols, periodic review, protocol modifications
        vi. Overview of semi-annual program reviews and lab inspections

2. Essential documents are made available to each IACUC member. These include, but are not limited to, the following:
        i. GVSU Assurance Letter with OLAW
        ii. GVSU IACUC Handbook of Policies and Procedures

iii. Animal Welfare Act Regulations

iv. Public Health Service Policy on Humane Care and Use of Laboratory Animals

v. Guide to the Care and Use of Laboratory Animals

vi. Euthanasia of Research Animals: American Veterinary Medicine Association Guidelines

vii. OLAW/Applied Research Ethics National Association IACUC Guidebook

3. Continuing Education
    a. The objective of providing ongoing training for IACUC members is to increase their knowledge, understanding, and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It also provides a regular forum for the IACUC to discuss concerns or questions brought forth by the faculty, staff, or members of the community.

    b. Continuing education for IACUC members may occur at IACUC meetings. Information provided for these sessions will include questions and concerns brought to the attention of the IACUC, official directives, relevant publications, conference announcements, seminar proceedings, animal facility staff and/or veterinarian's observations/recommendations, issues involving facility inspections and program evaluations, and compliance issues.

    c. The ORCI, through the Center for Scholarly and Creative Excellence, also provides funds for IACUC members to attend appropriate training, workshops, and conferences related to the humane practice of animal care and use.

4. Documentation of training is maintained by the ORCI through the use of IACUC member files.

Policy 2.30: IACUC Member Conflict of Interest
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. No IACUC member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest, except to provide information requested by the IACUC.

2. IACUC members and consultants are required to disclose any conflicts of interest according to the applicable GVSU Policies.

3. Any IACUC member is said to have a conflict of interest whenever that person, their spouse, domestic partner, or dependent child falls under any of the following conditions:
    a. Is an investigator or sub-investigator on the protocol.

    b. Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.

    c. Acts as an officer or a director of the sponsor or an agent of the sponsor.

    d. Has an equity interest in the sponsor.

    e. Has received payments or other incentives from the sponsor that when aggregated for the member and spouse/domestic partner/dependent children exceeds $5000.

    f. Is involved in a potentially competing research program.

    g. Has a philosophical or moral objection to the study itself.

    h. Has identified themselves for any other reason as having a conflict of interest.

Procedures

1. University policies governing conflict of interest include: General Personnel Policies for Faculty and Staff – Conflict of Interest (BOT 4.1.6), Conflict of Interest Policy (PC 10.1), and Conflict of Interest in Research Policy (SLT 3.4). Consult the GVSU Policies page for the latest version of these policies.

2. Members holding a financial or non-financial conflict of interests with the study or investigators shall:

a. Announce the presence of a conflict and disqualify themselves from accepting a protocol review or participating in a convened committee review, except to provide information on request.

b. Leave the meeting during the discussion and the vote on any motion to approve, require changes, or disapprove the research in question. (Note: When a person with a conflict of interest leaves the room, they cannot be counted towards a quorum. If quorum is lost, the protocol will be tabled. Those who dismiss or absent themselves during a meeting will be identified as doing so in the minutes.)

3. If an IACUC member is unsure if they have an actual or perceived conflict of interest with the research under review, the member shall inform the IACUC Chairperson of the potential conflict prior to engaging in the review of the research. The Chairperson will review the potential conflict, consulting with ORCI as needed, and determine if the member should recuse themselves from protocol review. In cases where the presence or appearance of conflict remains unclear following Chairperson/ORCI review, the member with the perceived or actual conflict of interest shall recuse themselves from protocol review.

Policy 2.40: IACUC Recommendations to the Institutional Official
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

The IACUC will make written recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training, as needed.

Procedures

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

2. Recommendations are prepared in writing by the Attending Veterinarian, the IACUC Chairperson, and/or any IACUC member. A copy of these recommendations is reviewed and approved at a convened meeting of the IACUC. Any minority views are noted and included in the final report.

3. The IACUC Chairperson or their designee submits recommendations, including minority views that are approved by the IACUC to the IO.

Policy 2.50: Conducting IACUC Meetings
Version: 2.0
IACUPPS Approval Date: 04/03/2025
IO Approval Date: 04/04/2025
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. There is no requirement that any particular member or category of members be present at all IACUC meetings. GVSU, however, must have a properly constituted IACUC in order for the IACUC to conduct valid official business.

2. Quorum
    a. The following IACUC actions require a quorum: full committee review of a research or animal use project, disapproval of an IACUC application, and suspension of an activity.

    b. A "quorum" is defined as a majority of the regular IACUC voting members.

    c. A protocol is approved only if a quorum is present, and if more than 50% of the quorum votes in favor of protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

        i. Example: If the IACUC has 7 voting members, at least 4 members must be present at a convened meeting to constitute a quorum.

        ii. Example: An IACUC has 9 voting members and 6 are present at a convened meeting, thus constituting a quorum. Approval of a protocol at the meeting would require a minimum of 4 votes whether or not there were abstentions.

3. Conflict of Interest
    If the investigator submitting a protocol believes that an IACUC member has a potential conflict, the investigator may request that the member be excluded from reviewing and voting on a protocol. The Chairperson will present the declared conflict and the IACUC will determine whether a conflict exists. Should an IACUC member declare involvement in any way in a research protocol under review by the IACUC, or state a conflict of interest with the research protocol, then the member:
    a. May remain in the meeting room to provide information requested by the IACUC

    b. Must leave the meeting room for discussion and voting

    c. Is not counted towards quorum

Procedures and Regulatory Guidance

1. University policies governing conflict of interest include: General Personnel Policies for Faculty and Staff – Conflict of Interest (BOT 4.1.6), Conflict of Interest Policy (SLT 10.1), and Conflict of Interest in Research Policy (SLT 3.4). Consult the GVSU Policies page for the latest version of these policies.

2. Both the PHS Policy (IV.B.6; IV.B.7; IV.C.2; IV.C.6) and the AWRs (§2.31(c)(8); §2.31(d)(2)); §2.31(d)(4); §2.31(d)(6)) allow the IACUC to conduct a full committee review of protocols, withhold approval of IACUC applications, and suspend a previously approved IACUC protocol.

3. In addition to the IACUC having the authority to suspend an active IACUC protocol, the IACUC Chairperson, the IACUC veterinarian, and/or the IO may suspend an animal activity when animal welfare concerns are identified, until such time that the IACUC can convene and consider the matter formally. See *IACUC Policy 5.10: IACUC Noncompliance*.

Policy 2.60: Ethical Cost-Benefit Analysis
Version: 1.1
IACUPPS Approval Date: 2/25/2022
IO Approval Date: 3/5/2022
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

The IACUC will critically evaluate protocols to ensure that the objectives and potential benefits of the proposed activity are acceptable when compared to the potential animal welfare concerns of the animals to be involved in the activity (i.e, a cost-benefit analysis).

Procedures and Regulatory Guidance

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

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

3. Investigators may seek training in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress.

4. The GVSU Statistical Consulting Center (www.gvsu.edu/scc) is available for

consultation and advice on methods that minimize the number of animals required to obtain statistically valid experimental results.

Policy 2.70: Comparison of IACUC Protocols to Grants
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

The IACUC, in conjunction with the ORCI, will evaluate protocols to ensure consistency with grant submissions, if applicable.

Procedures and Regulatory Guidance

1. PHS agencies will not make an award for research involving live vertebrate animals unless the applicant organization and all performance sites are operating in accordance with an approved Assurance and have provided verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the PHS Policy. Additionally, PHS agencies will not make an award for research involving live vertebrate animals to an individual unless that individual is affiliated with an organization that accepts responsibility for compliance with PHS Policy and has filed the necessary Assurance with OLAW. Regardless of when the review occurs, the PI should ensure that the research described in the grant proposal application is consistent with any corresponding protocol(s) reviewed and approved by the IACUC. Therefore, a copy of the funded or unfunded grant proposal application may be requested by the IACUC and reviewed by a designated member(s) to confirm that all research outlined in the grant is included in the approved IACUC protocol.

2. Verification of Protocol and Proposal Consistency
    a. The extents of the verification of consistency between grant proposals and IACUC protocols will be a confirmation that the species and procedures relating to use of animals described in the proposal are included in the protocol. This will be a unidirectional comparison of the procedures described in the grants. In conducting the verification, the IACUC focuses on the following two (2) questions:

        i. Are the species used in the grant proposal included in the IACUC protocol?

        ii. Are animal care and use procedures described in the grant proposal included in the IACUC protocol?

    b. Verification of grant and protocol consistency concentrates on animal care and use and **will not** include a judgment of scientific merit.

3. Timing of Verification
    The IACUC will compare the grant to the protocol during the review of the protocol. In addition, the IACUC will compare the grant to the protocol when a new funding source

for a protocol is proposed, or when the Office of Sponsored Programs (OSP) requests verification.

4. Protocol Amendments
    a. There are two types of amendments to animal research protocols that have specific relevance to this policy: 1) a change in funding source and 2) a change in animal use procedures. Submission of an administrative amendment requesting a change in funding source will include a verification of consistency between the new grant and the current protocol to which it is being linked. The verification will include a confirmation that the species and procedures relating to use of animals described in the proposal are included in the protocol.

    b. The IACUC understands that research projects evolve over time and therefore the specific direction of a protocol may change from the original description of animal use procedures. These changes should be submitted as a significant amendment to the protocol and should be consistent with the objectives, purpose, or aims stated in the original protocol. It is the PI's responsibility to explain how the changes relate to the original protocol. Because the determination of consistency between the grant and original protocol has already been established, there will generally be no need to "re-verify" grant-to-protocol consistency for amendments.

    c. For PHS-supported grants (e.g., NIH, Centers for Disease Control, etc.) it is the responsibility of the PI to indicate any significant changes in the use of vertebrate animals in the Progress Report Summary section of their Non-Competing Continuation Progress Report (PHS 2590).

5. Managing Grant-Protocol Inconsistencies
    The PI, through the IACUC, will be consulted regarding any apparent inconsistency. As noted above, significant changes require that the OSP notify the extramural Program Official. Verification of this request and subsequent approval must be shared with the IACUC.

Policy 2.80: Occupational Health and Safety
Version: 1.1
IACUPPS Approval Date: 4/13/2023
IO Approval Date: 04/25/2023
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

The IACUC is responsible for ensuring a safe working environment for personnel involved in the animal care and use program.

Procedures and Regulatory Guidance

1. At GVSU, the Laboratory Safety Program (http://www.gvsu.edu/labsafety) has been developed to protect the health and safety of faculty, students, and staff, including those who work with vertebrate animal species in the course of their research or educational activities. The program is designed to customize the participation requirements based on the type and degree of exposure to animals.

2. There are ethical and legal requirements to inform individuals of workplace health risks that could potentially affect them and appropriate precautions to mitigate those risks. The objectives of GVSU's Occupational Health and Safety Program can be achieved only if employees are appropriately trained and understand the hazards associated with their work area and job duties, and how those risks are mitigated through institutional policies, engineering controls, work practices, and personal protective equipment.

3. The IACUC will consult with the GVSU Laboratory Safety Officer when necessary and, when detected, report violations of GVSU Occupational Health and Safety Program rules to the GVSU Laboratory Safety Officer.

4. The IACUC, ORCI, and GVSU Laboratory Safety Office will provide all IACUC protocol personnel and animal care staff with the following:

    a. Access to GVSU occupational health and safety training programs

    b. Appropriate guidelines and training that outline general health and safety issues associated with working with animals, including the following as applicable:

        i. Zoonoses

        ii. Chemical safety

        iii. Microbiologic and physical hazards (e.g., allergens and radiation)

        iv. Hazards associated with experimental procedures

        v. Handling of waste materials

vi. Personal hygiene

vii. Precautions taken during pregnancy, illness, and immune suppression

c. Risk assessment

5. In general, the guidelines outlined by the *Guide*, and in the text, Occupational Health and Safety in the Care and Use of Research Animals (National Research Council, 1997) will be followed.

6. All animal caretakers, employees, and students working with animals are required to complete a medical evaluation or review of their health history prior to commencing work with the animals. This information must be reviewed and approved by a licensed medical provider. When appropriate, the medical provider may require evidence that the individual has been adequately immunized against diphtheria, *Haemophilus influenzae* type B, pertussis, polio, rabies, rubella, and/or tetanus. The medical provider may also require additional vaccinations and/or a physical exam to participate in the animal program; these items must be resolved prior to the individual receiving final approval to work with the animals.

7. Information on epizootic diseases and zoonoses frequently associated with species used in the facility will be kept on file by the GVSU Office of Laboratory Safety, and the animal caretakers will be made aware of this information. Animal caretakers will also be made aware of the Animal Welfare Act and the PHS policies on the humane care and use of animals in research. This involves an appropriate understanding of federal regulations and university policies and procedures on animal care and use by faculty and staff.

8. In the event of an animal bite, scratch, or other injury that requires medical attention, the affected individual must complete an Injury Report form (available on the GVSU Lab Safety website, https://www.gvsu.edu/labsafety/incident-and-injury-reporting-106.htm). Additionally, employees must complete the GVSU Workers' Compensation Injury Report Form (available on the GVSU Human Resources website, https://www.gvsu.edu/hro/workers-compensation-28.htm).

9. Prompt medical attention is available through GVSU Health Services housed in the Campus Health Center located on the GVSU campus, (616) 252-6030. Health Services provides primary health care for ill and injured students, faculty, and staff on the GVSU Allendale campus. It is open and staffed by a nurse practitioner during regular business hours from Monday to Friday. GVSU Health Services is affiliated with Trinity Health Medical Group. The GVSU Family Health Center, located at 72 Sheldon Blvd in Grand Rapids, is also open Monday through Friday during regular business hours to treat faculty, staff, and students (https://www.gvsu.edu/fhc/). If bites, scratches, injuries, etc., occur outside of business hours, GVSU Public Safety (616-331-3325; http://www.gvsu.edu/gvpd) should be notified. The affected individual will be required to complete an Injury Report Form as quickly as reasonably possible after their injury.

Public Safety officers can make recommendations for care. If serious injuries occur, the Allendale Fire Department (616-895-4544; http://www.allendalefirerescue.com) provides basic life support medical services to the Allendale campus. If an ambulance is needed, dial 911.

10. Chemical and biological hazard safety will be governed by the GVSU Lab Safety and Chemical Hygiene Plan. In addition, all investigators, employees, students, and animal caretakers will be required to take a course in laboratory safety administered by the GVSU Laboratory Safety Officer.

11. Protective clothing and gear will be made available to personnel working with animals and working in the animal facilities.

12. Nonhuman primates will not be housed at GVSU animal facilities. However, GVSU faculty, staff, and students may work with samples (such as tissues, blood, and bodily fluids) obtained from nonhuman primates. Such samples pose specific health concerns that need to be carefully considered. See *Appendix 1: Working with Nonhuman Primate Samples* for more information.

13. Individuals who handle radioisotopes will be required to take a course on radiation safety administered by the GVSU Radiation Safety Officer (616-331-8628; http://www.gvsu.edu/labsafety/gvsu-safety-contacts-25.htm) and will be required to gain approval from the Radiation Safety Committee.

Policy 2.90: Semiannual Program Review and Facility Inspections
Version: 2.0
IACUPPS Approval Date: 09/06/2024
IO Approval Date: 10/09/2024
IACUC Approval Date: 10/17/2024
IACUPPS Last Review Date: 04/03/2025

Policy

1. The IACUC will review GVSU's program for humane care and use of animals at least once every six months.

2. The IACUC will inspect animal facilities housing IACUC-approved animals at least once every six months.

3. The IACUC considers vehicles used by GVSU personnel to transport USDA-covered, IACUC-approved animals to be animal facilities, as outlined in *Policy 3.70: Transportation of Animals*.

Procedures and Regulatory Guidance

1. Semiannual Program Review
    a. Semiannual program reviews are conducted in accordance with the *Guide*. The animal care and use program review includes an evaluation of institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC recordkeeping and reporting procedures. It also includes a review of the adequacy and appropriateness of the veterinary medical care program, the training program for personnel, and the occupational health and safety program.

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

    c. Performing Semiannual Review
        i. During the regular convened meetings of GVSU's IACUC in January and July of each year, the IACUC reviews GVSU's animal care and use program using a Semiannual Program Review Checklist provided by OLAW. The checklist is designed to evaluate:

            1. Occupational health and safety

            2. Training for IACUC members, research and instructional staff, and husbandry staff

3. The institutional disaster plans

4. Sanitation and cleaning practices

5. Surgical support and post-operative analgesia

6. Compliance with approved protocols

7. Procedures for reporting allegations of inappropriate animal care or use

8. Accessibility to veterinary care during and after typical working hours

ii. Each area is evaluated and any deficiencies are categorized as minor or significant. No IACUC member is involuntarily excluded from participating in any portion of the program review.

iii. A quorum of the IACUC members must be present during the semiannual program review. The IACUC Chairperson requests additional comments and minority views from all members present.

iv. Semiannual Program Review Final Report

1. Findings from the semiannual program review, including a deficiency correction schedule if needed, are compiled into a final report that includes the following items:

    a. Description of the institution's adherence to the applicable regulations (AWRs, PHS Policy, the *Guide*) and identification of any deviations from these documents

    b. Review of IACUC actions

    c. Review of GVSU's Program for Animal Care

    d. Recent animal facility inspection report(s)

    e. Veterinarian's report summarizing veterinary care provided during the reporting period

    f. Minority views, if any

2. The AWRs require the report to be signed by a majority of the IACUC members.

3. The final report is distributed to the Vice Provost for Research Administration, the IO, and the Provost.

2. Facility and Vehicle Inspections
    a. Facility inspections are conducted in accordance with the *Guide*, AWRs, and PHS Policy. The AWRs do not include a clear definition of "animal facility;" however, housing is described in other terms throughout the AWRs. The *Guide* states than an animal facility consists of functional areas for animal housing, care, and sanitation; receipt, quarantine, and separation of animals, separation of species, or isolation of individual projects; and storage. The PHS Policy defines "animal facility" as "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."

    b. The *Guide* requires inspection of animal facilities in which animals are housed for at least 24 hours. The AWRs apply to animal study areas where animals are maintained for more than 12 hours (applicable only to USDA-covered species).

    c. Laboratories in which routine procedures, such as immunization, dosing, and weighing, are conducted may be evaluated by other means such as random inspections. The institution, however, through the IACUC, is responsible for all animal-related activities regardless of where animals are maintained or the duration of the housing. The IACUC must have reasonable access to these areas for the purpose of verifying that activities involving animals are being conducted in accordance with the proposal approved by the IACUC.

    d. The GVSU IACUC considers any vehicle used by GVSU personnel to transport USDA-covered, IACUC-approved animals to be an "animal facility" requiring inspection, regardless of the duration in which the animals remain in the vehicle. The procedures outlined below shall be followed for all types of facilities, including vehicles.

    e. All IACUC members are invited, and encouraged, to attend the facility inspections. This may be accomplished by assigning specific facilities to subcommittees, which must consist of at least two IACUC members. No member is involuntarily excluded from participating in any portion of the facility inspections.

    f. Ad hoc consultants may be used although the IACUC remains responsible for the evaluations and reports; ad hoc consultants must not be used as substitutes or replacements for IACUC members. The inspection team should have a working knowledge of the *Guide* and AWRs in order to fully evaluate the facilities that are being inspected.

    g. The IACUC may determine whether the supervisory personnel of various facilities should be notified of the date and time of an inspection. Advance

notification allows individuals to be available to answer questions; an unexpected visit may show the facility during usual operations but also may result in a visit having to be rescheduled if key individuals are not available. Although advance notification is not required, the IACUC may provide, as circumstances warrant, reasonable notice to investigators of the dates, times, and locations of inspections.

h. Performing Inspections
    i. Every six (6) months, the IACUC Chairperson, or delegate, organizes the inspection schedule of the animal facilities located on campus and any satellite facilities, as well as any vehicles used to transport animals.
        1. All facilities currently housing animals on GVSU IACUC-approved protocols will be inspected. If no animals are currently housed in a given facility on the date of the inspection, the facility will still be inspected if it is anticipated that animals will be housed in the facility before the next facility inspection date.
        2. Vehicles used to transport animals will be inspected prior to the initial transport of animals, and every six months thereafter for as long as the vehicle will be used for animal transport.
        3. Inspections are usually conducted during April and October each year, but may occur at any time, so long as it occurs within six months of the previous inspection.

    ii. Adherence to the following recommendations will assist the IACUC in performing inspections:
        1. An updated list of all facilities to be inspected shall be maintained by the IACUC.

        2. All proposals submitted to the IACUC should specify locations where animal procedures will be performed and if transport of animals will occur.

        3. It is helpful to maintain a list of all facilities including room number, function of the room, species and deficiencies identified during the previous inspection.

        4. For satellite areas, a contact person is useful.

        5. For facilities with multiple rooms, a floor plan can assist the inspectors.

        6. If a subcommittee is performing the inspection, a blend of IACUC members who last inspected the area with members who did not participate in the last review, can improve the process.

        7. Apparent deficiencies should be discussed with the person in charge of the facility to ensure that the team's perception of the

situation is accurate. In some cases an apparent deviation will be due to the experiment in progress, e.g., withholding of food prior to surgery.

8. The IACUC will use a facilities inspection checklist (such as those supplied by OLAW) during inspections to provide consistency and help document that all categories were assessed.

iii. Categories of items to be inspected may include, but are not limited to, the following:

1. Sanitation
2. Food and water provisions
3. Animal identification
4. Transportation methods
5. Appropriateness of caging
6. Waste disposal
7. Animal health records
8. Controlled and/or expired drugs
9. Environmental control
10. Occupational health and safety concerns
11. Staff training
12. Knowledge of animal care procedures
13. Knowledge of applicable rules and regulations, and security

iv. Deficiencies detected during facility inspections are categorized as minor or significant and discussed as necessary by the IACUC members conducting the inspection. If the members conducting the inspection recognize the matter as one of concern, the PI is promptly notified of the deficiency in their animal facility and a plan to rectify the issue is developed and included in the report. The PI is required to promptly provide a response to the deficiency notification with a description of how the deficiency has been corrected or to submit a written plan with a timeline outlining how the deficiency will be corrected. Facility

deficiencies raised by individuals who are not members of the IACUC will be brought to the attention of the IACUC Chairperson and addressed in this same manner.

v. Findings of the inspections, including any noted deficiencies, must be presented to a convened quorum of the IACUC for approval. The IACUC Chairperson requests additional comments and minority views from all members present.

vi. Facility Inspection Final Report

1. After the inspection, the IACUC prepares a report that summarizes the inspection's findings, including a deficiency correction schedule if necessary.

2. The report is distributed to the Vice Provost for Research Administration, the IO, and the Provost.

3. The AWRs require the report to be signed by a majority of the IACUC members.

4. The facility inspection report is also included in the next semiannual program review report prepared by the IACUC.

i. Deficiency Correction Schedule

i. All deficiencies identified during the facility inspections and/or semiannual program review are designated by the IACUC as minor or significant. A significant deficiency is defined as a situation that is or may be a threat to animal health or safety.

ii. For both categories of deficiencies, a reasonable and specific plan and schedule with dates for correction must be included in the final report. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic.

iii. A member of the IACUC, or staff member of the ORCI, must directly confirm that each deficiency has been corrected. The deficiency will not be considered corrected until this direct verification has occurred.

iv. If applicable, the IACUC, through the IO, must promptly report to OLAW and USDA any serious or continuing noncompliance with the PHS Policy or any serious deviation from the provisions of the *Guide* in accordance with GVSU's Assurance, and federally funded projects will have their relevant funding agency informed. If major deficiencies are not corrected by the deadline set by the IACUC, then the project will be suspended.

Policy 2.95: IACUC Review Fees
Version: 1.0
IACUPPS Approval Date: 04/13/2023
IO Approval Date: 04/25/2023
IACUC Approval Date: 06/15/2023
IACUPPS Last Review Date: 04/03/2025

Policy

1. IACUC review fees are charged to maintain the expertise and efforts needed to perform the numerous components of appropriate review, assessment and approval of research protocols, and to support post-approval monitoring.

2. Fees do not influence the decisions reached by the IACUC. If the IACUC votes to table or disapprove a protocol, no additional fee will be charged for reconsideration.

3. Protocols subject to IACUC review fees

    A. The following animal care and use protocols are subject to GVSU IACUC review fees:

        i. Protocols conducted by GVSU personnel that are both: 1) partially or fully sponsored by industry or other for-profit companies, and 2) that are covered by a Fee-for-Service Agreement.

        ii. Protocols conducted by institutions in which there is no collaboration with GVSU personnel, but in which GVSU serves as the reviewing IACUC.

    B. A request for a fee waiver or fee reduction may be made by contacting the GVSU Office of Research Compliance and Integrity (ORCI); however, approval of such requests is rare.

4. Protocols excluded from IACUC review fees

    A. The following animal care and use protocols are not subject to this policy:

        i. Protocols conducted by GVSU personnel, or in collaboration with GVSU personnel, that are not sponsored, in whole or in part, by industry or other for-profit companies.

        ii. Protocols conducted by GVSU personnel, or in collaboration with GVSU personnel, that are partially or fully sponsored by industry or other for-profit companies and that are covered by a Research Collaboration Agreement stipulating that the IACUC review fees are waived.

        iii. Protocols conducted by GVSU personnel, or in collaboration with GVSU personnel, that include students conducting the protocol as part of a for-

credit course (e.g., thesis, dissertation, capstone course, undergraduate research course, etc.).

iv. Protocols conducted by GVSU personnel, or in collaboration with GVSU personnel, that are partially or fully sponsored by industry or other for-profit companies, where the funding for the collaboration originates with a federal, state, county, or local government, or a not-for-profit organization.

v. Protocols conducted by GVSU personnel, or in collaboration with GVSU personnel, that are sponsored by funding agencies that prohibit payment of IACUC fees.

Procedures and Guidance

1. Fees will be administered by the GVSU ORCI. Fees collected for IACUC review will be used by the ORCI to support professional development for IACUC members, infrastructure costs (e.g., electronic database management systems), and/or outreach for GVSU researchers.

2. IACUC review fee schedule

   The fee amounts will be reviewed periodically and are subject to change.

Type of Review	**Full Committee Review**	**Designated Member Review**	**Administrative Review**
Initial and *de novo* reviews	$2500	$1000	No charge
Amendment	$1000	$500	$100
Continuing Review	$1000	$500	N/A
Reportable Event	No charge	No charge	No charge
Personnel Change	No charge	No charge	No charge

3. Requests for fee waivers or fee reductions

   A. The most common reason for a fee waiver or reduction is when the sponsor is supporting the animal activities by providing only certain supplies or nominal support, rather than funding the entire research.

   B. Requests may be made by emailing the GVSU ORCI (rci@gvsu.edu). The request for fee waiver or reduction should include all of the following information:

      i. A summary of the study objectives and procedures

      ii. Justification for the fee waiver/reduction, including the amount of the requested reduction if not requesting a complete waiver

iii. The study budget summary

C. Requests will be reviewed by the Vice Provost for Research Administration (VPRA). The VPRA may choose to seek additional guidance from other institutional personnel as needed, including, but not limited to: ORCI staff, the IACUC Chair and/or Vice Chair, and the Institutional Official.

D. The Principal Investigator (PI) will be notified of the VPRA's initial decision and given the opportunity to respond and provide any additional information they feel is relevant to the decision. Following the response from the PI, the VPRA will reconsider the decision if necessary, and render a final decision. All decisions by the VPRA are final. The ORCI will inform the requestor in writing of the VPRA's final decision.

4. IACUC review and outcomes

A. The review process and timetable for submissions remains the same for all protocols, regardless of whether the protocol is subject to IACUC review fees.

B. Fees are charged for services rendered. Because the IACUC and the ORCI commit full resources to each review, the fees are due in full even if the IACUC does not approve the study, animals are never used, or the study is terminated before objectives are achieved.

C. IACUC fees are non-refundable.

5. Types of agreement

A. Fee-for-Service Agreements: These agreements are legally binding contracts used when GVSU expertise is applied to solve problems within the business community. They include GVSU standards and terms & conditions that enable entities to conduct relevant work, the results of which will be owned by the business.

B. Research Collaboration Agreements: These agreements are a written contract between GVSU and one or more organizations that help define the relationship during a research program. This agreement develops the intent to share data and research materials, as well as publication of research findings. Generally, these forms also include terms and conditions on how the results of the research will be shared between parties.

C. More information about agreements can be found on the GVSU Technology Commercialization Office website (https://www.gvsu.edu/tco/agreements-17.htm).

Section 3: IACUC Protocol Personnel Responsibilities

Policy 3.10: IACUC Principal Investigator Responsibilities and Qualifications

Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. All animal research that is conducted by or under the direction of any employee, faculty, staff, student or agent of GVSU in connection with his or her responsibilities must be under the direct supervision of a GVSU faculty or staff member who shall serve as the Principal Investigator (PI) of the IACUC protocol. The PI shall ensure that the project meets and maintains IACUC approval.

2. Generally, faculty and staff are considered to be sufficiently knowledgeable to supervise and/or conduct research as determined by their appointment. The IACUC, however, may at its discretion, determine that a faculty member lacks sufficient expertise to carry out any particular research project based on their relevant training and experience.

3. The PI may delegate the performance of any or all components of the research to project personnel if they certify to the IACUC that the individuals are sufficiently trained to perform the functions assigned.

4. Individuals who do not meet any of the above criteria may, by demonstrating sufficient cause and necessary expertise, petition the IACUC Chairperson and IO for permission to submit an IACUC protocol.

Procedures

In order for work to begin on an approved animal use protocol the PI must certify that all of the following conditions are true, and that all personnel on the protocol will abide by the following conditions:

1. All students, staff, and faculty on this project are familiar with the AWA and the PHS Policy, the *Guide*, and recognize their responsibility in strictly adhering to approved protocols.

2. All individuals listed on this project are qualified or will be trained to conduct procedures involving animals under this proposal, and that they have completed approved GVSU Animal Care and Use training, and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept availability and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary), and procedures for reporting animal welfare concerns.

3. All procedures will be conducted in accordance with GVSU Occupational Health and Safety procedures, including those pertaining to personal protective equipment.

4. ANY change in the care and use of animals involved in the protocol, including ANY change in the personnel listed on the protocol, that would affect animal welfare will be promptly forwarded to the IACUC for review. Such changes will not be implemented until approval is obtained from the IACUC. Animals will not be transferred between investigators without prior approval.

5. The PI has reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternative to any procedures described herein which may cause more than momentary or slight pain, distress, or generalized discomfort to animals, whether it is relieved or not.

6. The PI has made every reasonable effort to minimize the number of animals used and reduce the amount of pain, distress, and/or discomfort these animals must experience.

7. That the activities described within the protocol submitted for IACUC review are consistent with those described in any related grant, contract, or subcontract.

8. That, to the best knowledge of the PI, the information contained in the animal use protocol is accurate.

9. That this animal use approval and/or any other animal use privileges may be revoked by the IACUC if the any of the aforementioned assurance statements are violated.

10. It is implicit upon submission of a protocol that the PI has read and agrees to abide by the above obligations.

Policy 3.20: Required Training for IACUC Protocol Personnel and GVSU Animal Users
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. All personnel on approved IACUC protocols and other personnel who work directly with animals on IACUC protocols (e.g. vivarium staff) must be appropriately qualified and trained to perform their specific assigned activities of the protocol.

2. PIs are responsible for assuring that appropriate training is accomplished and documented for all protocol personnel. IACUC may require additional specific training for protocol personnel. Training for non-protocol personnel who are responsible for the care and use of animals (e.g., vivarium staff) is the responsibility of the individual's supervisor.

Procedures and Regulatory Guidance

1. Although the PHS Policy and AWRs do not specify a particular training program or the frequency with which a training program should be offered, the requirement for competence is mandatory.

    a. The AWRs, in Sec. 2.32 (a) and (b), specify: It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities.

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

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

3. Training made available for each type of staff should be specific to the animal species involved and to the kind of procedures to be performed or animal-related interactions.

    a. For training purposes, staff can be grouped as:

i. Researchers (including PIs and their research assistants)

ii. Animal care technicians

iii. Laboratory and instructional support staff

iv. Other (e.g., maintenance or support staff)

b. In some instances, staff may not be clearly divisible into these groups if job responsibilities are more diversified than this classification suggests. For example, facility staff such as animal health technicians may have job functions that include both animal care and research procedures.

c. Training should also be made available to temporary staff, such as students and non-tenure track faculty.

4. Training requirements for IACUC protocol personnel and GVSU animal users
   a. All IACUC protocol personnel must complete the following requirements:
      i. CITI Animal Care and Use course

      ii. CITI Responsible Conduct of Research course

      iii. GVSU Laboratory Safety course

      iv. Medical evaluation form

   b. Expiration of Training Requirements
      i. Completion of the Animal Care and Use course and Responsible Conduct of Research course are valid for three years.

      ii. At this time, the Laboratory Safety course has no expiration date.

      iii. A new medical evaluation form must be completed every five years and at any time when the individual will be working with a new category of animals (e.g., rodents, amphibians, reptiles, etc.) that was not previously disclosed on a medical form submitted by the individual within the past five years.

      iv. A lapse occurring in any of the above training requirements during an active protocol will be treated as noncompliance according to *Policy 5.10: IACUC Noncompliance.*

   c. Courses Involving Students Who Will Be Handling Animals
      i. Some GVSU courses (usually laboratory courses) involve activities in which students handle live vertebrate animals as part of the course instruction. Such activities require IACUC approval prior to performing

the activity in the course. Course instructors must be included as protocol personnel on the IACUC protocol covering this activity if they will be handling live vertebrate animals; however, students registered for the course are not expected to be listed as IACUC protocol personnel for the activity.

ii. Students who only handle live vertebrate animals as part of receiving course instruction are not required to complete the IACUC training requirements above in order to participate in the course activity. However, the course instructor is responsible for providing sufficient training to prepare the students for their involvement in the activity (e.g., handling techniques to be used, etc.). The course instructor is also responsible for informing the students of any risk involved in the activity (e.g., allergies, specific risks related to handling of the specific animals, etc.).

d. Externally-Affiliated Protocol Personnel
IACUC protocol personnel who are collaborating with a GVSU PI and who are otherwise unaffiliated with GVSU must either complete the same IACUC training requirements as GVSU personnel, or provide evidence they are appropriately qualified by training and experience for their designated protocol roles. This evidence includes knowledge of applicable laws, regulations, codes and guidance; relevant ethical and profession standards; and competency to conduct protocol activities such that interactions with the animals will minimize risks and ensure the well-being of the animals.

e. The IACUC may, at its discretion, require additional training be completed for any protocol member prior to approving that individual to work on a protocol and/or to perform certain procedures on a protocol.

f. If a GVSU Animal Care Supervisor is necessary, they will be American Association for Laboratory Animal Science-certified at least at the technician level (Laboratory Animal Technician) and seek additional training on an appropriate basis to improve their knowledge in the care and handling of the species of animals in the facilities.

Policy 3.30: IACUC Protocol Personnel Conflict of Interest
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. IACUC protocol personnel are required to disclose any conflicts of interest according to the applicable GVSU Policies.

2. Any IACUC researcher is said to have a conflict of interest whenever that person, their spouse, domestic partner, or dependent child falls under any of the following conditions:

    a. Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.

    b. Acts as an officer or a director of the sponsor or an agent of the sponsor.

    c. Has an equity interest in the sponsor.

    d. Has received payments or other incentives from the sponsor that when aggregated for the member and spouse/domestic partner/dependent children exceeds $5000.

    e. Has identified themselves for any other reason as having a conflict of interest.

Procedures

1. University policies governing conflict of interest include: General Personnel Policies for Faculty and Staff – Conflict of Interest (BOT 4.1.6), Conflict of Interest Policy (SLT 10.1), and Conflict of Interest in Research Policy (SLT 3.4). Consult the GVSU Policies page for the latest version of these policies.

2. A conflict of interest affecting a protocol must be indicated in the protocol submission form.

Policy 3.40: Authorization to Conduct Research and Educational Activities Involving Live Vertebrate Animals

Version: 2.0
IACUPPS Approval Date: 04/03/2025
IO Approval Date: 04/04/2025
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. Research and educational activities involving the care and use of live vertebrate animals must have written approval from both an appropriate administrative official and the IACUC prior to initiating the activities involving animals.

2. IACUC review of proposed activities involving the care and use of live vertebrate animals will not be initiated until approval from the required Authorizing Official(s) (AOs) has been obtained.

Procedures

1. Authorizing Official (AO)
    a. The AO or their designee is a designated person with authority who reviews protocols prior to submission to the IACUC and verifies that the proposed activity is achievable and meets acceptable levels of risk for the discipline.

    b. The AO is typically defined as follows:

        i. Deans: The AO is the Provost or their designee.

        ii. Department/Unit/Program Heads: The AO is the appointing Dean or their designee.

        iii. Faculty members: The AO is the academic Unit Head or their designee.

        iv. Staff members: The AO is the Unit Head/Supervisor or their designee.

    c. AO approval is required for all new IACUC protocol submissions. AO approval is not required for Amendment submissions for previously approved protocols.

    d. The AO signature should be recorded in the IACUC submission form in the ORCI's electronic database management system.

    e. By signing the IACUC submission, the AO attests to the following:

        i. The AO understands that it is their responsibility to maintain compliance with all terms of the GVSU IACUC Handbook of Policies and Procedures.

ii. The proposed activity is feasible, and the PI and supporting department, unit, or program have sufficient time, materials, and resources to complete the project as planned and described in the protocol.

iii. The PI and other key personnel are appropriately qualified to supervise and/or conduct the project safely such that risks to animal welfare are minimized.

iv. The proposed activity design, procedures, and methods of data analysis meet the relevant discipline's standards for scientific merit and validity for academic research/educational activities.

v. The AO will report any direct knowledge of noncompliance on the part of the protocol personnel to the ORCI, the IACUC, and/or the IO.

2. Electronic Signatures

All electronic signatures executed by GVSU employees, agents, or representatives, located anywhere in the world, for purposes of authorizing research and educational activities involving the care and use of live vertebrate animals, are the legally binding equivalent of traditional hand-written signatures.

Policy 3.50: Minimizing Pain and Distress
Version: 2.0
IACUPPS Approval Date: 04/21/2021
IO Approval Date: 04/22/2021
IACUCP Approval Date: 05/20/2021
IACUPPS Last Review Date: 04/03/2025

Policy

1. The IACUC protocol PI is responsible for ensuring the health and well-being of all animals used on an IACUC protocol. The IACUC will critically evaluate protocols to ensure that pain and distress are minimized in animals and assure that appropriate steps will be taken to enhance animal well-being.

2. Animals experiencing more than momentary or slight pain or distress require appropriate sedation, analgesia, or anesthesia unless suitable, scientific justification is provided by the PI and approved by the IACUC. Researchers must follow the appropriate requirements related to the acquisition, storage, use, disposal, and recordkeeping of sedative, analgesic, and anesthesia agents.

Procedures and Regulatory Guidance

1. In design of the research, training, or educational activities, it is the responsibility of the PI to consider and include procedures that minimize animal pain or distress.

2. If a proposed activity may cause more than momentary or slight pain or distress to animals, the AWRs specifically require investigators to consult with the Attending Veterinarian or their designee during protocol development.

3. The PHS Policy and AWRs stipulate that the PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

4. The IACUC will ensure that the protocol addresses:

    a. Appropriate sedation, analgesia, and anesthesia;

    b. Criteria for timely intervention, removal of animals from study, or euthanasia if painful or stressful outcomes are anticipated; and

    c. Details of post-procedural care.

5. The protocol must provide adequate information for the IACUC to assess the potential animal pain and/or distress resulting from the activity and the effectiveness of the pain- and distress-relieving agents proposed for use. If necessary, criteria for re-dosing the animal should also be established.

6. Examples of procedures which the *Guide* suggests may have the potential to cause pain or distress, include the following:
    a. Physical restraint

    b. Survival surgeries

    c. Food or water restriction

    d. Death as an endpoint

    e. Noxious stimuli

    f. Skin or corneal irritancy testing

    g. Tumor burdens

    h. Intra-cardiac or orbital sinus blood sampling

    i. Abnormal environmental conditions

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

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

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

    b. Protocol methodology should be considered that decreases the potential for pain or distress. In addition to thorough searches of the literature, this can be done

through the careful use of pilot studies to determine earlier endpoints or less invasive alternatives.

c. Pharmacologic treatment of pain or distress should be given as consistent with the type of pain/distress and the needs of the research question. The Attending Veterinarian must be consulted for all such protocols and should provide guidance to investigators and the IACUC. Nonpharmacologic treatments should also be employed. This may include special housing considerations, dietary and other environmental enrichments, adjustments and careful supportive care.

d. It is the responsibility of the PI to show that they have considered all the options for minimizing pain and distress that do not compromise the scientific validity of the activity.

e. The IACUC's deliberations regarding the management of potential pain and distress in a protocol will be documented in the meeting minutes.

f. Personnel should be trained in pain and distress management.

g. The IACUC should ensure that there is a mechanism in place for prompt reporting of sick or injured animals to the following individuals as appropriate: PI, attending veterinarian, other GVSU personnel.

9. Use of Sedatives, Analgesics, and Anesthesia
    a. Under no circumstances may drugs used for sedation, analgesia, or anesthesia be expired.
        i. The expiration date is the date printed on the label/package for materials with a manufacturer's expiration.
        ii. For dilutions, preparations, reconstitutions, or mixtures of drugs of fluids prepared using aseptic technique and under proper storage conditions, the expiration date is no more than 30 days from the date of preparation. Such materials must be labeled by name, drug concentration, and include the new expiration date as soon as they are prepared.
        iii. An item is considered expired the day after the month or date indicated on the label. For example, an item labeled February 2021 would be considered expired on March 1, 2021.
    b. Items are to be stored only according to acceptable storage methods, in consultation with GVSU Laboratory Safety.
    c. Items are to be discarded only via accepted disposal methods in consultation with GVSU Laboratory Safety. Whenever possible, disposal should occur immediately after use.

d. Recordkeeping related to the use of sedatives, analgesics, and anesthetics should include, at a minimum, the following information: animal or group identification and the date of procedure; agent used, including dosage, route, and time of any drugs administered; on-going monitoring, including periodic assessment of anesthetic depth, activity of the animals, incision site observations, and any pain- or procedure-related complications and response to these actions; and identification of person performing monitoring. Records must be maintained for at least one year beyond the end of the approved protocol.

e. Several analgesics and anesthetics are controlled substances and may require certain authorizations and procedures prior to use in animals. Controlled substances must be properly stored with appropriate recordkeeping. The PI is responsible for determining if the agent to be used is a controlled substance; acquiring any authorizations, if needed; and ensuring appropriate acquisition, storage, use, disposal, and recordkeeping. When controlled substances are to be used, consultation with the Attending Veterinarian is required. Note that records related to controlled substances may need to be retained longer than one year beyond the end of the protocol.

Policy 3.60: Animal Procurement
Version: 1.0
IACUPPS Approval Date: 02/24/2021
IO Approval Date: 03/02/2021
IACUC Approval Date: 03/18/2021
IACUPPS Last Review Date: 04/03/2025

Policy

1. The source of animal procurement must be approved by the IACUC.

2. With the exception of PIs new to GVSU who are transferring animals from another institution (See *Policy 5.30: Animal Holding Policy*), PIs must have an active, approved IACUC protocol or a protocol under Policy 5.30 before ordering/acquiring/housing animals. The protocol must allow for the acquisition of the requested species, strain, and number of animals, and the number of animals to be received must not cause the number of approved animals on the protocol to be exceeded.

3. The PI is responsible for maintaining thorough and accurate recordkeeping regarding the procurement of animals.

Procedures and Regulatory Guidance

1. The approved protocol must indicate the source of the animals. Typical animal sources include commercial vendors, other institutions, or animals captured in the field; however, the IACUC may approve an alternate procurement source, if sufficient justification is provided.

2. For animals to be housed in the GVSU vivarium, the PI must additionally notify and receive approval from the Vivarium Supervisor prior to ordering/obtaining the animals.

3. Record keeping related to animal procurement should include, at a minimum, the following information: source of animals, number of animals, date of acquisition, and assessment of animal condition upon receipt, including a description of any abnormalities. Records must be maintained for one year following the submission of the protocol closure report.

Policy 3.70: Transportation of Animals
Version: 2.0
IACUPPS Approval Date: 01/27/2023
IO Approval Date: 01/30/2023
IACUC Approval Date: 03/16/2023
IACUPPS Last Review Date: 04/03/2025

Policy

1. The intrafacility and interfacility transportation of regulated species in the possession of GVSU personnel and personnel approved on a GVSU IACUC protocol must follow AWA and USDA standards.

2. GVSU personnel and personnel approved on a GVSU IACUC protocol are considered in possession of an animal from the time they initially receive the animal from a procurement/collection source to the time the animal is removed from a protocol (e.g., transferred directly to another non-GVSU investigator, released to a third-party courier to transport the animal to another researcher, released for adoption, released into nature, disposed of properly following euthanasia, etc.).

3. Risks to both the animals and the personnel transporting the animals must be minimized during transport. This includes maintaining the health and well-being of the animals, avoiding pathogen exposure, preventing injury, reducing the animals' exposure to stressors, and preventing escape of the animals.

4. Transportation of the animals through general public spaces should be minimized to the extent possible. When such transport must occur, the safety of the general public must be considered, and risks to the general public must be minimized to the extent possible.

5. The IACUC must inspect vehicles used by GVSU researchers to transport USDA-regulated animals prior to the first time the vehicle will be used for transporting the animal(s) and every six months thereafter for as long as the vehicle will be used for the transport of USDA-regulated animals. The IACUC may, at its discretion, choose to inspect vehicles used by GVSU researchers to transport non-USDA-regulated animals; however, such inspection is not required.

Procedures and Regulatory Guidance

1. Never leave an animal alone or unattended outside of secured animal housing facility or laboratory.

2. Animals and animal caging must be appropriately contained within the vehicle during transport to protect the animals, minimize risk of escape, and to protect personnel from potential exposure to hazards.

3. Transportation methods must minimize stress to the animals through maintaining appropriate ventilation, avoiding extremes in temperature and humidity, minimizing

noise and odors, preventing exposure to pathogens, and minimizing interactions with other animals or people.

4. Animal enclosures must have locking mechanisms or latches that cannot be dislodged by movement. Cages should be kept level at all times, and each cage must be secured appropriately. If possible, stacking of cages should be avoided; if stacking is necessary, care must be taken to ensure the cages are stacked safely and each cage is secured properly.

5. Animal enclosures must be appropriately cleaned and sanitized to prevent the spread of pathogens. Reusable enclosures must be sanitized between use to prevent the spread of pathogens.

6. When transporting animals through public spaces, the animals should be obscured from view as much as possible.

7. Transportation of rodents out of the animal facility requires a secondary enclosure, and cages must be covered during transport to minimize the release of animal allergens and bedding into the environment.

8. Whenever possible, University-owned vehicles should be used for animal transport. (See https://www.gvsu.edu/riskmanagement/vehicle-driver-protocols-57.htm for more information about using University-owned vehicles.)

9. If the animal is released to a third-party courier, the GVSU researcher is responsible for selecting a trusted courier and ensuring the animal is packaged appropriately and safely to the fullest extent possible.

Policy 3.80: Photography and Recording of Live Laboratory Animals
Version: 1.0
IACUPPS Approval Date: 10/27/2022
IO Approval Date: 12/07/2022
IACUC Approval Date: 01/19/2023
IACUPPS Last Review Date: 04/03/2025

Policy

1. The photography and recording (both video and audio) of live laboratory animals is prohibited, except under the following exceptions:
    a. When it is performed as described in an approved IACUC protocol or IACUC amendment;
    b. When it is performed to diagnose or document clinical disease, veterinary care, or treatment, and the resulting photographs/recordings are provided to the PI, IACUC Veterinarian, and/or vivarium staff for purposes of animal care;
    c. When it is performed to document potential compliance or animal welfare concerns, and the photographs/recordings are provided to an appropriate university official for the purposes of reporting the concern;
    d. When it is performed by IACUC members or Office of Research Compliance and Integrity (ORCI) staff members during IACUC-mandated inspections;
    e. When it is performed by regulatory inspectors; or
    f. When it is performed for media activities AND prior approval has been obtained in writing from the ORCI.

2. The act of collecting the photographs/recordings shall not result in any increase in risk to the animals (e.g., handling procedures that would cause increased pain and distress, or prolonged handling/restraint).

3. Individuals who may appear in the recordings or photographs must be informed in advance of the planned photography/recording and be given the option to decline participation. It is the responsibility of the individual collecting the photograph/recording to ensure all other applicable GVSU policies related to photography/recording are followed, and the appropriate GVSU photography/recording release forms are completed, if required.

Procedures and Guidance

1. When describing the requested photography/recordings in the IACUC protocols, include the following items:
    a. A description of what animals and activities will be photographed/recorded,
    b. Who, if anyone, will also potentially be included in the images/recordings,
    c. What devices will be used to capture the images/recordings,
    d. Where the images/recordings will be disseminated, and
    e. How the images/recordings will be securely stored and, if applicable, destroyed when no longer needed.

2. To request approval for media activities involving laboratory animals and/or laboratory animal use areas, email the ORCI (rci@gvsu.edu) with the name(s) and affiliation(s) of the visitor(s) conducting the activities, the location of the activity, and the reason for the requested visit.

3. Extreme care is needed when capturing photographs and recordings of the animals and animal use areas. The following factors should be carefully considered when capturing images and recordings:
    a. Record only as much of the animal as is needed.
    b. Ensure animals are being handled safely and using appropriate restraint methods.
    c. Ensure all personnel included in the photographs/recordings are wearing the appropriate personal protective equipment.
    d. Whenever possible, identifying landmarks (e.g., building and room numbers, personnel names, cage cards) should not be visible in the images/recordings.
    e. Images and recordings should be stored securely and destroyed when no longer needed.
    f. Images and recordings can only be utilized for scholarly or scientific purposes, and any scholarly or scientific dissemination products must be reviewed and approved by the PI prior to dissemination.
    g. Recognize that the public may not view the images with the same understanding as those capturing the photographs/recordings. Consider the context in which the animal is being photographed/recorded. (For example, if a picture of a sedated animal is captured, will it be clear to the public that the animal is sedated and not in pain or distress?)
    h. University personnel are subject to public records requests.

Policy 3.90: Animal Monitoring and Documentation
Version: 1.0
IACUPPS Approval Date: 03/15/2024
IO Approval Date: 04/08/2024
IACUC Approval Date: 02/15/2024
IACUPPS Last Review Date: 04/03/2025

Policy

1. All animals in IACUC-approved protocols that are housed for longer than 12 consecutive hours must be observed daily, including weekends and holidays, to assess their health and well-being.

2. Daily checks must include a health check of the animal itself, the animal's microenvironment (i.e., cage/enclosure), and the macroenvironment (i.e., animal room).

3. Daily checks must be documented in writing, and the documentation must be maintained in the animal facility for as long as the animals are kept in the facility.

4. Daily checks may be conducted by anyone with adequate training and access to the animals (e.g., research personnel, vivarium personnel, etc.); however, the PI is responsible for ensuring the daily checks are completed.

Procedures

1. Animal health checks
    a. Animals should be checked to ensure they are attentive and responsive.
    b. The observer should be alert for any animal health concerns, including any physical or behavioral issues. Issues to monitor will depend upon the species. General examples are provided below; this list is not meant to be all-inclusive.
        1. Physical issues
            a. Abnormalities of the eyes, ears, nose, mouth, or face
            b. Lacerations, ulcers, tumors/masses, bleeding, or discharge
            c. Excessive weight loss or gain
            d. Difficulty breathing or excessive sneezing
            e. Dehydration
            f. Altered/abnormal mobility
            g. Body discoloration/skin irritation
            h. Hair/fur loss
        2. Behavioral issues
            a. Aggression
            b. Poor posture
            c. Altered/abnormal mobility or activity level
            d. Lack of appetite
            e. Head tilt/circling
            f. Excessive scratching

g. Abnormal behavior relative to other animals in the cage, such as separation

c. Health checks can include a combination of visual observations and physical manipulations, where appropriate.
d. Any observed abnormalities must be documented in detail. This documentation must include, at a minimum, the species or strain, sex of animal, location, tag number (if any), and a description of the abnormality. If a treatment has been initiated, the treatment methodology used, including any pain management, must be included in the documentation.
e. Observations that require a time-sensitive response to reduce morbidity or mortality must be reported to the PI immediately.
f. Observations of clinical problems that are not described in the approved IACUC protocol, or for which a standing treatment order does not exist, must be reported to the IACUC Veterinarian.
g. If animals are found dead, the date the animals found dead, and the number of animals found dead, must be documented.

2. Microenvironment
    a. At a minimum, the following should be included in checks of the microenvironment:
        i. There is adequate food and water available to the animals.
        ii. Levels of waste are acceptable.
        iii. Enclosures and associated apparatuses (e.g., water bottles) are functioning properly.
    b. Any abnormalities must be documented.
    c. The PI is responsible for rectifying any abnormalities where possible, or for reporting abnormalities to the facility supervisor for further action.
3. Macroenvironment
    a. At a minimum, the following should be included in checks of the microenvironment:
        i. There are no noticeable problems with the facility and animal room (e.g., noise issues, flooding, air flow heating and ventilation).
        ii. Facility equipment used in conjunction with the protocol is operating properly.
    b. Any abnormalities must be documented.
    c. The PI is responsible for rectifying any abnormalities where possible, or for reporting abnormalities to the facility supervisor for further action.
4. The documentation record can be lab- or protocol-specific; the IACUC does not require a specific documentation template.

Section 4: IACUC Protocol Review

Policy 4.10: Activities Requiring IACUC Review

Version: 2.0
IACUPPS Approval Date: 04/13/2023
IO Approval Date: 12/20/2021
IACUC Approval Date: 06/15/2023
IACUPPS Last Review Date: 04/03/2025

Policy

1. All research and educational activities conducted by GVSU faculty, staff, and/or students on behalf of GVSU and that involve the use of vertebrate animals are subject to review by the IACUC prior to initiation, except the following:

    a. Activities involving animals that perform tasks, participate in club activities, or appear in exhibits or demonstrations on a GVSU campus;

    b. Use of tissues, organs or other parts of dead animals if received as such;

    c. Noninvasive observations of wild animals in their natural habitat or animals in non-GVSU exhibits where the observation does not interfere with their normal behavior; and

    d. Use of samples obtained from non-GVSU facilities, under certain circumstances (see Procedures and Guidance below).

2. With the exception of GVSU vivarium staff members operating within their capacity as vivarium staff, all individuals performing animal husbandry activities and/or any procedures associated with the protocol must be listed and approved as personnel on the protocol. If a vivarium staff member is operating as an investigator on a protocol, that individual must be listed and approved on the protocol prior to conducting any work related to the protocol other than animal husbandry.

Procedures and Guidance

1. Examples of activities performed by GVSU faculty, staff, and students that require IACUC review include, but are not limited to:

    a. Activities performed on the premises of GVSU;

    b. Activities performed involving the use of GVSU-owned animals;

    c. Activities satisfying a requirement imposed by GVSU for a degree program or completion of a course of study;

    d. Activities using internal or external funds administered through GVSU;

e. Activities, including clinical trials and/or those being conducted with privately-owned animals, to satisfy an obligation of a faculty appointment at GVSU; and

f. Field studies that involve killing, trapping, banding, darting, implantation of telemetry devices, or any other invasive manipulation.

2. Examples of activities performed by GVSU faculty, staff, and students that do not require IACUC review include:

   a. Unused or discarded clinical samples, provided samples were not collected specifically for the GVSU activity;

   b. Slaughterhouse tissues when the animal was not slaughtered specifically for the GVSU activity;

   c. Archival tissues from tissue banks, museum collections, or similar sources; and

   d. Student participation in activities at non-GVSU sites when the activity does not involve GVSU-owned animals and GVSU personnel do not influence (i.e., conduct or direct) animal use.

3. When a protocol has been reviewed and approved by another institution's IACUC, the GVSU IACUC may not require additional review and approval. However, the PI must inform the GVSU IACUC of the activity, and the GVSU IACUC must have documentation from the collaborating institution before the GVSU IACUC will make an acceptance decision regarding the activity. Refer to *Policy 4.60: Collaborations Involving Non-GVSU Institutions* for more details and procedures.

4. Consulting Activities
   Activities involving animals in which the faculty/staff/student acts in a consultant role require IACUC review and approval unless all of the following conditions are met:

   a. The investigator is hired on their own time,

   b. The investigator holds no rights in the work, and

   c. Neither the investigator nor GVSU retains any data.

5. Research in Foreign Countries
   a. The standards for ethical and responsible use of animals in research will not be relaxed even if different customs prevail. This includes the use of animals in foreign research institutions and fieldwork involving either domestic or wild animals.

   b. Research projects must also be approved by the local equivalent of an IACUC before they are initiated. Where there is no equivalent board or group,

investigators must rely on local experts or community leaders to provide approval. The IACUC requires documentation of this local approval, as well as documentation of any necessary permits, before granting final approval for the project.

c. With regard to activities supported by PHS funds, foreign institutions that serve as performance sites must also have Assurances on file with OLAW.

6. Use of Animal Tissues or Dead Animals
   a. IACUC review is not required prior to using dead animals or animal tissues (from live or dead animals), provided the material is obtained in one of the following ways:

      i. Acquired from a commercial source,

      ii. Obtained from animals sacrificed following an IACUC-approved project at GVSU or another institution, or a governmental agency,

      iii. Samples remaining from diagnostic tests performed by non-GVSU facilities (i.e. surplus samples), or

      iv. Found in nature, if animal is already dead at time of collection (e.g., roadkill, a dead animal found on campus, etc.). (Note that, while IACUC approval is not required, such collection might require a state or federal permit.)

   b. IACUC approval is required if an animal is both procured and sacrificed solely and specifically for a research or educational purpose.

   c. Samples obtained from non-GVSU facilities
      i. GVSU researchers obtaining samples from non-GVSU facilities must abide by any internal processes and approvals the facility has in place to collect and distribute such samples. Note that many facilities will likely require that their personnel collect the samples.

      ii. The need for IACUC approval varies depending upon the details of the study and sample collection. Common scenarios are listed below.

         1. Examples for which IACUC approval is not required:
            a. Samples to be used for research are *surplus* samples that would already be obtained during regular veterinary checks and animal husbandry activities in the absence of the research project.

            b. Passive sample collection (such as collecting dropped feces) that does not require additional animal handling

beyond normal husbandry activities. The sample collection must only include activities that are not foreseen to increase the animal's stress levels and do not increase the occupational risk of the personnel performing the activities.

c. Studies involving only observation and in which no environmental manipulation has occurred.

2. IACUC approval is required for the following scenarios:
   a. Sedation, surgery, and/or additional animal handling beyond normal husbandry that is specifically done to collect the research samples (i.e., activities outside regular veterinary checks and regular animal husbandry activities).

   b. Samples to be collected for research are *not* surplus, even if they are collected during regular veterinary checks and animal husbandry activities. (For example, if a zoo typically collects 2 cc of blood at veterinary checks but will now collect 3 cc in order to obtain enough blood for a research sample.)

   c. Passive sample collection (such as collecting dropped feces) that requires additional interactions with the animals beyond normal husbandry, and/or include additional interactions that are foreseen to increase the animal's stress levels and/or increase the occupational risk of the personnel (for example, due to more frequent animal interactions).

   d. Studies involving observation, but in which environmental manipulation also occurs. (For example, researchers place a new toy in the animal's enclosure to determine the animal's behavioral response.)

3. If IACUC approval is required, refer to *Policy 4.60: Collaborations Involving Non-GVSU Institutions*.

d. GVSU personnel using dead animals or animal tissues (from live or dead animals) must consider the health and safety aspects of using such materials and should consult with the GVSU Director of Laboratory Safety as necessary, prior to handling these materials. Note that there are specific concerns regarding the handling of tissues and bodily fluids obtained from non-human primates. (See Appendix 1.)

7. If it is unclear if an activity requires IACUC review, contact the ORCI for an official determination.

Policy 4.20: IACUC Protocol Submission and Review
Version: 1.2
IACUPPS Approval Date: 02/25/2022
IO Approval Date: 03/05/2022
IACUC Approval Date: 01/21/2021
IACUPPS Last Review Date: 04/03/2025

Policy

1. Protocol Submission
   An IACUC application is required for all research and educational activities involving the care and use of animals.

2. Protocol Review
   a. The IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed protocol is in accordance with PHS Policy, the AWRs, and the applicable U.S. Government Principles.

   b. If the IACUC does not have the scientific and technical expertise to evaluate all aspects of a proposal it may bring in outside expert consultants to provide information. Such consultants must not have a conflict of interest with the research activity and may not vote on any matters pertaining to the protocol.

   c. In all cases, it is the investigator's responsibility to justify and explain their proposed protocol to the satisfaction of the IACUC.

   d. Initial IACUC submissions are reviewed by either Full Committee Review (FCR), or Designated Member Review (DMR). Procedures for each level of review are described below.

   e. Under no circumstances will a protocol be permitted to begin (or resume) until IACUC approval is granted.

Procedures and Regulatory Guidance

1. Protocol Submission
   PIs must complete and submit the protocol application using the GVSU ORCI's electronic database management system. Each initial application is assigned a protocol number.

2. Protocol Review
   a. DMR/FCR Polling
      Upon receipt of a new protocol submission, the protocol submission form and all supporting documents are sent to all IACUC members. The IACUC members are allowed eight business days to review the submission and request either FCR or DMR, and to enter any comments related to the protocol into the ORCI's electronic database management system. Any IACUC member may call for FCR for a new protocol application. If no members request FCR, the protocol is sent to

DMR. Failure on behalf of the member to respond within the eight-business day member consideration period is considered as a request to use DMR for review. If all members select DMR prior to the end of the eight-business day review period, the IACUC Chairperson does not need to wait until the end of the eight-business day period to send the protocol to DMR for review. Procedures for FCR and DMR are described in further detail below.

b. Protocol or amendment proposals that include any of the following activities are required to be reviewed via FCR:

   i. Major survival surgery
   ii. Death as an endpoint
   iii. Radiation sickness
   iv. Tumor inducement
   v. Toxicology
   vi. Infectious disease
   vii. Blunt force trauma
   viii. Use of conditionally acceptable methods of euthanasia

c. IACUC Protocol Actions

   Upon review of protocols, the IACUC may take one of the following actions:

   i. Approval

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

   ii. Modifications Required to Secure Approval

      The IACUC may require modifications to the protocol before granting approval. If the IACUC determines that a protocol is approvable contingent upon receipt of a very specific modification, or clarification of a specific point, the IACUC may handle these modifications or clarifications as administrative details that any member, such as the Chairperson, could verify prior to granting approval. If a protocol is unusually complex or involves untried or controversial procedures the IACUC may impose restrictions (e.g., approval for the use of a limited number of animals as a pilot study with a written report of interim results, or close monitoring by veterinary or other qualified personnel). If such modifications represent significant departures from standard/acceptable procedures, the IACUC can ask the investigator to modify the protocol to

reflect the modifications imposed by the IACUC. If the protocol is missing substantive information necessary for the IACUC to approve the protocol, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be modified and resubmitted. If the IACUC wishes to shift to the DMR mode for the approval of the modified protocol, that shift will be explicitly noted in the meeting minutes and the requirements for DMR must be met.

iii. Defer (Table Review)
The IACUC may defer or table a review if the protocol requires any of the following: significant clarification in order for the IACUC to make a decision, IACUC members with certain expertise are not present, the IACUC wishes to seek external consultation, or any other reason that prevents the IACUC from conducting its review.

iv. Disapproval
When the IACUC determines that a protocol has not adequately addressed all of the requirements of the PHS Policy and AWRs, as applicable, or the described activities represent inappropriate or unethical use of animals, the IACUC may withhold approval. If approval is withheld the IACUC must provide the reasons for its decision and give the PI an opportunity to respond.

d. Full Committee Review
   i. FCR of protocols requires a convened meeting with a quorum of the IACUC members. A quorum of the committee is reached when a majority of the IACUC members are present.

   ii. After a committee discussion, IACUC members vote to approve without modification, approve pending receipt of modifications, table the protocol until the next meeting, or disapprove the protocol. A majority vote of the quorum present is required to approve an action on a protocol submission. If quorum is not reached, or a majority vote is not obtained, no official action can be taken regarding the protocol, and the protocol will be reviewed at the next convened meeting.

   iii. If the IACUC votes to approve pending receipt of modifications:

      1. If the required modifications are all administrative in nature, the IACUC can vote to have the modified protocol reviewed by the IACUC Chairperson via Administrative Review.

      2. If the modifications are not administrative in nature, and all members of the IACUC are present at a meeting, the committee may vote to have the modified protocol reviewed and approved by

DMR, or returned for FCR at a convened meeting.

3. If the modifications are not administrative in nature, and all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations, per NIH Notice NOT-OD-09-035:

    a. All IACUC members agree in advance in writing that the quorum of members present at the convened meeting may decide by unanimous vote to use DMR subsequent to FCR. However, any member of the IACUC may, at any time, request to see the modified protocol and/or request FCR of the protocol.

    b. If an active Assurance is on file with OLAW, GVSU has stipulated its intention to conduct reviews in this manner in the Assurance, or will provide information about this program change to OLAW in the next Annual Report.

    c. If all IACUC members do not agree in advance in writing that DMR subsequent to FCR can be used, the modified protocol will be subjected to the eight-business day review period outlined in Procedures 2a above.

4. If the IACUC votes to approve the application pending receipt of modifications, the Chairperson sends a request to the PI detailing the modifications needed to secure protocol approval and requests that the PI modify and resubmit the protocol. If the PI does not resubmit the modified protocol within 90 calendar days, or makes other arrangements with the ORCI or IACUC Chairperson to extend this 90-day time period, the submission will be considered withdrawn, and a new submission will be required if the PI still seeks to conduct the work.

iv. Investigators of protocols for which approval has been withheld may meet with the IACUC Chairperson to discuss the protocol.

e. <u>Designated Member Review</u>

i. The IACUC Chairperson designates one or more qualified members to review the proposal (or proposed amendment or annual renewal). All IACUC members will be able to send their comments to the DMR reviewer. It is at the discretion of the DMR reviewer to include comments from the other IACUC members when requesting modifications and/or further information from the PI.

ii. The DMR reviewer(s) can either approve, request modifications on the protocol, or refer the protocol to FCR. The DMR reviewer(s) may not withhold approval.

iii. If the protocol is assigned to more than one DMR reviewer, the reviewers must be unanimous in any decision. They will all review identical versions of the protocol and if modifications are requested by any one of the DMR then other DMR reviewer(s) must be aware of and agree to the modifications. If the DMR reviewers cannot reach an agreement on a decision, the protocol will be reviewed via FCR.

iv. If the DMR reviewer(s) approve(s) the protocol as written, it is sent to the Chairperson for final review. The Chairperson may confirm the approval or request additional information and/or modifications from the PI before approval. If the Chairperson wishes to request additional information and/or modifications from the PI, the Chairperson must notify the DMR reviewer(s) of this request and the DMR reviewer(s) must agree to the request. If the DMR reviewer(s) and Chairperson cannot reach an agreement on the request, the protocol will be reviewed via FCR.

v. If the DMR reviewer(s) request(s) additional information and/or protocol modifications
    1. The DMR reviewer(s) enter(s) the required additional information and/or modifications in the ORCI's electronic database management system and send(s) them to the Chairperson for review. The DMR reviewer(s) may choose to either review the protocol again when the modified application is resubmitted by the PI, or have the Chairperson conduct the review of the resubmission. Selection of the Chairperson review should only be made if the requested information and modifications are minor and/or administrative in nature.
    2. The Chairperson reviews the requested information and/or modifications, and if they wish to modify the information requested by the DMR reviewer, the Chairperson must communicate the proposed changes to the DMR reviewer(s), and the DMR reviewer(s) must agree to the changes before responding to the PI. If the DMR reviewer(s) and Chairperson cannot agree on the information to be requested, the protocol will be reviewed via FCR.
    3. The Chairperson contacts the PI in writing or by email detailing the application's deficiencies and requests that the investigator modify and resubmit their application. If the PI does not resubmit the modified protocol within 90 calendar days, or makes other arrangements with the ORCI or IACUC Chairperson to extend this 90-day time period, the submission will be considered withdrawn, and a new submission will be required if the PI still seeks to

conduct the work.

4. Modified applications from PIs are reviewed by the DMR reviewer(s), or Chairperson if designated by the DMR reviewer(s), to approve or request further modifications. If the DMR reviewer(s) selected the Chairperson to conduct the review of the modified submission, and the Chairperson determines the modifications are more than minor in nature, the Chairperson may send the protocol back to the DMR reviewer(s) for further review.

f. At any point during the review process, reviewers may contact the PI for clarifications, additional information, or in anticipation of questions the IACUC may raise.

g. The decision about a protocol will be sent to the PI, the AO, and any other relevant GVSU officials.

Policy 4.30: Amendments to Approved IACUC Protocols
Version: 1.1
IACUPPS Approval Date: 10/27/2023
IO Approval Date: 11/06/2023
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. An IACUC Amendment application is required for all proposed changes to previously approved IACUC protocols.

2. All changes to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur.

Procedures and Regulatory Guidance

1. Submission of Proposed Modifications
    a. All modification requests, with the exception of personnel removal requests, must be submitted by the PI using the appropriate form in the GVSU ORCI's electronic database management system.

    b. Requests to remove personnel may be submitted by the PI via either an email to the ORCI or through the ORCI's electronic database management system. ORCI staff members will review email requests to verify that the request meets the eligibility for email submission. If it does not, the PI will be informed that an amendment request form must be submitted through ORCI's electronic database management system.

2. Amendment requests are reviewed by the IACUC Chairperson and/or the ORCI to determine if the requested change is significant or non-significant in nature.

3. Significant Changes
    a. The GVSU IACUC interprets significant changes to mean those that have the potential to impact substantially and directly on the health and well-being of the animals. Significant changes include, but are not limited to, changes:

        i. In the methods of animal use

        ii. In the objectives of a study

        iii. From non-survival to survival surgery

        iv. In procedures that result in greater pain, distress, or degree of invasiveness

        v. In the species or in approximate number of animals used

        vi. In PI for the protocol

vii. In anesthetic agent(s) or the use of withholding analgesics

viii. In the method of euthanasia

ix. In the duration, frequency, or number of procedures performed on an animal

x. In housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC.

xi. Affecting the previously evaluated cost-benefit assessment (*Policy 2.60: Ethical Cost-Benefit Analysis*)

b. Amendment requests involving significant changes are reviewed under the same procedures used for reviewing an initial (i.e., new) IACUC protocol (FCR or DMR), as described in *Policy 4.20: IACUC Protocol Review*.

4. Non-Significant Changes
   a. The GVSU IACUC interprets non-significant changes to mean those that do not have the potential to impact substantially and directly on the health and well-being of the experimental animals. Examples of non-significant changes include, but are not limited to, changes in:

      i. Funding source

      ii. Personnel other than the PI

      iii. Protocol title

      iv. Proposed end date of a protocol, provided no additional changes to the care and use of the animals are proposed, and the protocol does not exceed three years in length

   b. Amendment requests involving non-significant changes may be reviewed and approved via Administrative Review.

5. Administrative Review (AR)
   a. The IACUC Chairperson or designee may administratively review and approve amendment requests that involve changes not considered significant by the IACUC. Designees may include other IACUC members and, for certain proposed changes, staff members in the ORCI.

   b. Review by ORCI staff
      i. Per NIH Notice NOT-OD-14-126, certain changes may be handled administratively without IACUC-approved policies, consultations, or

notifications. Per this federal guidance, ORCI staff members may review and approve the following items without IACUC review:

1. Correction of typographical errors
2. Correction of grammar
3. Contact information updates
4. Change in personnel, other than the PI. (ORCI staff must ensure that all such personnel are appropriately identified and have completed the training requirements outlined in *Policy 3.20: Required Training for IACUC Protocol Personnel and GVSU Animal Users*.)

ii. All other non-significant changes must be reviewed and approved via AR by the IACUC Chairperson or an IACUC member designated by the Chairperson, or via the DMR or FCR process.

c. Any significant concerns or questions raised through the AR process will result in the amendment request being reviewed under the same procedures used for an initial (i.e., new) IACUC protocol (FCR or DMR), as described in *Policy 4.20: IACUC Protocol Review*.

Policy 4.40: Three-Year Review of Approved IACUC Protocols
Version: 2.0
IACUPPS Approval Date: 2/25/2022
IO Approval Date: 3/5/2022
IACUC Approval Date: 5/19/2022
IACUPPS Last Review Date: 04/03/2025

Policy

A complete *de novo* review of all IACUC protocols must be conducted at least once every three years.

Procedures and Regulatory Guidance

1. PHS Policy IV.4.C.5 requires the IACUC to conduct continuing review of each previously approved, ongoing activity at appropriate intervals determined by the IACUC, including a complete review at least once every three years. Similarly, the USDA requires a new submission to the IACUC for review and approval at the end of the initial 3-year protocol term.

2. Many animal use protocols under the oversight of the IACUC pose no more than minimal risk to the animals. Thus, it is unlikely that IACUC determinations about potential risks to the animals would be affected by new information gathered directly from the research interim results of a protocol approved for three years. However, the IACUC may, at its discretion, choose to limit the approval period of any protocol to an interval of less than three years.

3. Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IACUCs conduct appropriate and meaningful reviews of ongoing animal protocols in the same responsible manner that initial reviews are done. This means that the IACUC will not automatically approve a protocol during the three-year review just because it had undergone a previous thorough initial review.

4. Three-Year Reviews
    a. The three-year period begins on the initial date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. If the PI plans to continue animal work beyond the original expiration date of the protocol, it is the responsibility of the PI to obtain approval of the third-year resubmission prior to protocol expiration. To aid investigators, the ORCI shall attempt to provide adequate warning of pending protocol expiration. The IACUC requires the third-year resubmission to be submitted as a new proposal.

    b. The third-year resubmission must be approved by the IACUC before the expiration date of the original protocol. If a PI fails to submit a third-year resubmission and receive approval by the expiration date of the protocol, the following actions are taken:

i. The IACUC Chairperson will notify the PI, the PI's dean (and/or unit head), the Attending Veterinarian, and the Director of the OSP (if the project is externally funded), that the animal protocol has expired. The PI will be notified in writing that all activities under the protocol must cease. Any ongoing work under the expired protocol is a serious violation and reportable to the appropriate agency.

ii. The Attending Veterinarian will be notified of the expired protocol and any remaining animals under that protocol will be cared for according to *Policy 5.30: Animal Holding Policy*.

iii. If the PI fails to successfully renew the protocol, the IACUC may consider suspension or recommending to the IO that the PI's animal use privileges should be terminated.

Policy 4.50: Withdrawal of Pending (Not Yet Approved) IACUC Submissions
Version: 1.1
IACUPPS Approval Date: 2/25/2022
IO Approval Date: 3/5/2022
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

The IACUC will administratively withdraw an application for failure to respond to a request for clarification and/or corrections. This includes initial submissions and amendment requests.

Procedures

The process for PI notification of IACUC administrative actions is as follows (measured in business days):

1. *Day 0:* The IACUC will communicate with the PI detailing the actions required to secure approval.

2. *Day 15:* If no response from the PI is received by this day, the IACUC will send a second correspondence to the PI requesting a response to the IACUC's previous correspondence.

3. *Day 30:* If no response from the PI is received by this day, then the:

    a. IACUC will send a third correspondence to the PI requesting a response to the IACUC's previous correspondence.

    b. IACUC will place a phone call to the PI.

4. *Day 45:* If no response by the PI is received by this day, then the IACUC will inform the PI of the withdrawal of the submission and indicate that a new protocol/amendment must be submitted to the IACUC if they wish to pursue the proposed activity.

Policy 4.60: Collaborations Involving Non-GVSU Institutions

Version: 1.0
IACUPPS Approval Date: 12/10/2021
IO Approval Date: 01/07/2022
IACUC Approval Date: 01/20/2022
IACUPPS Last Review Date: 04/03/2025

Policy

1. When a GVSU faculty or staff member collaborates on research and/or teaching activities involving live vertebrate animals with a non-GVSU institution (e.g., universities, research facilities, zoos, aquariums, veterinary practices, etc.), the formal IACUC review and approval of the activity may be conducted by the GVSU IACUC or delegated to the collaborating institution's IACUC via a written agreement. These agreements must include details such as oversight responsibilities, animal ownership, transportation of animals between institutions, and reporting requirements.

2. If the collaborating institution does not have an appropriately constituted IACUC, the GVSU IACUC must serve as the reviewing IACUC.

3. When an external collaborator is not otherwise covered by an IACUC agreement between their home institution and GVSU (i.e., either their affiliated institution does not have an IACUC or they are operating independently of any institution), the collaborator is required to complete an Independent Investigator Agreement (IIA; Appendix 2). The IIA binds the non-GVSU collaborator's activities to the GVSU IACUC, and to oversight and governance by the IACUC according to its policies and procedures.

4. When animals are transferred between institutions, written documentation of the transfer is required, and appropriate animal care records must be transferred to the receiving institution.

Procedures and Guidance

1. USDA and OLAW have agreed that dual IACUC review is not required, and the collaborating institutes are allowed to determine which IACUC will review and have oversight responsibilities.

2. Requests to rely on an external IACUC for approval, and requests for an external institution to rely on the GVSU IACUC for approval, must be submitted using ORCI's electronic database management system by the GVSU PI. Upon receipt of the submission, the ORCI will initiate and coordinate the completion of the agreement between institutions as needed; the IACUC has developed a template IACUC Collaboration Agreement (Appendix 3) that can be used for this purpose. The Institutional Official (IO) is authorized to approve IACUC Collaboration Agreements. If an agreement can be reached for GVSU to rely on an external institution's approval, a formal review by the GVSU IACUC is generally not required.

3. If the research with live vertebrate animals is being done externally by collaborators through a subaward or subcontract, with GVSU as the awardee institution, a separate agreement (such as the IACUC Collaboration Agreement) is not required if the subaward agreement contains a complete description of the oversight responsibilities, animal ownership, transportation of animals between institutions, and reporting requirements.

4. When the activity involving live vertebrate animals is supported by PHS, all awardees and performance sites must hold an OLAW-approved AWA.

5. IIAs are to be signed by the external collaborator and by the GVSU IO. IIAs signed by the external collaborator can be either attached to a protocol submission or submitted directly to the ORCI. The ORCI will obtain the signature of the GVSU IO and return a fully executed IIA to the PI and external collaborator.

6. Upon transferring animals between institutions, written documentation of the transfer should include confirmation of animal receipt by the receiving institution, the number of animals transferred and received, and any observed animal welfare concerns. Animal care records to be transferred should include, as appropriate: species, animal identifiers, sire and/or dam identifiers, sex, birth or acquisition dates, and source. Documentation via electronic correspondence is acceptable.

7. GVSU investigators are encouraged to discuss their plans for collaborative IACUC work with the ORCI prior to submitting an IACUC protocol application.

Section 5: Post-Approval Monitoring and Actions

Policy 5.05: Reporting Adverse Events and Abnormal Behavior/Conditions
Version: 2.0
IACUPPS Approval Date: 03/15/2024
IO Approval Date: 04/08/2024
IACUC Approval Date: 04/18/2024
IACUPPS Last Review Date: 04/03/2025

Policy

1. Everyone involved in the care and use of animals is responsible for knowing the reporting requirements for adverse events and abnormal behavior/conditions and must adhere to the timeframes outlined in this policy.

2. Reporting to the Attending Veterinarian and the IACUC is required for certain incidents. The reporting process assists PIs, animal care staff, and the IACUC to find the cause of the incident and to prevent recurrence. Reporting also helps the IACUC meet its federal requirements to monitor animal activities and meet the reporting requirements of external oversight agencies.

3. Failure to follow the reporting requirements outlined in this policy is considered noncompliance. Refer to *IACUC Policy 5.10: IACUC Noncompliance*.

Definitions

1. *Adverse Event (AE)*:
   a. Any event that 1) negatively impacts animal welfare or poses a threat of harm to a live vertebrate animal, and 2) that meets any of the following conditions:

      i. The event is protocol-related but is not identified in the approved protocol or occurs at a rate or severity higher than indicated in the approved protocol.

      ii. The event is not related to protocol procedures but may be the result of external factors, such as facility or housing malfunctions, weather-associated conditions, or shipping.

   b. An event or problem that significantly impacts the health and safety of personnel during their conduct of an IACUC protocol or has the potential to do so (e.g., animal bite, scratch, animal rights activity, etc.).

2. *Abnormal Behavior/Condition (ABC)*: Animals showing signs of unusual behavior, injury, or illness unrelated to the approved study procedures or that are unexpectedly found dead.

Procedures and Regulatory Guidance

1. If the situation is urgent, first ensure personnel health and safety, and then provide immediate care to the animal to the extent possible.

2. Reporting of AEs and ABCs

    a. Notify the Principal Investigator and Attending Veterinarian of all AEs and ABCs as soon as possible, but no later than within 12 hours of learning of the event. Notification can occur via phone (preferred), email, or in-person.

    b. The Attending Veterinarian will work with the research team to analyze the problem and develop a response plan.

    c. All AEs require additional reporting by the PI to the IACUC.

    d. The necessity of reporting an ABC to the IACUC will be at the discretion of the Attending Veterinarian.

    e. When reporting to the IACUC is required, a written report must be submitted by the PI to the IACUC within seven (7) calendar days of first learning of the event.

    f. Written notification of AEs (and ABCs, when required by the Attending Veterinarian) should be submitted through the ORCI's electronic database management system by the PI and must include the following items:

        - Protocol number
        - Funding source, if applicable
        - Classification of the event (adverse event or abnormal behavior/condition)
        - Full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., PI or co-investigator, technician, animal caretaker, student, veterinarian, etc.)
        - Description of actions taken by PI to address the situation
        - Description of short- or long-term corrective plans and implementation schedule(s)

3. AEs are reviewed by the IACUC at convened meetings.

4. The ORCI will determine when reporting to external agencies is required and will work with the Institutional Official to ensure the reporting occurs within the required timeframe.

5. Examples of AEs requiring reporting to the IACUC

a. A significant increase in mortality or morbidity related to protocol procedures.

b. Facility- or weather-related events that negatively affect animal welfare.

c. Protocol deviations, departures or mistakes made by protocol personnel that negatively impact animal welfare.

6. Examples of ABCs that require notification to Attending Veterinarian but do not typically require IACUC notification:
    a. Injury or illness unrelated to study procedures (e.g., fight wounds, barbering, age-related mortality, etc.).

    b. Facility- or weather-related incidents that may have negatively impacted the animals.

    c. Surgical complications that are not identified in the protocol and occur rarely. If high levels of complications are observed, reporting to the IACUC would likely be required by the Attending Veterinarian.

7. Events that do not require reporting to the Attending Veterinarian or IACUC:
    a. Animal death or injuries related to manipulations that fall within the parameters described in the IACUC-approved protocol, provided the rate of occurrence is equal to or below the rates indicated in the approved protocol.

    b. Death of animals that have reached the end of their natural life spans.

    c. Death or failure of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate.

8. For questions regarding the need for reporting, please contact the Attending Veterinarian and/or the ORCI.

Policy 5.10: IACUC Noncompliance
Version: 3.0
IACUPPS Approval Date: 04/03/2025
IO Approval Date: 04/04/2025
IACUC Approval Date: 04/18/2024
IACUPPS Last Review Date: 04/03/2025

Policy

1. All members of protocol teams involved in the care and use of animals must comply with all applicable federal, state, and local laws, research ethics standards, and the determinations, policies and directives of the IACUC, or other oversight authority such as study sponsors, or collaborating educational and private institutions as appropriate. Protocol noncompliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include but are not limited to: use of unauthorized animals, performing unauthorized surgery, unauthorized persons participating in a research project or educational activity, and injecting drugs that the IACUC has not approved. When faced with protocol noncompliance, the IACUC's first step, if possible, should be to find a way to bring the protocol into compliance.

2. Any person with direct knowledge or reasonable suspicion of research noncompliance must report that information directly to the ORCI, IACUC Chairperson, and/or IO. If willing, the person with direct knowledge of potential research noncompliance may also report that information to the PI. If reported to the PI, the PI shall take immediate corrective action to reduce or eliminate any imminent risk to animals or personnel that is posed by the potential reported noncompliance.

3. The IO, IACUC, and the ORCI are responsible for investigating cases of potential noncompliance in animal care and use activities involving GVSU personnel and/or for which GVSU serves as the reviewing IACUC. This included studies which have already received GVSU IACUC approval as well as studies in which GVSU IACUC approval was required but not obtained. Activities that are not subject to GVSU IACUC oversight do not fall under the domain of this policy. Each concern must be reviewed in a timely and systematic manner and, when necessary, prompt, appropriate corrective actions shall be taken.

Definitions

Research Noncompliance: Noncompliance is defined as failure by any member of the protocol team to comply with applicable federal, state, or local laws, research ethics standards or with the determinations, policies and directives of the IACUC, or other oversight authority such as study sponsors, collaborating educational or private institutions, etc. Noncompliance may be either significant or minor.

1. *Significant noncompliance*: Noncompliance is significant when the action or omission includes a significant breach of laws, regulations, or university policy which compromises the function of the IACUC or puts personnel or animals at risk. Examples

include, but are not limited to, the following:

a. Acquiring animals or performing unapproved procedures without IACUC approval.

b. Willful acts of abuse.

c. Performing a procedure in a manner that animals endure pain or suffering that is not addressed by the approved protocol.

d. Failure to provide adequate anesthesia or analgesia according to the protocol.

e. Repeated or willful incidents of minor noncompliance.

2. *Minor noncompliance*: Noncompliance is minor when the action or omission violates a law, regulation, or policy, but the risk of harm to personnel and animals is minimal, and the IACUC's authority or function has not been compromised. Examples include, but are not limited to, the following:

a. Failure to inform the IACUC of the addition of personnel, provided those personnel have been properly trained before working with animals.

b. Failure to conduct a daily health check, provided the missed inspection does not compromise animal welfare.

c. Personnel working on the protocol with expired training and/or medical forms.

d. Inadequate controlled substance logs or controlled substance storage.

e. Not maintaining records properly per IACUC policy and/or protocol requirements.

f. Minor protocol deviations which do not significantly compromise animal welfare.

Procedures and Regulatory Guidance

1. Reports of Noncompliance
    a. There are a number of options available to communicate concerns about animal care and use at GVSU, or to report instances of suspected noncompliance with laws, rules, regulations and policies. The names and phone numbers of contact persons including the Attending Veterinarian, the Director of the ORCI, and the IO should be posted in or near the entrance to animal facilities and readily available to institutional employees and protocol personnel. Any of these individuals can be contacted via phone, email, or in person to report

noncompliance. Additionally, GVSU's anonymous online reporting system can be used to report an incident.

b. Self-reporting is encouraged.

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

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

e. Minor issues that do not impact animal welfare concerns (such as documentation or minor animal issues) are not immediately deemed as noncompliant. In these instances the PI/personnel are given an opportunity to immediately address the issue to avoid a finding of noncompliance. This includes minor items identified by the ORCI during Post-Approval Compliance Reviews (see *IACUC Policy 5.60: Post-Approval Compliance Review*). If the issue is not addressed sufficiently in a timely manner, the incident will be deemed to be noncompliant.

2. Initial Evaluation and Actions
   a. The ORCI, the IACUC Chairperson, and/or the IO will conduct an initial assessment of the reported noncompliance to determine if the activity falls under the purview of the GVSU IACUC, and if so, to determine the immediate procedural steps required to reduce or eliminate any risk to animal subjects and protocol personnel.

   b. Preliminary information to be collected during the initial evaluation will vary depending on the circumstances, but will often include:

i. Interviewing the individual reporting the incident (if known), any persons against whom allegations were directed, and pertinent program officials;

ii. Observing the animals and their environment; and

iii. Reviewing any pertinent records (e.g., animal health records, protocol, and other documents).

c. If the reported noncompliance does not fall under the purview of the GVSU IACUC, the ORCI and/or IO will attempt to contact the appropriate authority overseeing the activity on behalf of the complainant.

d. If the reported noncompliance affects an active IACUC-approved protocol and the risk minimization procedures include suspension or termination of some or all protocol-related procedures, the IACUC Chair and IO shall inform the PI. See IACUC Policy 5.20: Suspension or Termination of Animal Activities.

e. After discussion of the initial assessment, if the IACUC Chairperson, IO, and ORCI determine the incident does not constitute noncompliance, this determination is documented, and if necessary, the PI will be notified. No further action is necessary.

f. If the incident constitutes noncompliance, the IACUC Chairperson will determine whether the noncompliance is significant or minor and inform the ORCI and IO of this decision.

3. Review of Minor Noncompliance
    a. Attempts to resolve minor noncompliance will initially be made through direct communication between the ORCI and the PI (and if necessary, the personnel involved in the incident). The ORCI will document the incident and how it was corrected.

    b. Resolved issues of minor noncompliance will be reported to the IACUC at the next convened meeting.

    c. If the issue is not sufficiently resolved, or is determined to be more serious, the procedures for resolving significant noncompliance will be followed.

4. Review of Significant Noncompliance
    a. If the reported incident is determined to be significant noncompliance, a formal investigation will commence.

    b. The IO shall issue a written statement summarizing the initial assessment and that an investigation will be undertaken (if any) to the PI, the PI's Authorizing Official, the Chairperson of the IACUC, and other individuals deemed appropriate by the IO.

c. IACUC Subcommittee Investigation

i. The IACUC Chairperson shall establish an IACUC Assessment Subcommittee (IAS) consisting of at least two IACUC members. The IACUC Chairperson will provide the IAS with a review of the incident and the preliminary information collected by the ORCI and IACUC Chairperson. The IAS can either meet in person, via teleconferencing or videoconferencing, or correspond via email discussion. The IAS will consult with the PI and others as appropriate (e.g., other protocol personnel, ORCI staff, the IACUC Chairperson, other members of the IACUC, etc.) to complete the investigation.

ii. Following completion of the formal investigation, the IAS shall provide the IACUC Chairperson and the IO with a written report summarizing the proceedings and findings of the investigation. The report will summarize and include the following as applicable:

1. The concern(s);

2. The results of interview(s);

3. The condition of animals and their environment;

4. The results of records and other document reviews;

5. Any supporting documentation such as correspondence, reports, and animal records;

6. Identity of additional individuals or other institutional or non-institutional offices who may require notification of the incidence; and

7. Conclusions regarding the substance of the concerns as they relate to the requirements of the AWRs, the PHS Policy, the *Guide*, and institutional policies and procedures.

The report must also include the following items:

1. A determination if noncompliance occurred, and if so, if that noncompliance was serious or minor;

2. If any serious protocol deviations occurred;

3. If any serious deviations from the *Guide* occurred; and,

4. Recommended corrective actions, or recommendation of no further actions if that is the unanimous conclusion of the IAS.

iii. The IACUC Chairperson and IO will review the report, and if needed, seek clarifications and/or additional information from the IAS. If needed, the IAS will amend the report to address the clarifications and missing information. If desired, the IO and/or IACUC Chairperson may forward the report to other members of the IACUC for additional review.

iv. If the IAS determines that noncompliance did not occur and no further action is needed, the IO will send the final report to the PI and AO, and the incident will be considered closed.

v. If the IAS determines that the incident involved noncompliance—or that the incident was in compliance but still requires further action (for example, an animal welfare concern)—the IO will forward the draft of the written report summarizing the formal investigation proceedings and findings to the PI. The PI's Authorizing Official will be notified that the PI has received the report. The PI will have ten business days to provide a written response to the IO if desired. If changes are required to the report, the IO will coordinate with the IAS to incorporate the changes, and the IAS shall prepare an amended report. If the PI fails to respond to the IO within ten business days, the report will be accepted as final.

vi. The IO will forward the report to the PI, the IACUC Chairperson, the PI's Authorizing Official, and other individuals as deemed appropriate by the IO. The PI's response(s) to the draft report, if any, will also be forwarded to the recipients of the final report.

d. <u>IACUC Review</u>

i. If the IAS determined that the incident involved noncompliance, or that the incident was in compliance but still requires further action, the IACUC must review the IAS report at a convened meeting. The IACUC Chairperson will determine if an emergency meeting of the IACUC is necessary or if the review can occur at the next scheduled meeting of the IACUC.

ii. The convened IACUC may table the IAS report and request that additional facts be collected for its determinations and/or that revisions be made to the report. If either are needed, the following steps will be taken:

1. The IAS shall attempt to collect the additional information requested and will amend the report appropriately.

2. The amended report will be sent to the IACUC Chairperson and the IO.

3. The IO will forward the draft of the amended report to the PI. The PI's Authorizing Official will be notified that the PI has received the report.

4. The PI will have ten business days to provide a written response to the IO, if desired. If the PI fails to respond to the IO within ten business days, the report will be accepted as final.

5. If further changes are required to the report following review of the PI's written response, the IO will coordinate with the IAS to incorporate the changes, and the IAS shall prepare an amended report.

6. The revised report will be reviewed at a future convened meeting.

iii. The convened IACUC will make the following determinations:

1. A determination of noncompliance occurred, and if so, if that noncompliance was serious or minor;

2. If any serious protocol deviations occurred;

3. If any serious deviations from the *Guide* occurred; and,

4. Recommended corrective actions, or recommendation of no further actions. Such corrective actions include, but are not limited to, the following:

a. Suspension or termination of IACUC approval,

b. Requiring additional information from the PI with a plan for corrective action,

c. Transferring the research to another investigator,

d. Modifying the protocol,

e. Requiring periodic updates/reports to the IACUC,

f. Implementing measures to prevent reoccurrence, and

g. Other actions deemed appropriate by the IACUC.

iv. The IACUC is responsible for making determinations and determining corrective actions, if any, related to the animal welfare regulations, GVSU

IACUC policies, and the IACUC protocol(s) affected by the noncompliance or animal welfare concern. The rationale for all decisions made by the IACUC must be documented in the meeting minutes.

v. The IACUC Chairperson will issue the PI a formal letter, outlining the determinations made by the IACUC and any subsequent actions required by the IACUC.

e. IO Review

i. Independent of any IACUC review and any IACUC required corrective actions, subsequent administrative actions may be determined by the IO, either independently or in consultation with university counsel and other individuals as deemed appropriate by the IO. The IO will seek input from the IACUC as needed.

ii. The IO will issue a final letter indicating the matter has been reviewed and outlining the results of the investigation, including any corrective or administrative actions as determined by the IO. This final letter will be issued to the PI, the PI's Authorizing Official, the Chairperson of the IACUC, and other individuals as deemed appropriate by the IO. The IO will monitor the PI's completion of any identified corrective or administrative action.

5. External Reporting

a. Failure by GVSU-affiliated individuals and/or IACUC protocol personnel to follow federal and GVSU regulations, guidelines, policies, and procedures may require reporting to the appropriate institutional, local, state and/or federal agencies.

b. Reportable violations may include, but are not limited to:

i. Suspension or termination of a protocol

ii. Serious or continuing noncompliance with the PHS Policy

iii. Serious deviations from the *Guide*

iv. Serious deviations from IACUC policies and procedures

c. If reporting is necessary, the IACUC Chairperson, ORCI staff, and IO will prepare the necessary report. The report should include a full description of the violation(s) and the appropriate corrective actions that have been taken and/or are planned. A timeline for the implementation of future planned corrective actions should be included as appropriate. The IO is responsible for submitting the report to the appropriate institutional or agency.

6. The IACUC Chairperson, in consultation with ORCI staff, will provide a final update to the individual(s) who originally reported the animal welfare/noncompliance concern, if such notification is determined to be warranted.

7. Confidentiality
    a. All deliberations of the IACUC related to a noncompliance investigation are confidential and should not be referenced in non-IACUC-related matters.

    b. Only the final report will be shared as deemed appropriate by the IO.

Policy 5.20: Suspension or Termination of Animal Activities
Version: 2.0
IACUPPS Approval Date: 04/03/2025
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IACUPPS Last Review Date: 04/03/2025

Policy

The IACUC will take appropriate action to minimize risks to the well-being of animals used for research and educational activities. These actions may include suspension or termination of some or all animal activities.

Procedures and Regulatory Guidance

1. The reasons an IACUC protocol may be subject to suspension or termination include, but are not limited to:
    a. Failure to comply with applicable laws, IACUC policies and procedures, or instructions from the IACUC

    b. Failure to submit required documents or reports in the time frame specified by the IACUC

    c. Failure to promptly and accurately disclose to the IACUC important material information concerning known or suspected risks to animal subjects

    d. Implementation of unapproved animal activities that require IACUC review and approval

    e. Falsification of documents or otherwise conceal information related to risks to animal subjects

    f. Failure to maintain records as required by the IACUC, including records of unexpected problems or adverse events

    g. New information revealing a significant increase in potential risk to animal subjects

    h. Serious unanticipated problems or adverse events

2. Suspension of Animal Activities
    a. When animal welfare concerns are identified, the IACUC Chairperson, the IACUC veterinarian, and/or the IO may suspend an animal activity when, until such time that the IACUC can convene and formally consider the matter. See *IACUC Policy 5.10: IACUC Noncompliance*.

    b. The IACUC is authorized to suspend or terminate any activity involving animals if it determines that the activity is not being conducted in accordance with the

approved protocol, provisions of the AWA, PHS Policy, the *Guide*, or GVSU's Assurance.

c. In order to suspend or terminate an approved activity, it will be necessary to convene a meeting of the IACUC with a quorum present. A majority vote of the quorum present in favor of suspension is required to suspend or terminate an activity.

d. If the IACUC votes to suspend or terminate an approved activity, the IO, in consultation with the IACUC, will notify in writing or by email the Provost, the Vice Provost for Research Administration, the PI, and the PI's Unit Head that the ongoing activity has been suspended.

3. Reporting Requirements
   a. The suspension or termination of animal activities may require reporting to the appropriate local, state and/or federal agencies.

   b. If reporting is necessary, the IACUC Chairperson, ORCI staff, and IO will prepare the necessary report. The report should include a full description of the violation(s) and the appropriate corrective actions that have been taken and/or are planned. A timeline for the implementation of the planned corrective actions should be included. The IO is responsible for submitting the report to the appropriate agency.

Policy 5.30: Animal Holding Policy
Version: 1.1
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. Circumstances can arise in which animals held for a study are no longer covered by an IACUC approved protocol. The IACUC provides approval under this policy to provide for the health and well-being of the animals. This policy establishes a mechanism for holding animals not assigned to a current GVSU protocol. It is intended as a temporary mechanism to avoid euthanasia and assure animal well-being. During this time, investigators must take the necessary actions to gain approval of their animal use protocol in order to avoid forfeiture of their animals.

2. When animals are transferred to the holding policy, the following conditions exist:
    a. A member of the IACUC will be appointed to serve as the Acting Principal Investigator and will be responsible for the animals' care and well-being.

    b. Feeding, sanitation, and environmental enrichment will be performed as expected for the species.

    c. Animals cannot be used for research, instructional purposes, or testing.

    d. Animals must not be euthanized for research purposes. No tissue may be obtained from animals that are housed or euthanized under the Animal Holding Policy. Any use of animals housed under the Animal Holding Policy will be treated as serious noncompliance.

    e. The Attending Veterinarian has full discretion and authority for all veterinary treatment and euthanasia of animals on the Animal Holding Policy.

Procedures and Regulatory Guidance

1. Acting Principal Investigator
    a. The following individuals, in order, are responsible for the animals on the Holding Policy and will serve as the Acting Principal Investigator:

        i. IACUC Chairperson

        ii. IACUC Vice Chairperson

        iii. A member of the IACUC, appointed by the Director of the ORCI

b. In the event the individual listed is not able to fulfill the duties of Acting Principal Investigator (i.e., due to availability and/or a conflict of interest such as serving as personnel on the protocol from which the animals originated), the responsibility will fall to the next individual on the list.

2. Use of the Animal Holding Policy
Situations when the Animal Holding Policy can be utilized include, but are not limited to, the following:

a. Animals from an expired or terminated protocol

b. Animals on a protocol that has been suspended or is under investigation for potential noncompliance issues where the welfare or well-being of the animals are in question

c. Investigators new to GVSU who do not have an IACUC-approved protocol, but need immediate housing of animals at GVSU

d. Investigators leaving GVSU, but who do not have the necessary approvals to transfer animals to the new institution

e. Investigators whose ability to serve as an active PI is unexpectedly compromised

3. Conditions and Limitations of Work with Animals on the Animal Holding Policy
   a. Animal Care Details
   The Acting Principal Investigator and Attending Veterinarian must be notified of any significant research or health-related conditions prior to the transfer of animals to the Animal Holding Policy. Examples of important information include, but are not limited to:

      i. Existing surgical implants

      ii. Zoonotic and/or infectious disease potential

      iii. Special dietary needs

      iv. Past surgical history

      v. Genetic anomalies that affect the appearance, health and normal behavior of the animal

      vi. Viral vectors

      vii. Poor fecundity

b. Maintenance/Husbandry of Animals
The Acting Principal Investigator may delegate maintenance/husbandry responsibilities (e.g., feeding, sanitation, environmental enrichment, etc.) to other qualified individuals, such as Animal Care staff, investigators from other animal protocols, personnel from the protocol from which the animals originated (depending upon the circumstances), or other persons with sufficient knowledge about the particular species being held.

c. Necessary Special Diets or Oral Medications
Special diets or necessary medications may continue to be provided to the animals while on the Animal Holding Policy under veterinary oversight.

d. Euthanasia
The Acting Principal Investigator does not have the authority to euthanize any animals on this policy without prior explicit permission from the Attending Veterinarian.

e. Time on Holding Policy
Animals remaining on the Animal Holding Policy for over 60 days will initiate a review by the IACUC. The IACUC will determine if ongoing maintenance on the Animal Holding Policy is appropriate or, if disposition of the animals is necessary, an appropriate course of action for disposition.

f. Reporting to the IACUC
The ORCI will report any transfers that have occurred in accordance with this policy to the IACUC at its next scheduled meeting.

g. Costs
Costs associated with maintaining animals on this Animal Holding Policy will be the responsibility of the PI and/or the academic unit(s) from which the protocol originated. If animals are being housed under this policy for a new GVSU investigator, the costs will be the responsibility of the academic unit(s) to which the new investigator will locate.

Policy 5.40: Removal of Animals from the Vivarium
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

An animal that has been admitted into the vivarium will remain in the vivarium until it is euthanized or adopted out.

Procedures

Exceptions to this policy require the approval of the IACUC. If a PI would like to temporarily remove an animal from the vivarium and then readmit the same animal, they must submit an amendment to their protocol justifying this practice. The amendment must be approved prior to the temporary removal of the animal.

Policy 5.50: Animal Adoptions
Version: 1.0
IACUPPS Approval Date: 11/07/2019
IO Approval Date: 12/10/2019
IACUC Approval Date: 11/21/2019
*IACUPPS Last Review Date: 04/03/2025***Policy**
Retired animals used in research and/or educational activities may be adopted out of GVSU by the PI of the protocol of record for that animal. All IACUC animal adoptions require approval from the Attending Veterinarian before the animal may be released for adoption.

Procedures and Regulatory Guidance

1. Retired animals are defined as animals obtained or bred during an approved IACUC protocol that are no longer needed for completion of the protocol and which will not be transferred to a different protocol or to another animal facility for further research or educational purposes.

2. A GVSU IACUC Adoption Form (Appendix 4) must be completed for any animal adopted from an IACUC protocol. No animal may be adopted out without a completed form and prior approval of the Attending Veterinarian. The PI shall provide a copy of the completed form to the ORCI within five (5) business days of removing the animal from GVSU property.

3. The ORCI shall retain the adoption documents for a minimum of three years from the date of adoption. A copy of the completed form will be provided to the Vivarium Supervisor for any animal that is adopted out of the GVSU vivarium.

Policy 5.60: Post-Approval Compliance Review
Version: 2.0
IACUPPS Approval Date: 04/03/2025
IO Approval Date: 04/04/2025
IACUC Approval Date: 11/21/2019
IACUPPS Last Review Date: 04/03/2025

Policy

1. The purpose of post-approval compliance review is to ensure adequate protection of animal subjects used in research and educational activities. The principal use is in monitoring the implementation of approved protocols, identifying areas that need improvement, targeting education needs of researchers, and gathering information for continuous improvement of IACUC processes.

2. Compliance review of approved research protocols may be conducted either randomly or for cause at any time. Compliance review authority may include, but is not limited to, the following:

    a. Observation of animal husbandry

    b. Observation of procedures involving animals

    c. Inspection of physical spaces (animal storage rooms, laboratories, food storage locations, etc.) and all equipment associated with the protocol

    d. Review of all documents and materials pertaining to the permission for or conduct of research activities, including training records of protocol personnel

Procedures

1. Selection of protocols for compliance review
    a. Reports of animal welfare concerns
    If an animal welfare concern or complaint is discovered or reported to the ORCI staff, any member of the IACUC, or the IO, *Policy 5.20: Animal Welfare Concerns and Noncompliance* will be followed.

    b. For-cause compliance reviews
    If a concern or complaint unrelated to animal welfare is discovered or reported to the ORCI staff, any member of the IACUC, or the IO, a for-cause compliance review may be initiated. The determination of the need for a for-cause compliance review shall be made by the IACUC Chair in consultation with the IO and the ORCI. A for-cause compliance review may occur at any time.

    c. Selected not-for-cause compliance reviews

Certain animal use protocols may be selected for a compliance review based on the following study factors: USDA oversight; external sponsorship; and/or the use of animals meeting USDA Reporting Code Category D or E, even if the animals used are not subject to USDA oversight (e.g., laboratory mice).

d. Random compliance reviews
Animal use protocols may be randomly selected for a compliance review at any time. No more than 30 percent of all open research protocols shall be chosen for selected not-for-cause and random compliance reviews per academic year.

e. Requests from PIs for voluntary post-approval compliance reviews will be considered.

2. Conducting a compliance review
   a. The ORCI has the principal responsibility for conducting compliance reviews of protocols involving animal subjects. At the discretion of the ORCI, assistance conducting a review may be requested from the IACUC Chair, IACUC members, or other experts.

   b. Due to the nature of the work involved, routine compliance review of field studies may be limited to review of records and an interview with the PI (and, if applicable, other study team members).

   c. External sponsors of animal protocols may conduct research compliance audits, investigations, site visits, or evaluations as detailed in the sponsor contract. Such audits, investigations, site visits and evaluations may be random or for-cause and must be coordinated in advance through the GVSU Office of the Provost under the direction of the IO. The procedures detailed in this policy are applicable only to internal audits of protocols; audits conducted by an external sponsor may be carried out via different procedures than those described in this policy.

3. Confidentiality
The content of any findings resulting from compliance review proceedings shall be kept appropriately confidential by all parties involved in the compliance review, provided no animal welfare issues are identified during the review. A signed confidentiality agreement may be requested of participating parties. Aggregate, de-identified summary of routine reviews (i.e., those not identifying animal welfare issues) will be periodically provided to the IACUC; see Section 7 for more details. If an animal welfare issue is identified during the review, confidentiality cannot be promised; see Section 8 below for more details.

4. Notification of Investigators

The PI of a protocol selected for random or selected not-for-cause compliance reviews shall be notified at least ten (10) working days in advance of the compliance review visit and will be provided with a self-assessment checklist at the time of notification. The PI of a protocol who has been selected for a for-cause compliance review will generally, but not always, be notified at least one (1) working day in advance of the compliance review visit; a self-assessment checklist may, but not always, be provided at the time of notification of a for-cause compliance review.

5. Compliance Review Visit and Final Report
   ORCI, along with any identified experts if needed, will meet with the PI and other team members as appropriate to conduct an in-person compliance review visit. Informal feedback will be given to the PI during the visit; following the completion of the compliance review, ORCI will draft a final written report. This report will be sent to the PI for review. If the PI wishes to respond to the report, they must do so, in writing, within five (5) business days. Pertinent documents related to the compliance review visit, including any subsequent written response from the PI following the final report, will be stored in ORCI's electronic database management system.

6. Reporting to the IO and RIO
   If subsequent to the conduct of a compliance review, the ORCI has reasonable suspicion of serious or continuing noncompliance, the final written report shall be submitted to the IO. If the ORCI has reasonable suspicion of research misconduct as defined by GVSU policy, the final written report shall be submitted to the Research Integrity Officer (RIO).

7. Reporting to the IACUC
   An aggregate report of all compliance reviews and subsequent findings, including corrective action plans and preventive measures, but excluding personal identifiers, shall be made to the IACUC at least annually by the ORCI. This report will be shared with the Provost upon request.

8. Animal Welfare Concerns and Noncompliance
   Any suspicion or evidence of animal welfare concerns (e.g., animal misuse, mistreatment, or neglect), and/or serious or continuing noncompliance identified during the review will be reported to the IACUC Chair, and the IO immediately. Such concerns will be reviewed per *Policy 5.10: IACUC Noncompliance*.

Policy 5.70: Closure of IACUC Protocols
Version: 1.0
IACUPPS Approval Date: 10/22/2020
IO Approval Date: 11/04/2020
IACUC Approval: 01/21/2021
IACUPPS Last Review Date: 04/03/2025

Policy

1. Once a study has concluded and/or the protocol has expired, the PI is responsible for submitting a closure report to the IACUC.

2. The PI may close an IACUC protocol at any time during the approval period of the protocol. If a protocol is voluntarily closed, but the PI wishes to restart the animal work, a new protocol must be submitted to the IACUC for approval.

3. Unless a protocol has been previously closed, it will be considered closed upon the third anniversary of its approval date. PIs who wish to continue protocols beyond the three-year approval period must submit a new protocol to the IACUC for approval.

4. Failure to submit a closure report within 30 calendar days after the protocol expiration date is considered noncompliance. Refer to *IACUC Policy 5.10: IACUC Noncompliance*.

Procedures

1. Report Submission
    a. PIs must complete and submit the closure report using the GVSU ORCI's electronic database management system.

    b. The ORCI will attempt to send the PI email notification reminders at 90, 60, 30, and 7 days before protocol expiration, on the date of protocol expiration, and if the closure report is not submitted, at 20 and 30 days after protocol expiration.

    c. No research, testing, or instructional use of animals may occur upon protocol closure.

2. Report Review
    a. Upon receipt of a closure report, the report and all supporting documents are sent to the IACUC Chair, or delegate IACUC member, for review.

    b. The reviewer will ensure that:
        i. The protocol was conducted in accordance with the approved protocol.
        ii. Modifications received IACUC approval prior to implementation.
        iii. No unanticipated or adverse events were experienced, or such events were documented and reported appropriately.

c. Any potential compliance issues identified in the review will be further investigated by the IACUC. Refer to *IACUC Policy 5.10: IACUC Noncompliance*.

Appendices

Appendix 1: Guidance on Working with Nonhuman Primate Samples

Background

Tissue, blood, and bodily fluids from nonhuman primates (NHPs) can pose numerous health problems, most notably exposure to *Macacine herpesvirus 1*. This virus occurs naturally in macaque, rhesus, cynomolgus, and possibly other monkeys. While infection of *Macacine herpesvirus 1* is extremely rare in humans, when it does occur, the infection can result in severe brain damage or death if not treated soon after exposure. Infection is typically caused by animal bites or scratches or mucosal contact with body fluids or tissues. *Macacine herpesvirus 1* can be present in saliva, feces, urine, or nervous tissue of infected monkeys and may be harbored in cell cultures derived from infected monkeys. The virus status on an animal can change over time; therefore, all NHP-derived materials should be considered potentially infectious. *Macacine herpesvirus 1* may survive for hours on the surface of objects, particularly surfaces which are moist.

Additional viruses may also be present in NHP samples, including Simian Immunodeficiency Virus (SIV) and Type D Retroviruses (Simian retroviruses [SRV]).

Possible routes of transmission to humans include:

- Bite or scratch from an infected animal
- Needlestick puncture from contaminated syringe
- Scratch or cut from contaminated equipment with a sharp-edged surface
- Exposure to nervous tissue or skull of infected animals (especially brain)
- Splash of body fluids to mucous membranes (eyes, nose, mouth)

Safety Precautions

Working with NHP materials requires approval from the GVSU Institutional Biosafety Committee. For training and implementation of procedures for working with these samples, and to obtain the appropriate personal protective equipment, please contact the Biosafety Officer.

Extreme caution should be taken when working with NHP-derived samples. Such precautions include:

- Wear gloves, preferably nitrile with a thickness of at least 4 mm
- Practice thorough handwashing before and after gloving
- Wear long pants and closed-toed shoes
- Wear safety glasses, goggles, or a face shield with a surgical mask.
- Reduce or eliminate sharps and glass
- Disinfect work surfaces after completing work, using Virkon S or 1 part bleach to 10 parts water, followed by 70% ethanol
- Dispose of all items coming into contact with NHP material through the appropriate waste stream.

- A kit should be available in the laboratory with disinfectant soap and exposure instructions. Contact the Biological Safety Officer for assistance.

Additionally, personnel who work with NHP-derived samples should be routinely screened for tuberculosis. This screening is available at the GVSU Family Health Center.

In Case of Exposure

The following exposures require immediate first aid and medical follow-up:

- NHP bites or scratches/abrasions from the NHP or the soiled cages
- Punctures or lacerations by an instrument or needle contaminated by NHP secretions (saliva, secretion from mouth, mucous/genital membranes, conjunctiva)
- Splashes in the mouth, nose or eye (mucous membranes) with NHP secretions, including feces and urine

Unless the injury is severe, first aid should be performed before seeking medical care.

For punctures and lacerations with a contaminated instrument: Cleanse the wound immediately with a Betadine sponge scrub for 15 minutes. Rinse thoroughly. Seek further medical attention. Follow reporting required in *Policy 2.80: Occupational Health and Safety*.

For splashes of potentially contaminated fluid to the nose, mouth, or eyes: Flush the site for 15 minutes with water or saline solution. Seek further medical attention. Follow reporting required in *Policy 2.80: Occupational Health and Safety*.

Institutional Biosafety Committee (IBC) Review

The use of nonhuman primate samples may require review and approval from the GVSU IBC. Please consult with the Office of Research Compliance and Integrity if you plan to use nonhuman primate samples.

Version: 1.0
Date: 04/13/2023

Appendix 2: Individual Investigator Agreement Template

Individual Investigator Agreement
For non-GVSU affiliated research personnel

Individual Investigator's Name: Click or tap here to enter text.
Project Title: Click or tap here to enter text.

GVSU IACUC Protocol Number (if known): Click or tap here to enter text.

The protocol identified above will be covered by this Agreement during which the above-named individual is listed as a co-investigator or participating study personnel on the above animal care and use protocol. This Agreement will be in effect for the following time period: Click or tap here to enter text.

1. The above-named Individual Investigator has reviewed the relevant institutional policies and procedures for the protection of animal subjects.

2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the welfare of animal subjects involved in the project conducted under this Agreement.

3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for animal subjects in the project conducted under this agreement.

4. The Investigator will abide by all determinations of the GVSU Institutional Animal Care and Use Committee (IACUC) and will accept the final authority and decisions of the IACUC, including but not limited to directives to suspend or terminate participation in designated project activities.

5. The Investigator will complete any educational training required by the Institution and/or the IACUC prior to initiating the project covered under this Agreement.

6. The investigator will not initiate changes in the project without prior IACUC review and approval, except where necessary to eliminate apparent immediate hazards to the animal subjects.

7. The Investigator acknowledges that they are responsible for safeguarding the welfare of each animal subject and will report immediately to the Principal Investigator of the protocol any adverse events involving the animals covered under this Agreement.

8. The Investigator acknowledges and agrees to cooperate in the IACUC's responsibility for review, record keeping, reporting, and certification for the project referenced above. The Investigator will provide all information requested by the IACUC in a timely fashion.

9. The Investigator will not conduct project activities under this Agreement prior to its review and approval by the IACUC.

10. This Agreement does not preclude the Investigator from taking part in research or other activities not covered by this Agreement.

Investigator Signature

_____ Date: _____
Print Full Name and Degree(s): Click or tap here to enter text.
Institutional Affiliation (if applicable): Click or tap here to enter text.
Phone #: Click or tap here to enter text.
Address: Click or tap here to enter text.
Email: Click or tap here to enter text.

Signature of Authorizing Official for GVSU IACUC

_____ Date: _____
Full Name: Jeffrey A. Potteiger, Ph.D.
Institutional Title: Authorizing Institutional Official
Contact information: 616-331-7207 and Jeffrey_Potteiger@gvsu.edu

Appendix 3: Collaboration Agreement Template

Institutional Animal Care and Use Committee Collaboration Agreement

This agreement designates one Institutional Animal Care and Use Committee (IACUC) to provide oversight of a collaborative research project involving animal care and/or use. Completion of this agreement provides assurance that the designated IACUC will review and oversee animal activities for the duration of the collaboration and in compliance with applicable rules and regulations, including the Animal Welfare Act Regulations and the PHS Policy on Humane Care and Use of Laboratory Animals. This agreement must be signed and kept on file by both parties and provided to federal oversight agencies upon request.

I. Institutional Collaborators and Project Information

Institution A (Institution providing IACUC review and oversight of animal research activities)	
Institution A Name	
PHS Animal Welfare Assurance #	
USDA Registration #	
AAALAC Accreditation Status	
IACUC Office Contact Information (address, phone, email)	

Institution B (Institution relying on IACUC review by Institution A)	
Institution B Name	
PHS Animal Welfare Assurance #	
USDA Registration #	
AAALAC Accreditation Status	
IACUC Office Contact Information (address, phone, email)	

Project Information	
Name of Research Project (grant/contract title)	
Sponsor or Funding Agency, if any	
Grant Award Number, if any	
IACUC Protocol Title	

IACUC Protocol #	
Principal Investigator (name, phone, and email)	
Date of Initial IACUC Approval	
Date of IACUC Expiration	
Duration of Collaboration (mm/yyyy – mm/yyyy)	

Scope of Animal Activities	
Identify the site(s) where this research takes place	
Describe the scope of the animal activities that will occur at each site by Institution A/B researchers	
Describe the species and number of animals that will be used and time period spent at that site	

II. Delegation of Responsibilities

Place an "X" in the appropriate column marking which party is responsible for each item. Attach additional pages with detailed explanations for any item that is not clearly the responsibility of one party.

Responsible Party			**Responsibility**
Inst. A	**Inst. B**	**N/A**	
			IACUC review and oversight
			Animal acquisition (or capture)
			Daily feeding and husbandry
			Treating sick and injured animals
			Contacting veterinarian for diagnosis and intervention Veterinarian Name: Phone:
			Decision to euthanize
			Decision to remove an animal from the study
			Transportation of animals
			Purchase of animals
			Animal ownership during the collaboration
			Animal ownership after the collaboration

			Animal husbandry, including feeding, housing, and animal care staff
			Veterinary care and medical supplies
			Other (explain):

III. Documentation

A. As an attachment to this collaboration agreement, Institution A must submit proof of initial IACUC approval and subsequent amendment approvals, as applicable.

B. Within 30 calendar days of any of the following events, Institution A must provide written notification to the IACUC office at Institution B.

1. Notification of unexpected events, incidents, significant deficiencies or animal welfare issues related to the IACUC protocol indicated in Part I; or

2. A termination or change in status of either Institution's PHS Assurance, USDA registration, or AAALAC accreditation; or

3. Renewal or amendment approvals to the IACUC protocol indicated in Part I.

IV. Termination

Either institution may terminate this agreement at any time and for any reason by providing the other party with 30 calendar days' written notice. The notice must be provided to the contact listed in Part I.

V. Certification and Signatures

The undersigned institutions agree to the terms and conditions of this collaboration agreement.

Institution A: Institution B:

Signature: _____ Signature: _____

Date: _____ Date: _____

Name: _____ Name: _____

Title: _____ Title: _____

Email: _____ Email: _____

Phone: _____ Phone: _____

Email this agreement and supporting documentation to the IACUC offices at both institutions.

Appendix 4: Animal Adoption Form

Request for Adoption of Purchased Research/Teaching Animals

I, _____ do hereby request permission to adopt the animal: Description of Animal, Facility ID #, sex, species, breed if appropriate:

I certify that I am aware of any special needs of the animal, that I will provide appropriate husbandry and health care. I will not offer the animal for sale, use as a breeding animal, or serve as food for other animals. I assume full fiscal responsibility for the care of the animal once adoption proceedings are completed. I understand that the adoption is final and I will not be able to return the animal to GVSU after adoption. By my signature and to the fullest extent permitted by law, I hereby release, acquit and forever discharge GVSU, its Board of Trustees, officers, agents, employees, insurers, attorneys, representatives, successors and assigns from harm for any injury, illness or accident that occurs as a result of my adoption of this animal. I further understand that a licensed veterinarian has examined this animal and found no discernible health problems at the time of the examination but that I am advised to have the animal examined by a licensed veterinarian of my own choosing.

Signature

_____

Date

mm/dd/yyyy