



Grand Valley State University
A4449-01
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

Animal Welfare Assurance for Domestic Institutions

I, **Jon Jellema, M.A.** as named Institutional Official for animal care and use at **Grand Valley State University**, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

Grand Valley has two major campuses and several satellite sites. The main campus is in Allendale, MI, where the primary animal care facility is located (a small 500 square foot, USDA registered facility). The second major campus is in Grand Rapids (Pew Campus), and is split between two locations. Smaller campuses or satellite sites are located in Holland (Meijer campus) and in Muskegon (two separate facilities). No animals are held at the Grand Rapids, Holland, or Muskegon campuses. The major academic components of the university are: College of Liberal Arts & Sciences (Allendale), College of Health Professions (Grand Rapids), Kirkhof College of Nursing (Grand Rapids), College of Engineering & Computing (Grand Rapids, MI), Seidman College of Business (Grand Rapids, MI), College of Community and Public Services (Grand Rapids), College of Education (Grand Rapids) and College of University-wide Interdisciplinary Initiatives (Allendale)

Other significant satellite sites of GVSU include the Annis Water Resources Institute and the Michigan Alternative and Renewable Energy Center –both in Muskegon, MI. Fish are periodically held in aquaria at the Annis Water Resources Institute.

- B. The following are other institution(s), or branches and components of another institution:

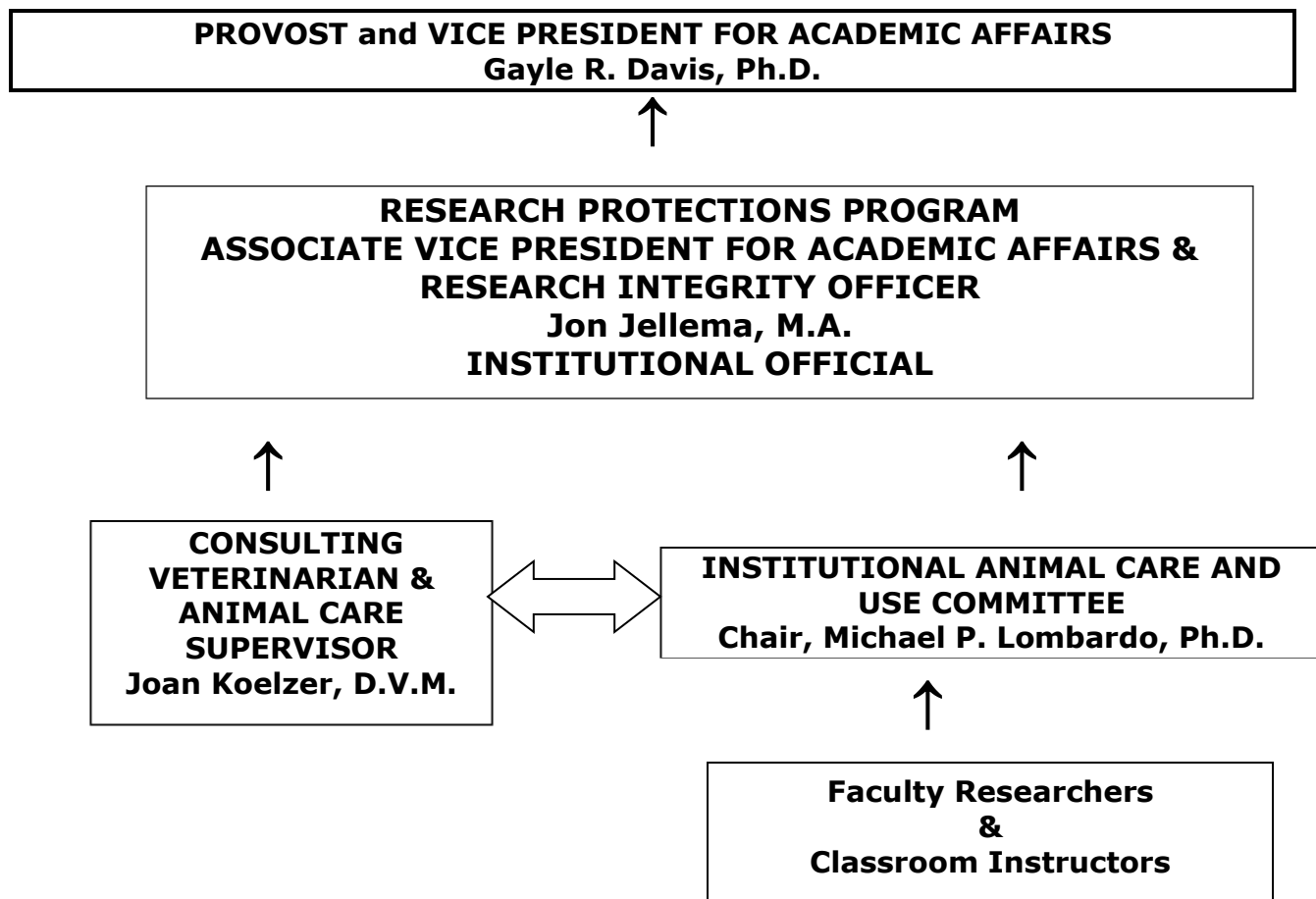
Not applicable to this Assurance.

II. Institutional Commitment

- A. GVSU will comply with all applicable provisions of the [Animal Welfare Act](#) (AWA) and other Federal statutes and regulations relating to animals.
- B. GVSU is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. GVSU acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. GVSU has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).
- E. GVSU agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:



B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Consulting Veterinarian

Name: Joan Koelzer, D.V.M.

**Degrees: B.S., Michigan State University, East Lansing, MI. 1983.
D.V.M., Michigan State University, East Lansing, MI. 1985.**

Training and/or experience in laboratory animal medicine: Dr. Joan Koelzer, D.V.M. is the consulting veterinarian for the GVSU Animal Care and Use committee and all research involving the use of animals. Dr. Koelzer received her D.V.M. in 1985 and has been in private practice since that time. For 22 years Dr. Koelzer has served as the Consulting Veterinarian for numerous research facilities, including the West Michigan Regional Lab, VanAndel Research Institute, and Grand Valley State University. In addition, Dr. Koelzer is the Contract Veterinarian in small animal practice in West Michigan. Dr. Koelzer conducts regular inspections of animal research facilities at Grand Valley State University.

Authority: Dr. Koelzer has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals.

Dr. Koelzer's Duties: as Consulting Veterinarian include:

- 1. Serve as a member of the IACUC at Grand Valley State University, making reports related to animal care at meetings of this committee.**
- 2. Conduct announced and unannounced monthly animal facility inspections.**
- 3. Provide animal care as necessary.**
- 4. Consult GVSU faculty regarding treatment of research animals that become ill during their stay in the research facility.**
- 5. Function in an advisory capacity to the IACUC as to new animal care legislation: federal, state and local.**
- 6. Submit to the IACUC and the IO an annual written report on laboratory operations related to the care of subject animals.**
- 7. In a timely manner, notify the IO, the IACUC Chair, and the Faculty Researcher/Laboratory Manager of any problems and/or deficiencies related to animal care, and the steps that need to be taken to correct such problems.**
- 8. Dr. Koelzer has delegated program authority for the animals at the institution and the authority to implement PHS Policy and provisions of the Guide.**
- 9. This is anticipated to take eight to ten hours a month and approximately 5 percent of her professional time.**

On those occasions when the Consulting Veterinarian is unavailable to provide necessary care to research animals held in the GVSU facilities, Dr. Diane Vander Wall, D.V.M. will be contacted for such care (please see her qualifications below). Dr. Vander Wall is a practicing veterinarian at Cascade Hospital for

Animals. She has worked as the back-up veterinarian for Dr. Koelzer for several years.

Back-up Veterinarian

Name: *Diane Vander Wall, D.V.M.*

Qualifications:

Degrees: *B.S., Biology, Calvin College, Grand Rapids, MI. 1994.
D.V.M., Michigan State University, East Lansing, MI. 1998.*

Training and/or experience in laboratory animal medicine: *Dr. Vander Wall is a practicing veterinarian and has been in private practice at Cascade Hospital for Animals, Grand Rapids, MI since 1999. She has experience in internal medicine, surgery, and preventative medicine in dogs, cats, rodents, and rabbits. In addition, since 1999 she has been the back-up veterinarian for West Michigan Regional Laboratory, and Calvin College, Grand Rapids, MI.*

Authority: *Dr. Vander Wall has delegated program authority and responsibility for GVSU's animal care and use program when Dr. Koelzer is not available.*

Time Contributed to Program: *Dr. Vander Wall is responsible for back-up veterinary services when Dr. Koelzer is not available.*

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

- a. **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 occupational health and safety; training for IACUC members, research staff, and husbandry staff; the institutional disaster plan; sanitation and cleaning practices; surgical support and post-operative analgesia; compliance with approved protocols; procedures for reporting allegations of inappropriate animal care or use; and accessibility to veterinary care during and after typical working hours. Each area of evaluation 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. Fifty percent plus one of the members of the IACUC must be present during the Semiannual Program Review.**
- b. **Findings from the Program Review, including a Deficiency Correction Schedule, are compiled and prepared for IACUC review and discussion no later than at the next regular, convened IACUC**

meeting following the Program Review. The IACUC Chair requests additional comments and minority views from all members present.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
 - a. **Every six (6) months, usually during March and September, the IACUC Chair organizes the inspection schedule of the animal facilities located on campus and any satellite facilities. These inspections are conducted using a Facilities Inspection Checklist provided by OLAW the Guide, the PHS Policy on Humane Care and Use of Laboratory Animals, and as applicable, 9 CFR Chapter I, subchapter A, as a basis for evaluation. Semiannual inspections of occupied facilities are conducted during April and October each year.**
 - b. **Deficiencies detected during inspections are categorized as minor or significant. All IACUC members are invited, and encouraged, to attend the facility inspections. At a minimum, two (2) members are present for each inspection. No member is involuntarily excluded from participating in any portion of the facility inspections.**
 - c. **A responsible party (e.g., PI) is notified, in writing or email, of any minor or significant deficiency identified in their laboratory, facility or designated space. Responsible parties are 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.**
 - d. **Findings from the Facility Inspections, including a Deficiency Correction Schedule, if necessary, are compiled by the IACUC Chair and prepared for IACUC review and discussion no later than at the next regular, convened IACUC meeting following the inspections. The IACUC Chair requests additional comments and minority views from all members present.**
 - e. **The IACUC may determine whether the supervisory personnel of various facilities should be notified of the date and time of an inspection.**
 - f. **Performing Inspections - Adherence to the following recommendations assists the IACUC in performing inspections:**
 - i. **An updated list of all facilities to be inspected are maintained by the IACUC.**
 - ii. **All proposals submitted to the IACUC must specify locations where animal procedures will be performed.**
 - iii. **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, is sought to improve the process.**

- iv. **Apparent deficiencies will be discussed with the person in charge of the facility to ensure that the team's perception of the situation is accurate.**
 - v. **The IACUC will use a Facilities Inspection checklist supplied by OLAW during inspections to provide consistency and help document that all categories were assessed.**
- g. Categories assessed during inspections include**
- **Sanitation,**
 - **Food and water provisions,**
 - **Animal identification,**
 - **Waste disposal,**
 - **Animal health records,**
 - **Controlled and/or expired drugs,**
 - **Environmental control,**
 - **Occupational health and safety concerns,**
 - **Staff training,**
 - **Knowledge of animal care procedures, and**
 - **Knowledge of applicable rules and regulations, and security.**
- h. Reporting the Results of Facility Inspections –**
- i. **After the inspection, the Chair of the IACUC prepares a report that summarizes the inspection's findings.**
 - ii. **Concerns raised by IACUC members during the inspection are discussed by the IACUC. If the majority of the IACUC recognizes the matter as one of concern, a proposal to rectify the issue is developed. The proposal is forwarded to the IO and GVSU Provost for review and recommendation.**
 - iii. **Concerns raised by individuals not members of the committee will be brought to the attention of the Chair of the IACUC in writing or by email and addressed in a manner identical to that described above.**
 - iv. **The Chair's report is distributed to (1) IACUC members for their review and comment, (2) the investigator(s) using the animal facilities, (3) the Chair(s) of the investigator's department(s), and (4) the IO and GVSU Provost's Office.**
- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

Once every six months the Chair of the IACUC, using the Semiannual Program and Facility Review Checklist (Checklist) provided by OLAW, prepares a report (i.e., Semiannual Review) that (i) summarizes IACUC actions, (ii) summarizes recent animal facility inspections, (iii) reviews the institution's program for the humane care and use of animals during the previous six months, and (iv) reports the Institution's adherence to the Guide for the Care and Use of Laboratory Animals; any departures from the Guide, PHS Policy, or the AWAR during the reporting period will be identified specifically and reasons for each departure will be stated and reported to the IO in the Semiannual Report covering the period during

which the IACUC approved departure is in place. The report is distributed to other IACUC members for their review and comments before a final draft is submitted to the IO and GVSU Provost. The report will be signed by a majority of IACUC members before being distributed to the IO and the GVSU Provost.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
 - a. **Evaluation of Animal Care and Use Concerns - To help ensure that laboratory animals receive humane care, use or treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC reviews and, if warranted, addresses any animal-related concerns raised by the public or institutional employees. Procedures have been established to ensure that concerns are communicated to the IACUC. The IACUC will review each concern in a timely and systematic manner and, when necessary, takes prompt, appropriate corrective actions.**
 - b. **Methods for Reporting**
 - i. **To facilitate communication, there are a number of options available to communicate concerns about animal care and use at GVSU, or to report instances of suspected non-compliance with laws, rules, regulations and policies. The names and phone numbers of contact persons including the Attending Veterinarian, the Directors of the Office of Sponsored Programs (OSP) and the Center for Scientific and Creative Excellence (CSCE) are posted in or near the entrance to animal facilities and readily available to GVSU employees.**
 - ii. **Although written concerns are more convenient to handle, complainants may not be willing to submit them in this manner. In such cases, individuals who receive verbal concerns will document them fully to ensure that the issues are clear and to prevent misunderstandings.**
 - iii. **Requests for anonymity are honored to the extent possible. This includes protecting the confidentiality of those who report verbal concerns as well as anyone against whom allegations are directed, while allegations are under investigation. GVSU's policy prohibits unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.**
 - c. **Procedures for the Investigation of Animal Care and Use Concerns**
 - i. **Initial Evaluation and Actions**
 1. **Concerns may include situations or activities ranging from those in which animals are reported to be in immediate, actual or perceived jeopardy to those in which violations of the Animal Welfare Regulations (AWRs) or GVSU's Assurance with OLAW are alleged to**

be occurring but animals are not in apparent danger. They may focus on allegations of past policy and procedure violations or protocol non-compliance.

2. The course of action taken by the IACUC is driven by the potential significance of the alleged situation. Conditions that reportedly jeopardize the health or well being of animals will be evaluated immediately. To cope promptly with such situations, the Attending Veterinarian is authorized to halt procedures which they think do not comply with institutional policies until the IACUC can be convened and formally consider the matter. Similarly, situations that may involve potential criminal activity or human safety will be reported promptly to the GVSU's Public Safety or occupational health and safety officials. Allegations of other ongoing policy or procedural matters may not require such same-day attention, but will not be deferred merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

ii. **The Complaint Assessment Subcommittee**

1. Upon receipt of a concern, the IACUC Chair will establish and convene a meeting of the Complaint Assessment Subcommittee (CAS) comprised of IACUC members designated by the Chair. The CAS can either meet in person, or via email discussion. After initial review of the complaint, the CAS will determine whether it requires further investigation and immediate action, further investigation but no immediate action, no further investigation, or no action. Once this decision has been made, the CAS will determine which individuals or other institutional or non-institutional offices may require notification.
2. If immediate action appears warranted because animal or human welfare may be compromised, the IACUC will notify the IO and proceed accordingly. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately to protect animal or human welfare. In accordance with the AWRs, if an activity is suspended, the IO will report that action to Animal and Plant Inspection Service (APHIS), if appropriate, and any federal agency funding that activity. If the PHS supports the activity in any way, the IACUC, through the IO, will promptly notify OLAW.

iii. Investigation

- 1. If the IACUC determines that further investigation is required, the CAS will conduct the investigation and report back to the IACUC.**
- 2. The IACUC will charge the designated person or group with its requirements for information gathering and impose a completion date. The assigned completion date will depend on the IACUC's determination of whether immediate remedial action is required. The nature of the information required will vary depending on the circumstances, but often involves:**
 - Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;**
 - Observing the animals and their environment; and**
 - Reviewing any pertinent records, (e.g., animal health records, protocol, and other documents).**
- 3. The CAS will provide a report to the IACUC, which summarizes:**
 - The concern(s),**
 - The results of interview(s),**
 - The condition of animals and their environment, and**
 - The results of records and other document reviews.**
- 4. The CAS report will also contain:**
 - Any supporting documentation such as correspondence, reports, and animal records,**
 - Conclusions regarding the substance of the concerns vis-à-vis requirements of the AWRs, the PHS Policy, the Guide, and GVSU policies and procedures, and**
 - Recommended actions, if appropriate.**

iv. Outcomes and Final Actions

- 1. Upon receipt and evaluation of the report, the IACUC may request further information or find that:**
 - There was no evidence to support the concern or complaint,**
 - The concern or complaint was not sustained, but related aspects of the animal care and use program requires further review,**
 - Other institutional programs may require review, or**
 - The concern or complaint was valid.**

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5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

- a. **After consulting with PIs, the consulting veterinarian, and other members of the IACUC, the Chair prepares a written recommendation to the IO regarding any aspect of GVSU's animal program, facilities, or personnel training.**
- b. **Drafts of the recommendation are distributed to IACUC members for their review and comments.**
- c. **The final versions of recommendations, including minority views, are submitted to the IO.**

6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

a. **Protocol Review**

i. **General Scope of Review - The following kinds of activities involving vertebrate animals are subject to review by the IACUC prior to initiation:**

1. **Activities conducted by GVSU regular faculty, affiliated faculty (i.e. those holding Visitor, Adjunct, or Affiliated status), staff, or students;**
2. **Activities performed on the premises of GVSU;**
3. **Activities performed with or involving the use of facilities or equipment belonging to GVSU;**
4. **Activities satisfying a requirement imposed by GVSU for a degree program or completion of a course of study; and/or**
5. **Activities certified by a dean or department head to satisfy an obligation of a faculty appointment at GVSU, including requirements for clinical or adjunct appointments.**

ii. **Specific Types of Activities Reviewed by the GVSU IACUC**

1. **Research - Many of the vertebrate animals covered in IACUC review are used in research, that may include medical, biological, and behavioral research as well as agricultural research. Most of these animals are acquired and housed by GVSU; some may include free-ranging wildlife. Field studies that involve killing, trapping, banding, darting, implantation of telemetry devices, or any invasive manipulation require IACUC approval. Review may be required even if the activity does not seem to qualify as "true research" (e.g. when the results are not intended for publication, will not advance work in**

another area, or will not contribute to generalizable knowledge).

2. **Teaching** - The use of vertebrate animals in educational settings may be subject to IACUC review.
3. **Research Projects in Which the Investigator is a Consultant** - in some instances, GVSU faculty or staff may serve in an advisory capacity for a research project conducted outside the GVSU community. IACUC review is required unless the investigator has a strict consulting relationship in which the investigator is hired on his or her own time and is not compensated by GVSU for such work; the investigator holds no rights in the work; and neither the investigator nor GVSU retains any data.

Unless all three of these criteria are met, the IACUC must review the project. Review by another institution or facility's IACUC is insufficient unless a cooperative arrangement between that IACUC and GVSU's IACUC is agreed upon prior to initiating the consultant relationship.

4. **Research in Foreign Countries** - Research conducted by the GVSU investigators in foreign countries falls under GVSU's purview and guidelines.

All animal-based research conducted in foreign countries is subject to IACUC review. This includes the use of animals in foreign research institutions, and fieldwork involving either domestic or wild animals.

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

iii. **Exemptions** - the following activities are exempt from GVCSU IACUC review:

1. Activities involving animals that perform tasks, participate in club activities, or appear in exhibits or demonstrations.
2. Use of tissues, organs or other parts of dead animals if received as such.
3. Noninvasive observations of wild animals in their natural habitat.

- iv. **Who Can Be a Principal Investigator at GVSU?** - 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 member of the faculty of GVSU. Students with independent projects must have a faculty sponsor. The student and the faculty sponsor shall share responsibility of ensuring that the project meets and maintains IACUC approval. Generally, faculty 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.

Research conducted by non-faculty, academic support staff, post-doctoral students, staff appointments, graduate students or undergraduate students must be under the direction of a faculty member, as defined above. In such cases, the faculty member shall be considered the PI. The PI may delegate the performance of any or all components of the research to non-faculty if they certify to the IACUC that the individuals are sufficiently trained to perform the functions assigned.

Individuals that do not meet any of the above criteria may, by demonstrating sufficient cause and necessary expertise, petition the Director of the OSP for permission to submit an application for approval of an IACUC protocol. Such agreement shall be in writing and require the individual to comply with all relevant IACUC and GVSU policies for the conduct of research involving animal subjects.

b. **Protocol Submission Procedures**

- i. Applications for the use of animals in teaching and research are available on the IACUC website (www.gvsu.edu/iacuc).
- ii. Investigators fill out the application online and electronically submit the completed application and necessary supplementary documents (e.g., permits) to the GVSU Research Protections Program (RPP). Each application is given a project number.
- iii. Completed applications are electronically distributed to IACUC members. IACUC members are given two weeks to request a full IACUC review (i.e., Full Committee Review; see below) of an application. An IACUC meeting to review applications is convened if any member thinks that FCR is necessary. If FCR is not requested then the protocol is sent to Designated Member Review (DMR) (see below).

c. **Protocol Review Criteria** - In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC will conduct a review of those components related to the care and use of animals and determine that the

proposed research projects are in accordance with PHS Policy, AWRs, and the applicable US Government Principles.

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.

d. **Protocol Review Procedures** - The following pertains to review of initial protocols as well as to review of proposed significant changes in previously approved protocols.

i. **Full Committee Review (FCR)** - Full committee review of protocols requires a convened meeting of a quorum of the IACUC members. A quorum of the committee is reached if 50 percent plus one of the IACUC is present. Proposals reviewed by the full committee must receive the approval vote of a majority of the quorum present in order receive approval.

After a committee discussion, IACUC members vote to approve without modification, withhold approval pending receipt of revisions, table the application until the next meeting, or withhold approval. A majority vote of the quorum present is required to require modifications necessary to secure approval or to withhold approval.

If the IACUC votes to approve the application pending receipt of revisions the chair sends a request to the PI in writing or by email detailing the application's deficiencies and requesting that the PI revise and resubmit the protocol. Depending on the extent of the necessary revisions, revised applications are reviewed by either by the Chair, the full IACUC, or DMR.

When substantive information is lacking from a protocol, the committee may have questions requiring a response from the PI. In such situations, the IACUC may take the following actions:

If all members of the IACUC are present at a meeting, the committee may vote unanimously to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR, or returned for FCR at a convened meeting. If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulation: All IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. The results of the DMR will be appended to the meeting minutes.

If the revisions are significant (those other than minor

administrative revisions) the IACUC reviews the revisions by FCR, then votes to approve, withhold approval pending the receipt of further revisions, or withhold approval.

Revisions that are administrative in nature are reviewed by the IACUC Chair. (see below)

Investigators of protocols for which approval has been withheld, may meet with the IACUC to discuss the protocol and to resubmit a revised application.

The IACUC's ultimate decision about an application will be sent, in writing or by email, to the (i) PI, (ii) his/her department Chair, (iii) the IO, and (iv) any other relevant GVSU officials.

In situations of Conflict of Interest, the member recused may not contribute to the quorum. The IACUC ensures the consistency of a quorum when a member is recused.

- ii. **Designated Member Review (DMR)** – As described above, all animal care and use protocols submitted to the RPP will be sent to all IACUC members. Failure to respond within the two-week member consideration period is considered as approval to use DMR for review. These responses are sent to the IACUC Chair via email. If any one IACUC member votes to subject a protocol to FCR, then the protocol is placed on the agenda for the next IACUC meeting. If all members vote to allow the DMR to review the protocol before the end of the member consideration period, then the IACUC Chair sends the protocol to DMR for review.

The IACUC Chair (or in his/her absence, the Vice-Chair) 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.

The DMR can either approve, request modifications on the protocol, or refer the protocol to FCR. The DMR may not withhold approval. If the DMR requests protocol revisions, the Chair contacts the PI in writing or by email detailing the application's deficiencies and requests that the investigator revise and resubmit their application.

Revised applications are reviewed by the DMR to approve or request further revisions. If the protocol is assigned to more than one DMR, 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 the other DMR must be aware of and agree to the modifications.

The ultimate decision about a protocol will be sent, in writing or by email, to the PI, his/her department Chair, the IO, and other IACUC members.

Under no circumstances will animal work be permitted to resume or begin until final IACUC approval is granted.

Primary reviewers can also take the initiative to contact the PI prior to the meeting for clarifications, additional information, or in anticipation of questions the IACUC may raise. Primary review differs from DMR which delegates authority to approve a proposal to one or more members.

- iii. **Administrative Review (AR)** - Amendment/modification applications to existing protocols that involve certain changes not considered significant by the IACUC during FCR or DMR may be reviewed (and approved) administratively by the Chair of the IACUC, or in his/her absence the Vice-Chair.
- iv. **Notification of Review Outcome** - The IACUC will notify PIs and the IO in writing or by email 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. The IACUC procedures to notify investigators and the IO of its decisions regarding protocol review are as follows:
 - 1. **Upon completion of the review process, each PI receives a written or email notification of review decisions and whether any special monitoring provisions will be required. Records of communication are maintained within the IACUC protocol files.**
 - 2. **Upon completion of the review process, a copy of the meeting minutes is provided to the IO informing the IO of all actions taken by the IACUC.**
- e. **Range of IACUC Actions** - Upon review of protocols, the IACUC may take one of several different actions depending upon the findings of the committee: approval, modifications required to secure approval, and withhold approval.
 - 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 project, thus granting the PI permission to perform the experiments or procedures as described. The IACUC-approved proposal 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 Chair, could verify prior to granting approval. If a study 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, the IACUC can ask the investigator to revise the protocol to reflect the modifications imposed by the IACUC. If the protocol is missing substantive information necessary for the IACUC to make a judgment, or the IACUC requires extensive or multiple modifications, then the IACUC can require that the protocol be revised 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. **Withhold approval** - 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.
 - iv. **Defer or table review** - If the protocol requires significant clarification in order for the IACUC to make a judgment, IACUC members with certain expertise are not present, the IACUC wishes to seek external consultation, or any of a number of other reasons prevent the IACUC from conducting its review, then the IACUC may defer or table review until a future FCR.
- f. **Required Principal Investigator Certifications** - In order for work to begin on an approved animal use protocol proposal the PI must certify the following.
- i. All students, staff, and faculty on an approved project are familiar with the AWA and the PHS Policy on Humane Care and Use of Laboratory Animals, the Guide, and recognize their responsibility in strictly adhering to approved protocols.
 - ii. All individuals listed a protocol are qualified or will be trained to conduct procedures involving animals under the approved protocol, and that they have completed approved GVSU Animal Care and Use training (see below), and GVSU Medical Evaluation (see below), and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary), the concepts related to the 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 GVSU procedures for reporting animal welfare concerns.
 - iii. All procedures will be conducted in accordance with GVSU Occupational Health and safety procedures, including those pertaining to personal protective equipment.

- iv. **Any change in the care and use of animals involved in an approved protocol, including any change in the personnel listed on the protocol, that would affect their 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 PIs without prior IACUC approval.**
 - v. **He/she 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.**
 - vi. **He/she 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.**
 - vii. **That the activities described in a protocol submitted for IACUC review are consistent with those described in any related grant, contract, or subcontract.**
 - viii. **That, to the best knowledge of the PI, the information contained in the animal use protocol is accurate**
 - ix. **That the approved protocol or any other animal use privileges may be revoked by the IACUC if the any of the aforementioned assurance statements are violated.**
 - x. **It is implicit upon submission of a protocol that the PI has read and agrees to abide by the above obligations.**
- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:
- a. **Significant changes to an IACUC-approved protocol must be reviewed and approved by the IACUC before they occur. 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 experimental animals. Examples of significant changes include, but are not limited to, changes:**
 - **in the methods of animal use;**
 - **in the objectives of a study;**
 - **from non-survival to survival surgery;**
 - **resulting in greater discomfort or a grater degree of invasiveness;**
 - **in the species or in approximate number of animals used;**
 - **in PI;**
 - **in anesthetic agent(s) or the use or withholding of analgesics;**
 - **in the method of euthanasia; and**
 - **in the duration, frequency, or number of procedures performed on an animal.**

b. Methods for Requesting Significant Changes to an IACUC-approved Protocol

- i. PI submits proposal in writing for significant change in approved protocol to IACUC.**
- ii. Proposals are distributed to all members of the IACUC as described above.**
- iii. Proposals for significant changes are subjected to the same procedures for review as described above for protocol review.**

8) Notify investigators and the Institution 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 according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

- a. The IACUC's ultimate decision about an application will be sent, in writing or by email, to the (i) PI, (ii) his/her Unit head, (iii) the IO, and (iv) any other relevant GVSU officials.**
- b. Investigators of protocols for which approval has been withheld, may meet with the IACUC to discuss the protocol and to resubmit a revised application.**

9) 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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

a. Continuing Review: The Annual Review

- i. At GVSU, the IACUC requires an Annual Report on the status of each protocol. In doing so, the PI verifies that completed activities were conducted in accordance with the approved protocol, describes any proposed departures from the approved protocols, and provides information about activities projected for the upcoming year. In addition, the number of animals used over the course of the previous protocol year needs to be provided.**
- ii. When Annual Report Forms, available on the IACUC website, are submitted electronically to the RPP prior to the protocol's expiration date, the protocol is considered active and experiments can be conducted while the annual renewal is under review.**
- iii. Procedures for Conducting Annual Reviews**
 - 1. Sixty (60), 30, 15, 7, and 1 day before the first and second anniversary of the protocol approval, the PI is sent an email notification requesting the status of the protocol (active or inactive), requesting any proposed modifications to the protocol, and asking for the number of animals the PI has used in the previous 12 months.**

The PI must complete the Annual Report Form and return it to the RPP by the first and second anniversary of the protocol approval. The IACUC Chair reviews the Annual Report Form. If a PI fails to submit an Annual Report Form by the first and second anniversary of the protocol approval, the following action is taken:

- 2. Depending on the species covered in the protocol:**
 - a. If the protocol covers species that are not regulated by the USDA, then the IACUC Chair (or in his/her absence, the Vice-Chair) will notify the PI, the Attending Veterinarian, and the Director of the OSP (if the project is externally funded), that all work under the animal protocol must cease until further notice. The Attending Veterinarian, in consultation with the IACUC Chair (or in his/her absence, the Vice-Chair), will determine if any threat to animal well-being is posed and if so will take the appropriate action.**
 - b. If the protocol includes species that are regulated by the USDA, the protocol will be treated as expired. If this is the case, the PI must promptly provide, in writing or by email, a statement that he or she will not use any animals under the protocol for teaching or research until the IACUC has reviewed and approved the annual Renewal. If the PI fails to promptly provide such a verification statement and continues animal work, then GVSU will report such incident to OLAW.**
- 3. When a PI has successfully submitted and obtained approval of the annual renewal after an appropriate review method (as described above), animal work may continue.**
- 4. If the PI fails to successfully renew the protocol within 30 days of the protocol anniversary date, the protocol will be considered to be permanently expired and the PI will be required to resubmit a new protocol in order to restart work. Additionally, the IACUC may consider suspending or terminating that PI's animal use privileges. If a protocol is allowed to lapse the IACUC, including the Attending Veterinarian, will make a determination (after possible consultation with the Directors of the CSCE and OSP and the relevant Deans and Unit heads) on whether the animals can be safely and humanely maintained temporarily, or if they should instead be transferred to another study, placed with an outside agency, or euthanized.**
- 5. If the animals have been used primarily for teaching or demonstration and were originally privately held animals**

that were not purchased with university funds, they may be able to be returned back to the original owners or another experienced individual. Requests for such transfers can be made to the IACUC.

b. Continuing Review – The Triennial Review

The PHS Policy requires that a complete IACUC *de novo* review of PHS-supported protocols be conducted at least once every three years. The three-year period begins on the initial date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. Since protocol approval period cannot be extended, investigators must be cognizant of the protocol approval period. To aid investigators, the RPP shall attempt to provide adequate warning of pending protocol expiration. It is the responsibility of the investigator to submit the third-year resubmission by the appropriate deadline date for Full Committee Review or Designated Member Review prior to protocol expiration. The IACUC requires a Third Year Resubmission be submitted as a new proposal, using the most recent version of the application.

i. Procedures for Conducting Triennial Reviews

- 1. Ninety (90), 60, 30, 15, 7, and 1 day prior to the three-year anniversary of the animal protocol approval date, the PI is sent a notification requesting a resubmission of the protocol. The PI must resubmit the entire protocol to the IACUC on the most current application forms. A *de novo* review of the third-year resubmission is conducted as described above in III.D.6. 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:**
 - a. On the third anniversary of the protocol approval, the IACUC Chair (or in his/her absence, the Vice-Chair) will notify the PI, the PI's dean (and/or department chair), the Attending Veterinarian, and the Director of the Office of Sponsored Programs (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 and any ongoing work under the expired protocol is a serious and reportable violation of PHS Policy.**
 - b. The Attending Veterinarian will be notified of the expired protocol and any remaining animals under that protocol will be transferred to a holding protocol. If appropriate, per diems for animal care will be charged to the PI. In the event that animal care charges are being charged to a sponsored project, an alternate account must be identified for such charges.**
 - c. When the PI has successfully obtained approval of the protocol animals will be transferred from the holding**

protocol to the new approved protocol.

- d. If the PI fails to successfully renew the protocol, the IACUC may consider suspension or recommending to the Institutional Official that the PI's animal use privileges should be terminated.**

10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

- a. The IACUC is authorized to suspend any activity involving animals if it determines that the activity is not being conducted in accordance with the previously approved protocol, provisions of the Animal Welfare Act, PHS Policy, the Guide, or the institution's Assurance Letter with OLAW. Usually, the IACUC will initiate suspension of an activity and report through the IO to OLAW. In order to suspend a previously 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 will be required to suspend an activity.**
- b. If the IACUC needs to suspend a previously approved activity, the IO, in consultation with the IACUC, shall first review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW. If suspension is deemed necessary, the IACUC Chair will notify in writing or by email the Provost, the IO, the PI, and the PI's Unit head that an ongoing activity should be suspended. A full report of that action, with a full explanation, will be sent from the office of the IO to OLAW.**

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

- 1. Information about the Occupational Health and Safety Program at GVSU can be found at <http://www.gvsu.edu/facilitieservices>. At GVSU, the Occupational Health and Safety Program and the Lab Safety Specialist (<http://www.gvsu.edu/labsafety>) help to protect the health and safety of faculty, students, and staff who work with vertebrate animal species in the course of their research or teaching. The program is designed to customize the participation requirements based on the type and degree of exposure to animals. A set of questionnaires (an initial health risk assessment, a baseline health assessment and one for periodic updates) is used to assess this degree of risk. The IACUC will consult with the GVSU Safety Officer and Lab Safety Officer and report violations of GVSU Occupational Health and Safety Program rules to the GVSU Safety Officer when necessary.**
- 2. The IACUC and GVSU Laboratory Safety Office will provide all those that come into contact with animals appropriate guidelines and training that outline general health and safety issues associated with working with animals, access to GVSU occupational health and safety training programs, and hazard and risk assessment regarding allergies, physical hazards, the handling of waste materials, precautions taken during pregnancy, illness, and immune suppression.**

- 3. GVSU Policies Regarding Occupational Health and Safety Programs or Personnel Working in Laboratory Animal Facilities or Have Frequent Contact with Animals**
- a. In general, the guidelines outlined by the Guide, and in the text, Occupational Health and Safety in the Care and Use of Laboratory Animals (National Research Council, 1997) will be followed.**
 - b. All animal caretakers, employees, and students working with animals are likely to be either GVSU employees or students. A medical evaluation, and reviewed by health professionals (see below) will be required from all those who will come into contact with animals prior to their commencing work with animals. Employees working with laboratory animals will be required to present evidence that they have been adequately immunized against diphtheria, *Haemophilus influenzae* type B, pertussis, polio, rabies, rubella, and tetanus when appropriate.**
 - c. Information on epizootic diseases and zoonoses frequently associated with species used in the facility will be kept on file, and the animal caretakers will be made familiar with these files. Animal caretakers will be made aware of AWA 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.**
 - d. In the event of animal bites, scratches, or other injury, prompt medical attention will be obtained following the GVSU Workers' Compensation Injury Report Form, which is available on the GVSU Human Resources website (www.gvsu.edu/hro). In addition, Injury Report forms are available in all laboratories.**
 - e. 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 daily by a nurse practitioner from Monday to Friday. Nurse practitioners, registered nurses, physician assistants, or medical doctors may perform medical evaluations and obtain health histories from those that visit Health Services for care. Physicians are also available during regular business hours at the Campus Towne medical center at 10383 42nd Ave. Suite A, Allendale, Michigan 49401 or <http://www.metrohealth.net/locations/neighborhood-outpatient-centers/gvsu/> located across the street from the GVSU campus. Physicians are also available by pager or telephone call. If bites, scratches, injuries, etc, occur outside of business hours, GVSU Public Safety is notified. The affected individual will be required to complete an Injury Report Form as quickly as reasonable after their injury. Public Safety officers can make recommendations for care. If serious injuries occur, the Allendale Fire Department provides basic life support medical services to**

the Allendale campus. In addition, LIFE EMS provides ambulance service to GVSU. GVSU Public Safety (616) 331-3325 or <http://www.gvsu.edu/gvpd/> and the Allendale Fire Department (616) 895-4544 or <http://www.allendalefirerescue.com/>.

- f. **Safety with regards to chemical and biological hazards are governed by the GVSU Lab Safety and Chemical Hygiene Plan. In addition, all investigators, employees, students, or animal caretakers that could come in contact with chemicals while at work, will be required to take a course in laboratory safety administered by the GVSU Laboratory Safety Officer**
<http://www.gvsu.edu/labsafety/>.
 - g. **Protective clothing and gear will be made available to all personnel working with animals and in the cage wash area.**
 - h. **No nonhuman primates and no species larger than rabbits will be housed at current GVSU animal facilities.**
 - i. **At the current time, there are no plans to handle radioisotopes at GVSU animal facilities. All that handle radioisotopes will be required to take a course on radiation safety administered by the GVSU Radiation Safety Officer (616) 331-8628 or**
<http://www.gvsu.edu/labsafety/gvsu-safety-contacts-25.htm>.
 - j. **An Animal Care Supervisor has not yet been deemed necessary at GVSU because of the small scale of current laboratory animal use.**
 - k. **GVSU Occupational Health Program Education and Training will include information about zoonoses, chemical safety, microbiologic and physical hazards (e.g., allergens and radiation), hazards associated with experimental procedures, handling of waste materials, and personal hygiene.**
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table. (see Part X.).
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
- 1. **Training Requirements for GVSU Animal Users - The IACUC requires all personnel that conduct any research and/or teaching that involves handling, manipulating, or performing procedures on live vertebrate animals, whether in the laboratory or in the field to complete this training.**
 - a. **Investigators will seek training in the humane practice of animal care and use, and pursue additional training in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress. The IACUC makes available to all investigators, animal caretakers, students, and employees extensive resources regarding the humane practice of animal care and use and training in the humane practice of animal care and use via an**

online training program administered by the GVSU Laboratory Safety Officer.

- b. If a GVSU Animal Care Supervisor is necessary in the future, he/she will be AALAS certified at least the technician level (LAT) and seek additional training on an appropriate basis to improve their knowledge in the care and handling of the species of animals in our facilities.**
 - c. Investigators will oversee and document the training of individual animal caretakers and prospective investigators. The IACUC checks the documentation of animal caretaker training during its semiannual inspections of animal care facilities.**
 - d. Evaluation of the training program in the humane use and care of animals will be accomplished by the IACUC.**
 - e. Computerized reference sources are available through GVSU libraries (www.gvsu.edu/library) for investigators to search for the latest methods and techniques that may reduce the number of animals used. Additional information on the latest methods and techniques which may reduce the number of animals used are also made available to investigators through the GVSU IACUC website.**
 - f. 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.**
- 2. Education and Training for IACUC Members**
- a. New Member Orientation - New IACUC member orientation consists of the following: a description of the IACUC and responsibilities; U.S. Government Principles; criteria for membership; authority of the IACUC; protocol review process; monitoring of approved protocols, periodic review; protocol modifications; records; semiannual reviews; roles and responsibilities; and federal regulations. Documentation of training is maintained through the use of IACUC member files.**
 - b. IACUC members are supplied with appropriate literature (e.g., the Guide) regarding the humane practice of animal care and use. Essential documents for each IACUC member include the GVSU Assurance Letter with OLAW, GVSU IACUC Handbook of Policies and Procedures, Animal Welfare Act Regulations, Public Health Service Policy on Humane Care and Use of Laboratory Animals, Guide to the Care and Use of Laboratory Animals and Euthanasia of Research Animals: AVMA Guidelines, OLAW/ARENA IACUC Guidebook. In addition, the GVSU IACUC website contains extensive resources regarding the humane practice of animal care and use.**

- c. **The office of the GVSU IO provides funds for IACUC members to attend appropriate training, workshops, and conferences related to the humane practice of animal care and use.**

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2)—not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 - 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 - 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the IO, **Jon Jellema**.
 - 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (**January 1 – December 31**). The IACUC, through the IO, will submit an annual report to OLAW by **January 31** of each year. The annual report will include:
 - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 - 3. Any change in the IACUC membership
 - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the IO, **Jon Jellema**.
 - 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the IO, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy
 - 2. Any serious deviations from the provisions of the *Guide*
 - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.