

## **MARIAN UNIVERSITY**

### **Animal Welfare Assurance for Domestic Institutions**

I, Alan J. Silva, as named Institutional Official for animal care and use at Marian 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, NASA and/or NSF. 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:

Marian University – Indianapolis Campus (3200 Cold Spring Road, Indianapolis, Indiana)

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

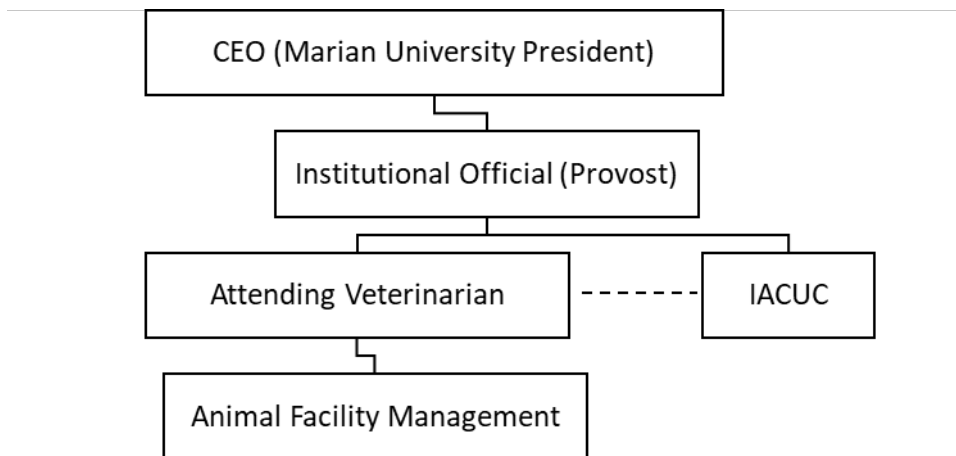
Not applicable.

#### **II. Institutional Commitment**

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution 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. This Institution 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. This Institution 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:

1) Name: Nancy Johnston, DVM, MS, DACLAM

Qualifications

- Degrees:  
DVM, MS in Comparative Medicine, Diplomate of the American College of Laboratory Animal Medicine
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  - Dr. Johnston completed her veterinary degree from University of Illinois College of Veterinary Medicine. She then was selected for a rotating Large Animal Medicine and Surgery Internship at Washington State University. After two years of private practice, she was admitted to the Comparative Medicine residency program at the University of Washington. During this 4-year program, Dr. Johnston worked with a wide variety of species and completed formal training. She is Board Certified by the American College of Laboratory Medicine. She has over 18 years of experience working for academic institutions as a laboratory animal veterinarian.

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

Time contributed to program:

Contracted for part time, approximately 2 hours per month, 100% contributed to the animal care and use program (under contract through January 1, 2023).

2) Name: Keely Szilagyi, DVM, MPH, DACLAM

Qualifications

- Degrees:  
DVM, MPH
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

- Dr. Szilagyi completed a 3-year ACLAM-recognized formal laboratory animal training program (University of Illinois-Chicago). She became an ACLAM (American College of Laboratory Animal Medicine) Diplomate in 2017 and has a total of 9 years + 9 months experience as a laboratory animal veterinarian.

Responsibility: Dr. Szilagyi serves as the backup veterinarian for Dr. Johnston and, when filling such role, has assigned responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

Part time, as needed (under contract through January 1, 2025).

- 3) Responsible individual: Dr. Jonathan Lowery, through his duties as Assistant Provost for Research & Scholarship, has responsibility for day to day oversight of the animal care and use program.
- 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:

The IACUC conducts a program review every 6 months as detailed by Animal Welfare Act regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals. All members (standing, alternate and *ex officio*) are eligible to participate in the semiannual review but, at minimum, the review must be performed by at least two standing members of the IACUC. No IACUC member (standing, alternate or *ex officio*) wishing to participate in an evaluation may be excluded from participating.

Procedure:

1. Members may be assigned to subcommittees. The subcommittees comprise of at least two (2) IACUC members. The subcommittees/members evaluate the program using the OLAW recommended checklist and the Guide, including:
  - a. The IACUC's policies, procedures and responsibility;
  - b. Training program(s);
  - c. Occupational health program;
  - d. Animal environment, housing, security, and management practices;
  - e. Veterinary medical care.
2. The subcommittee/team is provided with an opportunity to evaluate the previous inspection results.
3. Administrative details of the program review:
  - a. IACUC Chair (or her/his designee) will coordinate the Program review activities.

b. IACUC Chair (or her/his designee) will notify all IACUC members of the review schedule in accordance with AWA regulations and PHS policy, which require that all IACUC members must have the opportunity to participate.

c. The IACUC Chair (or her/his designee) will provide the subcommittee a recommended Program review checklist based on the PHS template checklist. At the end of the Program review, the IACUC subcommittee members submit their comments and checklist to the IACUC Chair (or her/his designee). The IACUC Chair (or her/his designee) will prepare a written report (including any minority views) that is compiled for review and approval by signature from a majority of voting members of the IACUC. The report must include information about the status of the program including any recommendations; a description of the nature and extent of the Institution's adherence to the Guide; any departures from the Guide, identified specifically with reasons for each departure stated; any program or facility deficiencies, distinguishing significant deficiencies (i.e., a threat to animal health or safety such as the following: failures in heating, ventilating, and air conditioning systems; inoperative water systems; general power failures of sufficient duration to affect critical areas; inadequate veterinary medical or post-surgical care of animals) from minor deficiencies, and include plans and schedules for correcting each deficiency.

d. The final report must be submitted to the IO. Failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected must be reported in writing within 15 business days by the IACUC, through the IO, to the U.S. Department of Agriculture (USDA) and any federal agency funding that activity.

- 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:

The IACUC monitors the animal care and use program by conducting thorough reviews of the program and inspections of the animal facilities at least every 6 months, utilizing the standards in the Guide as the basis for conducting its reviews. All members (standing, alternate and *ex officio*) are eligible to participate in the semiannual review but, at minimum, the review must be performed by at least two standing members of the IACUC. No IACUC member (standing, alternate or *ex officio*) wishing to participate in an evaluation may be excluded from participating.

Facility reviews are a physical inspection of all buildings, rooms, areas, enclosures and vehicles (including satellite facilities in which animals are housed for more than 12 hours) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. USDA animal welfare regulations exempt areas containing free-living wild animals in their natural habitat from inspection. While semiannual inspections of field study sites are not required, and in many circumstances are impractical, the IACUC should be apprised of the circumstances under which studies are conducted so that they can consider risks to personnel and impact on study subjects. This may be partially accomplished by written descriptions, photographs, or videos that document specified aspects of the study site. The IACUC should also ensure that appropriate permits are in place.

1. Members may be assigned to a subcommittee or volunteer to be on an inspection team. The subcommittees/teams consist of at least two (2) IACUC members. The subcommittees/teams evaluate the facilities and areas, referencing the OLAW recommended checklist and the Guide. Specifically, they evaluate:

a. Facilities, personnel, and equipment are present to provide adequate veterinary care to the animals;

- b. Cleanliness of facilities, lab areas, and equipment;
  - c. Safety of areas for personnel and evaluation of potential hazards;
  - d. Conditions of the animals;
  - e. Personnel training records;
  - f. Adherence to aseptic techniques, understanding of anesthesia monitoring and post-operative care;
  - g. Records for surgery, anesthesia, and post-operative care;
  - h. Euthanasia practices;
  - i. Storage and expiration date of pharmaceuticals, including related records;
  - j. Animal husbandry.
2. The subcommittee/team is provided with an opportunity to evaluate the previous inspection results.
3. Administrative details of the inspections:
- a. The IACUC Chair (or her/his designee) will coordinate the subcommittee/team, as described above, for the inspection and prepare a schedule before the inspection cycle begins.
  - b. The IACUC Chair (or her/his designee) will notify all IACUC members of the schedule in accordance with AWA regulations and PHS policy, which require that all IACUC members must have the opportunity to participate in inspections.
  - c. The IACUC Chair (or her/his designee) will provide the subcommittee/team an inspection checklist/form based on the PHS template checklist and a list of animal use areas (e.g. laboratories) associated with each animal facility.
- 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:

At the end of each inspection and program review, the IACUC subcommittee members submit their comments and checklist to the IACUC Chair (or her/his designee). The IACUC Chair (or her/his designee) will prepare a written report (including any minority views) that is compiled for review and approval by signature from a majority of voting members of the IACUC. The report must include information about the status of the program including any recommendations; a description of the nature and extent of the Institution's adherence to the Guide; any departures from the Guide, identified specifically with reasons for each departure stated; any program or facility deficiencies, distinguishing significant deficiencies (i.e., a threat to animal health or safety such as the following: failures in heating, ventilating, and air conditioning systems; inoperative water systems; general power failures of sufficient duration to affect critical areas; inadequate veterinary medical or post-surgical care of animals) from minor deficiencies, and include plans and schedules for correcting each deficiency.

The final report must be submitted to the IO. Failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected must be reported in writing

within 15 business days by the IACUC, through the IO, to the U.S. Department of Agriculture (USDA) and any federal agency funding that activity.

At present, none of the institution's facilities are accredited by AAALAC or another accrediting body recognized by the PHS. This accreditation status (or lack of) will be included in each semi-annual report to the IO. Should accreditation status change, we will report this via the annual report as detailed in Section VI.A.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The IACUC investigates all concerns regarding the care, treatment, and use of animals for teaching and/or research at the university. The mechanism for reporting concerns is posted in the facility.

Reporting concerns can be accomplished through using the IACUC e-mail (iacuc@marian.edu) or by contacting IACUC Chair, the Attending Veterinarian or Institutional Official (IO) or by filing an anonymous tip at [integrareport.com](http://integrareport.com) or calling 855-858-3344. The IACUC is cognizant of the rights of whistleblowers under federal law, which prohibits discrimination against or reprisal for reporting violations of regulations or standards. Marian University will not tolerate retaliation against whistleblowers for reporting potential misconduct or concerns. Marian University will keep details of investigations confidential to the maximum extent possible, consistent with resolution of the issue and in compliance with applicable laws.

The IACUC is empowered to suspend a project if it finds noncompliance with, deviation from, or goes beyond the approved protocol, organizational guidelines, PHS Policy, *Guide*, Assurance, or violations of the Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the suspension vote of a majority of the quorum present. Further, the IACUC must notify the Institutional Official (IO) regarding the reasons for the suspension. The IO must, in consultation with the IACUC, review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the U.S. Department of Agriculture (if regulated species are involved), OLAW (if PHS funds are involved), any other federal agency funding the activity, AAALAC (if applicable) and any other appropriate funding agency/agencies.

The IO and/or certain administrators including the respective dean, IACUC chair, and IACUC veterinarian may halt any animal activity for any reason without IACUC concurrence, particularly when there is concern about animal welfare. Notably, in these instances, the official is acting for the University not the IACUC. Additionally, these officials do not have the authority to approve an animal activity in the absence of IACUC approval.

#### **Procedure:**

1. In response to a report of noncompliance, the IACUC Chair or designee(s) will determine if further investigation is needed.
  - a. If needed, the IACUC Chair or designee(s) will consult with other members of the IACUC to determine if further action is needed.
  - b. If no further action is needed, the report of possible noncompliance will be placed on the agenda for the next convened meeting. This will provide an opportunity for all IACUC members to review the determination by the IACUC Chair or designee(s).
  - c. If further action is needed, the IACUC Chair or designee(s) will convene an IACUC subcommittee to investigate the reported concern.

- i. The concern or issue will be investigated by carefully reviewing the existing protocol and amendments, interviewing the principal investigator (PI) and personnel involved with the specific animals and protocol, and conducting any additional interviews and/or reviewing any additional information needed to determine whether or not a violation has occurred.
  - ii. If it is determined that noncompliance has occurred, significance of the noncompliance will be assessed. Consideration will be given to whether or not the noncompliance involves harm to or mistreatment of animals or personnel.
- d. After the investigation has been completed, the Chair or designee will develop a report for the IACUC.
  - i. The subcommittee will report the findings to the IACUC at the next meeting. IACUC members will discuss the report and based upon the subcommittee's recommendations, and in consultation with the IO, decide what action(s) to take. The recommendations may include, but are not limited to :
    - 1. requiring more frequent laboratory inspections and/or monitoring,
    - 2. requiring additional training,
    - 3. removing approval of certain individuals to use animals under a specific protocol, or
    - 4. suspending or terminating the protocol.
  - ii. The IACUC Chair or designee will communicate, in writing, the results of the IACUC evaluation of a reported concern to responsible individuals. The communication will contain:
    - 1. a summary of the concern,
    - 2. the findings of the investigation,
    - 3. determinations of the IACUC, and
    - 4. the recommended corrective actions/sanctions.
  - iii. The letter will also inform the responsible individuals of his/her option to appeal the decision by writing the IACUC Chair or designee, within 10 days of receipt of this letter. An appeal must contain details for the basis of the petition.
  - iv. Notification of the noncompliance will also be provided to external agencies, by the IO, as required by law, which may include but is not limited to OLAW, USDA, AAALAC, relevant granting agencies, and other local, state, or federal government agencies.
    - 1. If regulated species are involved in the research, then the USDA also shall be notified.
    - 2. If the noncompliance involves a Veteran's Administration PI (VA PI), the IACUC will follow the VHA handbook 1058.01 for reporting noncompliance. The reports shall include the reasons for the suspension and the corrective action(s) taken. The PI (and his/ her staff) will not be allowed to continue the research with these animals during the period of the suspension. The PI will be responsible for continued housing per diems as well as any additional animal care costs incurred as a result of the transfer.

2. The IACUC may suspend any activity if determined that the activity is not being conducted in accordance with applicable provisions.
  - a. The IACUC may suspend an activity only after review at a convened meeting of a quorum and with the vote of suspension by a majority of the quorum present.
  - b. If the IACUC suspends an activity involving animals, the Committee will review the reasons for suspension, take appropriate corrective action at a special meeting or the next scheduled meeting of the IACUC and report that action with a full explanation to OLAW, USDA, AAALAC, relevant granting agencies, and other local, state, or federal government agencies.
  - c. At any point during an investigation of possible non-compliance, if the health and welfare of animals are an immediate concern, then the Attending Veterinarian, IACUC Chair, or a designee, will be notified and assess the health status of the animals involved to ensure that animal health and welfare issues are resolved as soon as possible.
3. If the IACUC Chair or another official temporarily halts an activity involving animals, the reason for doing so will be discussed at a special meeting of the IACUC or the next scheduled meeting of a quorum of IACUC members. The IO, in consultation with the IACUC, will review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to the NIH Office for Lab Animal Welfare (OLAW), USDA and AAALAC, if applicable.
- 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:

The IACUC maintains open communication with the IO through the IACUC Chairperson. The IO is regularly cc'd on committee business and the IACUC submits formal recommendations on the animal care and use program, facilities, and personnel training through the semiannual report.

- 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:
  1. Individuals proposing activities involving vertebrate animals must complete and submit IACUC Form 1. Upon receipt, the IACUC Chair will review the information and, if necessary, consult with IACUC members or others to make an initial determination of whether the activities are 1) exempt from IACUC review (e.g., involving only invertebrate species or 2) requires regular review by the IACUC. Whenever possible, the initial determination will occur within ten business days of submission.
  2. Upon notification that a regular IACUC review is required, the investigator(s) is/are expected to consult with the IACUC veterinarian in the development of any protocol that may cause more than momentary or slight pain or distress (i.e., USDA category D or E). Upon submission, the IACUC Chair will perform an administrative review and any questions raised during this review are resolved with the PI. The protocol is subsequently submitted to the IACUC members for review via either the Designated Member Review (DMR) or Full Committee Review (FCR).
  3. The IACUC may invite consultants, internal or external, to assist in its duties in the performance of protocol review. Such consultants cannot vote, but can provide their professional opinion.

4. In the event that the Attending Veterinarian has a conflict of interest, the Backup Veterinarian will review any proposed protocol, amendment or continuing review. If both the Attending Veterinarian and Backup Veterinarian have conflicts of interest, the IACUC will obtain consultation by a veterinarian with appropriate qualifications to review the proposed protocol, amendment, or continuing review.
  - a. Ad-hoc reviewers cannot vote on a protocol unless they are appointed to the IACUC by the Institutional Official.
5. Any member of the IACUC (standing, alternate or *ex officio*) can request for an outside scientific merit review.
6. The IACUC must coordinate the review and approval of protocols with the appropriate safety committee. To that end, PIs must include prior approval notification from the Institutional Biosafety Committee with proposed animal use protocols when appropriate. Other approvals from Institutional entities may be required.
7. By default, the IACUC uses the designated member review (DMR) process, but any IACUC member (standing, alternate or *ex officio*) has the option to call for a full committee review.
8. A quorum of the IACUC is required for full committee reviews of protocols, suspension of an activity, approval of exemptions to federal guidelines due to unusual circumstances, and to approve policies or guidelines. Convened IACUC protocol reviews can only be approved if a quorum is present and more than 50% of the quorum votes in favor.
9. Federal regulations do not permit an IACUC member to participate in the review of research in which he/she has a conflicting interest, except to provide information requested by the IACUC. This requirement helps to ensure that financial or other personal interests do not compromise the welfare of animals used in research or the objectivity of the IACUC review process.

A conflict of interest is a financial interest or other opportunity for tangible personal benefit of an individual or his/her immediate family (spouse, domestic partner, or dependent children) that may exert a substantial and improper influence on the individual's professional judgment in exercising any University duty or responsibility, including the review of research. Conflicts of interest may also be non-financial, such as when an IACUC member is asked to review research in which he/she is also participating as a member of the research team. Other "personal or professional" conflicting interests include any of the following:

- IACUC member (or member of his/her immediate family) is a member of the research team or advisory committee involved in the design, conduct, or reporting of the research
- IACUC member (or member of his/her immediate family) is related to a member of the research team or advisory committee involved in the design, conduct, or reporting of the research
- Other conflicting interest that appears to preclude objective assessment, at the IACUC Chairperson's discretion. Examples may include:
  - Principal investigator of the research is the IACUC member's immediate supervisor or the supervisor of the member's immediate family member
  - IACUC member (or member of his/her immediate family) has an interest in competing research or is competing directly for resources such as funding or sponsorship
  - IACUC member personal biases may interfere with an impartial judgement. A Principal Investigator (PI) submitting a protocol may

- request that a member be excluded from review if the PI believes the IACUC member has a potential conflict.
- o Departmental or unit affiliation is not automatically considered to be a conflicting interest, except as described above. Veterinary consultation is not considered a conflicting interest.
- a. When a conflict of interest is identified or disclosed, an IACUC member may not participate in any type of review of the research conducted by the IACUC, including initial or continuing reviews, review of amendments, or other reviews (e.g., event reports, potential noncompliance). This requirement applies to reviews conducted by the convened IACUC and those performed by designated member procedures. Any member with an identified conflict of interest at a convened meeting will be asked to leave the room during the discussion and voting, unless asked to be present to answer questions or provide information to the IACUC.
- b. The IACUC secretary (or his/her stand-in if conflicted) is responsible for documenting that an IACUC member did not participate in the convened review of research in which the member had a conflicting interest. IACUC minutes will record when the member left the room, with the reason noted as being because of a "conflict of interest." IACUC members out of the room due to a conflict of interest are not counted toward quorum for that item. The IACUC chairperson (or his/her stand-in – e.g., IACUC Vice-Chair – if conflicted) is responsible for monitoring IACUC meeting attendance to ensure that quorum is maintained. If quorum is not maintained for the item, no official votes may occur and the item must be taken up at a later time.
- c. If an alternate member is present for the standing member with the conflict, that person can vote and be counted toward the meeting quorum for that review item only.

#### 10. Designate Member Review (DMR)

- a. IACUC members are notified of all protocol submissions; notifications will include at least the PI name, title of the protocol, and the purpose of the proposed activities as stated within the protocol. The full protocol will be available to all members via the IACUC Canvas course.
- b. Individual IACUC members are provided with the option to either request a full committee review or allow the protocol to be reviewed by a DMR. Members must request full committee review within four business days; the IACUC may consider the lack of member replies within this prescribed time period as no requests for full review. If any member of the IACUC notifies the IACUC Chair of a request for full committee review (FCR), the protocol is then reviewed at the next IACUC meeting or a special meeting called within one month of submission for the review. If any member requests FCR, if appropriate, any questions or comments that had been submitted about the protocol will be forwarded to the PI to provide an opportunity for him/her to provide answers or clarification prior to the convened meeting.
- c. The IACUC Chair will designate at least one (1) member of the IACUC qualified to conduct the DMR. The assigned reviewer(s) shall review the proposed protocol and have the authority to approve, require modifications (to secure approval) or request FCR of assigned protocols.
  - a. DMRs may ask questions of and/or seek additional information from the PI in order to adequately review the protocol.

- b. If a member does not request FCR of a protocol, that member may submit questions and/or comments for consideration by the DMR(s) during the review process.
  - c. The DMRs will review identical information relating to the protocol, including additional information provided by the PI and/or any modifications to the original protocol.
  - d. Approval of a protocol required unanimous approval by all DMRs. In the event that DMRs are unable to reach unanimous agreement, the protocol will be reviewed by FCR.
- d. Following approval by DMR
- i. The IACUC considers the date of approval as the date on which the final reviewer approved the protocol and all additional IACUC requirements (e.g., personnel training, biosafety clearance, etc.) have been met.
  - ii. Protocol approval is granted for a period up to three (3) years with instructions that any changes must be submitted, before the change is implemented, for review via the amendment process.

#### 11. Full Committee Review (FCR)

- a. If full committee review (FCR) of the protocol is requested, approval of those protocols may be granted only after completion of the review at a convened quorum of the IACUC and with the approval vote of the majority present. Either a special meeting is called to review the protocol or the protocol is placed on the agenda for review at the next regularly scheduled meeting.

The committee may vote to adopt any one of the following categories of action for the outcome of a FCR.

- i. Approval: A protocol will be approved only when the PI has satisfactorily addressed all significant points and potential concerns. Granting approval means that the PI has permission to conduct the project that was described, with the number of animals that was indicated in the protocol.
- ii. Require Modifications: This action will be taken when the IACUC deems that specific aspects of the protocol may be problematic or vague, requiring further explanation, justification, documentation, or information. The revised protocol will be reviewed via FCR at a subsequent convened meeting of the IACUC with a quorum present (as detailed above). This process will be repeated until the PI's response satisfies the conditions previously set forth by the Committee.
- iii. Table: The IACUC may decide to defer action on, or table, a protocol until a later date. The reason for deferring action usually involves having insufficient information upon which to make a judgment about the protocol. A protocol may be deferred until the information needed by the committee is available. The review may continue at a regularly scheduled meeting or at a special meeting held via teleconferencing as per the "Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals" - Notice Number: NOT-OD-06-052.
- iv. Withhold Approval/Disapproval: At a convened quorum of the IACUC, members may vote to disapprove a protocol application. To appeal a decision to disapprove, the PI must present the IACUC with additional, pertinent evidence or expert opinions. This presentation shall be made by the PI, in writing or in person, at a convened meeting of the IACUC

where a quorum of the voting members is present. The intention to appeal must be announced no less than ten (10) calendar days prior to the IACUC meeting.

- b. Following approval by Full Committee Review (FCR), the IACUC considers the date of approval the date that appears in the notification (e-mail) of approval to the principal investigator.
  - c. Protocol approval is granted for a period of up to three (3) years with instructions that any changes must be submitted, before the change is implemented, for review via the amendment process.
- 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:

The process by which proposed changes to ongoing protocols are considered is described in an IACUC approved policy. The text is copied below.

The IACUC must review modifications to a protocol that have animal welfare implications before any change is implemented. The federal regulations give the IACUC authority to determine which changes are considered significant and how the IACUC will evaluate changes to the protocol. Modifications to protocols are submitted through amendments and are processed via administrative review (if eligible, see conditions below) or regular review involving Designated Member Review (DMR) or Full Committee Review (FCR). The PI must submit the amendment to the IACUC.

Procedure:

- 1. Upon receipt, the IACUC Chair will make an initial determination of whether the proposed modification is eligible for administrative review or requires regular review by DMR or FCR amendment. The process for each is detailed below.
- 2. Administrative Review
  - a. Consistent with PHS Policy IV.D.1.a, the IACUC has an approved policy allowing the IACUC Chair authority to approve each of the following types of changes without additional input by the IACUC.
    - i. Changes in title of protocol;
    - ii. Change in funding source;
    - iii. Addition of a qualified investigator or collaborator
    - iv. Small increase (less than or equal to 10%) in the number of animals used;
      - 1. In making her/his determination, the IACUC Chair must address whether the requested change is in keeping with the original rationale for the number of animals approved; take into consideration if there is a change in study objectives; and take into consideration if the change may result in a negative impact on animal welfare.
    - v. Change in animal use area provided that the area has been approved by the IACUC.
- 3. Regular Review
  - a. According to PHS Policy IV.C.1., significant changes must be approved by one of the valid IACUC approval methods (DMR or FCR). Significant

changes include changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some activities that may not have a direct impact on animal welfare are also considered to be significant.

- b. Any proposed change that is not eligible for administrative review as detailed above will be reviewed by DMR or FCR [according to the process described above in III.D.6]. Additionally, the following categories of amendments are explicitly mentioned by OLAW guidance (<https://olaw.nih.gov/guidance/significant-changes.htm>) as requiring approval DMR or FCR:
    - i. change from non-survival to survival surgery;
    - ii. changes resulting in greater pain, distress, or degree of invasiveness;
    - iii. change in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
    - iv. change in species;
    - v. change in study objectives;
    - vi. change in Principal Investigator (PI); and
    - vii. changes that impact personnel safety.
- 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:

#### Notifications of Approval, Withhold approval, or Modifications required

- a. The IACUC Chair shall notify investigators in writing, via e-mail, of its decision to approve, withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval.
  - b. The IACUC Chair will communicate the concerns submitted by the reviewers to the PI via email. The PI responds to the IACUC's concerns in writing. The PI has the opportunity to revise the protocol per the recommendations of the IACUC or provide further justification or information on why the procedures should be performed as originally described. The IACUC members assigned to review the protocol (DMRs) will review the PI's response to ensure that all of the IACUC's concerns were adequately addressed. This procedure is in accordance with the DMR review process.
  - c. Approval to conduct the activities described in the protocol will be withheld until the PI's satisfies the conditions previously set forth by the IACUC. If all IACUC members assigned to the review reach a consensus to approve, then the protocol will be approved. In cases where consensus between the IACUC members cannot be obtained, an evaluation of the response and the decision to approve/withhold approval will be determined by a majority vote at the next IACUC meeting.
  - d. If necessary, the IACUC will ask the PI to attend the next meeting of the IACUC to discuss and try to resolve the concerns of the IACUC members.
- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy, 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:

Protocols are approved for a maximum of three years, at which time the protocol must undergo complete review as a new protocol by DMR (default) or FCR via the processes detailed above (Part III.D.6).

Continuing protocol review consists of an annual update.

1. The IACUC must receive an annual report on each current protocol. The annual report is reviewed by the Designated Member Review (DMR) process. At any time during the DMR, the annual review may be moved to Full Committee Review (FCR).
  2. The annual report is due by the anniversary date of the protocol's approval and may be received as early as thirty days prior to that date. Current protocols that are not supported by annual report are subject to disqualification at the discretion of a majority vote of the IACUC.
  3. Failure to adhere to scheduled reporting or deviance from protocol must be reported by the IACUC within 15 days of the failure to any agency from which the protocol is receiving funding.
  4. Any changes in personnel or substantive change in procedures may not be made through the annual report and must be communicated via a protocol addendum and approved by the IACUC prior to implementation.
- 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:

The IACUC is empowered to suspend a project if it finds noncompliance with, deviation from, or goes beyond the approved protocol, organizational guidelines, PHS Policy, Guide, Assurance, or violations of the Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the suspension vote of a majority of the quorum present. Further, the IACUC must notify the Institutional Official (IO) regarding the reasons for the suspension. The IO must, in consultation with the IACUC, review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the U.S. Department of Agriculture (if regulated species are involved), OLAW (if PHS funds are involved), any other federal agency funding the activity, AAALAC (if applicable) and any other appropriate funding agency/agencies.

Procedure:

1. In response to a report of noncompliance, the IACUC Chair or designee(s) will determine if further investigation is needed.
  - a. If needed, the IACUC Chair or designee(s) will consult with other members of the IACUC to determine if further action is needed.
  - b. If no further action is needed, the report of possible noncompliance will be placed on the agenda for the next convened meeting. This will provide an opportunity for all IACUC members to review the determination by the IACUC Chair or designee(s).
  - c. If further action is needed, the IACUC Chair or designee(s) will convene an IACUC subcommittee to investigate the reported concern.
    - i. The concern or issue will be investigated by carefully reviewing the existing protocol and amendments, interviewing the principal investigator (PI) and personnel involved with the specific animals and protocol, and conducting any additional interviews and/or reviewing any additional information needed to determine whether or not a violation has occurred.
    - ii. If it is determined that noncompliance has occurred, significance of the noncompliance will be assessed. Consideration will be given to whether or not the noncompliance involves harm to or mistreatment of animals or personnel.

- d. After the investigation has been completed, the Chair or designee will develop a report for the IACUC.
- i. The subcommittee will report the findings to the IACUC at the next meeting. IACUC members will discuss the report and based upon the subcommittee's recommendations, and in consultation with the IO, decide what action(s) to take. The recommendations may include, but are not limited to :
1. requiring more frequent laboratory inspections and/or monitoring,
  2. requiring additional training,
  3. removing approval of certain individuals to use animals under a specific protocol, or
  4. suspending or terminating the protocol.
- ii. The IACUC Chair or designee will communicate, in writing, the results of the IACUC evaluation of a reported concern to responsible individuals. The communication will contain:
1. a summary of the concern,
  2. the findings of the investigation,
  3. determinations of the IACUC, and
  4. the recommended corrective actions/sanctions.
- iii. The letter will also inform the responsible individuals of his/her option to appeal the decision by writing the IACUC Chair or designee, within 10 days of receipt of this letter. An appeal must contain details for the basis of the petition.
- iv. Notification of the noncompliance will also be provided to external agencies, by the IO, as required by law, which may include but is not limited to OLAW, USDA, AAALAC, relevant granting agencies, and other local, state, or federal government agencies.
1. If regulated species are involved in the research, then the USDA also shall be notified.
  2. If the noncompliance involves a Veteran's Administration PI (VA PI), the IACUC will follow the VHA handbook 1058.01 for reporting noncompliance. The reports shall include the reasons for the suspension and the corrective action(s) taken. The PI (and his/ her staff) will not be allowed to continue the research with these animals during the period of the suspension. The PI will be responsible for continued housing per diems as well as any additional animal care costs incurred as a result of the transfer.
2. The IACUC may suspend any activity if determined that the activity is not being conducted in accordance with applicable provisions.
- a. The IACUC may suspend an activity only after review at a convened meeting of a quorum and with the vote of suspension by a majority of the quorum present.
  - b. If the IACUC suspends an activity involving animals, the Committee will review the reasons for suspension, take appropriate corrective action at a special meeting or the next scheduled meeting of the IACUC and report that action with a full explanation to OLAW, USDA, AAALAC, relevant granting agencies, and other local, state, or federal government agencies.
  - c. At any point during an investigation of possible non-compliance, if the health and welfare of animals are an immediate concern, then the Attending Veterinarian, IACUC Chair, or a designee, will be notified and assess the health status of the animals involved to ensure that animal health and welfare issues are resolved as soon as possible.
3. If the IACUC Chair or another official temporarily halts an activity involving animals, the reason for doing so will be discussed at a special meeting of the IACUC or the next scheduled meeting of a quorum of IACUC members. The IO, in consultation with the IACUC, will review the reasons for the suspension, take appropriate corrective action, and report that action

with a full explanation to the NIH Office for Lab Animal Welfare (OLAW), USDA and AAALAC, if applicable.

- 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:

MU IACUC Policy 13 describes the occupational safety and health program for the Marian University IACUC and the process by which members of the Marian University community 1) report and seek assistance with an occupational safety incident related to use of vertebrate animals in teaching and/or research and 2) practices to reduce the risk of zoonotic disease.

- a. The occupational safety and health planning/monitoring for the Marian University IACUC is provided by James Pike, DO, who is contracted with Marian University for this service through January 2025.
- b. The program is based on risk assessment and hazard identification.
- c. The occupational safety and health program encompasses all personnel that have contact with animals.
- d. Training in zoonoses, allergies, and hazards is provided by for all persons involved in animal care and/or handling through informational handouts and mandatory virtual training through the CITI Program.
- e. Information related to pregnancy, illness, or decreased immunocompetence is provided during the pre-placement medical evaluation by the medical staff. It is also discussed in an information handout that is provided to all persons involved in animal care and/or handling.
- f. The IACUC's occupational safety and health program covers all persons who have contact with animals (regardless of position within the University and thus inclusive of maintenance, police and safety, security, and housekeeping staff). Occupational safety and health for persons not involved in animal care or handling is provided through the Office of Human Resources, the Marian University Laboratory Safety Committee, the Institutional Biosafety Committee and/or the Chemical Hygiene Officer.
- g. As detailed in the Marian University Employee Handbook, workplace-related injuries (including as those related to animal care/handling) are addressed through contacting Campus Safety, who is available 24 hours per day and coordinates appropriate care based on the severity of situation. This may include treatment by the first responder, escorting the affected person to the Student Health Center or, if necessary, transporting them to a nearby medical facility. This information is summarized in a form that is posted in the animal facility. As per state law and university policy, all injuries (regardless of severity) must be reported to Human Resources within 24 hours of the incident. The incident must also be reported to the IACUC Chairperson within 24 hours.

The IACUC occupational safety and health policy reads as follows:

Federal requirements mandate that each institution must establish and maintain an occupational safety and health program as an essential part of the overall animal care and use program. This policy encompasses all personnel that have contact with animals and should be tailored to the specific facility, activities, hazard and animal species involved. The program includes each of the following components, which are required by federal policy:

- pre-placement medical evaluation;
- identification of hazards to personnel and safeguards appropriate to the risks associated

- with the hazards;
- appropriate testing and vaccinations;
- training of personnel regarding their duties, any hazards, and necessary safeguards;
- policies and facilities that promote cleanliness;
- provisions for treating and documenting job-related injuries and illnesses;
- facilities, equipment, and procedures designed, selected, and developed to reduce the possibility of physical injury or health risk to personnel;
- good personal hygiene practices, prohibiting eating and drinking, use of tobacco products, and application of cosmetics and/or contact lenses in animal rooms and laboratories; and
- personal protective equipment (PPE).

### **Procedure:**

1. Medical clearance and requirements for participating in research/teaching involving animals:
  - a. Pre-placement medical evaluation: Every person involved in activities under the oversight of the Marian University IACUC must receive approval from medical staff (based on medical evaluation and evaluation of health history including information on date of most recent tetanus vaccination, current/previous medical problems, and allergies) prior to engaging in said activities. This evaluation is performed at no cost to the animal user by the Student Health Center and the required form is attached to the policy as an appendix.
    - i. All persons involved in activities under the oversight of the Marian University IACUC must receive the occupational safety and health brochure, which contains information on zoonoses, allergies, potentially hazardous agents, and special considerations for pregnant women and those with compromised immune systems.
    - ii. Pre-employment or pre-exposure serum collection is advisable only in specific circumstances as determined by the pre-placement evaluation.
    - iii. Vaccinations:
      - i. Tetanus: Everyone who has animal contact must be vaccinated for tetanus within the past 10 years. Evidence of tetanus booster within the last 10 years is required for all individuals who have recurrent animal contact. This is based upon the recommendation of the US Department of Health and Human Services and the American Association for Laboratory Animal Science. All persons (faculty, staff, student, etc.) involved in animal care may obtain this vaccination – at no cost to the animal user – through the Student Health Center.
      - ii. Rabies: Anyone with exposure to unvaccinated dogs/cats, carnivores or rabies-suspect species must be vaccinated for rabies.
      - iii. Other infectious diseases: Vaccination is recommended if research/teaching is to be performed on infectious diseases for which effective vaccines are available.
      - iv. Exemptions: Valid exemptions for the required tetanus vaccination or other vaccinations recommended by medical staff may be granted for medical and/or religious reasons. For medical exemptions, when submitting the medical evaluation form, the animal user must provide a letter from a physician stating the reason for the exemption and whether it is temporary or permanent. For religious exemptions, when submitting the medical evaluation form, the animal user must provide a letter signed by the minister, priest, rabbi, or head of church.
      - v. Allergies: If you work with animals, you have the potential of becoming allergic to them. Additional information on allergies is provided to the animal user in an appendix.

2. Biological, chemical, and environmental hazards:
  - a. Laboratory safety related to biological, chemical, and environmental hazards is governed by the Marian University Laboratory Safety Committee and the Institutional Biosafety Committee. All participants in IACUC protocols must adhere to the policies of those respective committees, which relate to hazards to personnel and safeguards appropriate to the risks associated with the hazards; training of personnel regarding their duties, any hazards, and necessary safeguards; and policies and facilities that promote cleanliness.
  - b. All personnel involved in the care and use of animals are trained on the IACUC function, the ethics of animal care and use, methods for reporting concerns, and pertinent occupational health and safety issues. Following recommendations in the Guide, the training program requirements for personnel are based on the type of animal, degree of exposure, and required animal care and use procedures. This includes any specialized training required for handling hazardous materials.
  - c. Proper personal hygiene, personal protective equipment (PPE), and care of scratches and bites are paramount in the prevention of zoonoses (see below).
  - d. All injuries, allergic reactions, and medical care occurring due to contact with these animals must be reported to the IACUC Chairperson.
3. Zoonoses: Transmission of zoonotic diseases from animals is primarily by direct contact, indirect contact with insect vectors and contaminated inanimate objects, oral ingestion or inhalation of aerosolized materials. We can protect ourselves from most diseases by using the following basic hygiene procedures:
  - a. Do not eat, drink, apply cosmetics or use tobacco products while handling animals or in animal housing areas.
  - b. Wear eye and respiratory protection when appropriate.
  - c. Handle animals safely to prevent bites or scratches. Thoroughly wash any wounds and report injuries.
  - d. Wear gloves and/or protective sleeves when handling contaminated water, animals, animal tissues, body fluids and waste, and wash hands after contact.
  - e. Wear dedicated protective clothing such as a laboratory coat, coveralls or apron when handling animals. Launder the soiled clothing separate from your personal clothes and preferably at the animal facility.
  - f. Cover abraded skin, cuts, scrapes or sores and do not allow wound contact with animals, animal contaminated materials or aquarium water. Persons with infected wounds indicated by swelling, redness, pain and draining fluids with or without a fever should seek medical treatment.
  - g. Keep animal areas clean and disinfect equipment after using it on animals or in animal areas. Use cleaning techniques that do not aerosolize contaminated water or other materials.

Most importantly, familiarize yourself about the animals that you will be working with and the potential zoonotic diseases associated with each species; specific guidance related to zoonoses from reptiles/amphibians may be found in an appendix provided to all animal users. If at any time, you suspect that you have acquired a zoonotic disease, inform your supervisor and the IACUC Chairperson and seek medical care.

- 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.

Please see the attached 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:

This policy describes the training requirements for persons involved in animal use protocols. The IACUC utilizes CITI for online training modules and the courses/modules detailed below are available through that website. The effectiveness of this training is evaluated by the completion of mandatory quizzes associated with courses/modules, on which the user must score at least 80% correct.

**Procedure:**

1. The following training courses/modules are required for **all persons** involved in animal use protocols (i.e., "Learner Group 1"), with a score of at least 80% on the associated quizzes.
  - a. Working with the IACUC
    - i. Required Modules:
      1. Working with the IACUC: Introduction
      2. About the IACUC
      3. Federal Laws, Policies, and Guidelines
      4. Planning Research and Completing the Protocol Form
        - a. This module includes information required by PHS policy related to training or instruction on research or testing methods that minimize the number of animals required to obtain valid results and minimize distress. This module is required for all scientists, animal technicians, and other personnel involved in animal care, treatment, or use including IACUC members.
      5. Procedures: Surgery, Antibody Production, and Blood Collection
      6. Personnel and Their Welfare
      7. Special Animal Welfare Considerations
      8. Making Changes to an Approved Animal Use Protocol
      9. Reporting Animal Use Concerns
    - ii. The initial training is valid for a period of three years, at which time the member must complete the Working with the IACUC - Refresher Course and score of at least 80% on the associated quizzes. The refresher training is valid for a period of three years, at which time the member must complete the refresher course every three years.
2. Additionally, investigators working with **wild vertebrate animals** (i.e., as per the USDA, "any animal which is now or historically has been found in the wild, or in the wild state, within the boundaries of the United States, its territories, or possessions. This term includes, but is not limited to, animals such as: deer, skunk, opossum, raccoon, mink, armadillo, coyote, squirrel, fox, wolf, etc.") must complete the Researchers Working with Wildlife course, with a score of at least 80% on the associated quizzes. The initial training is valid for a period of three years, at which time the member must complete the refresher course and score of at least 80% on the associated quizzes. The refresher training is valid for a period of three years, at which time the member must complete the refresher course every three years.
3. Additionally, investigators working with **mice or rats** must complete the Researchers Working with Mice or Rats course, with a score of at least 80% on the associated quizzes. The initial training is valid for a period of three years, at which time the member must complete the refresher course and score of at least 80% on the associated quizzes. The refresher training is valid for a period of three years, at which time the member must complete the refresher course every three years.
4. Additionally, investigators working with **any of the following species and/or groups** must complete the respective course/module below, with a score of at

least 80% on the associated quizzes. The initial training is valid for a period of three years and must be renewed upon expiration.

- a. Researchers Working with Amphibians
- b. Researchers Working with Cats
- c. Researchers Working with Cattle
- d. Researchers Working with Dogs
- e. Researchers Working with Ferrets
- f. Researchers Working with Fish
- g. Researchers Working with Genetically Modified Mice
- h. Researchers Working with Gerbils
- i. Researchers Working with Guinea Pigs
- j. Researchers Working with Hamsters
- k. Researchers Working with Horses
- l. Researchers Working with Non-Human Primates
- m. Researchers Working with Rabbits
- n. Researchers Working with Reptiles
- o. Researchers Working with Sheep and Goats
- p. Researchers Working with Swine
- q. Researchers Working with Zebrafish (*Danio rerio*)

#### **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 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) was received and reviewed.

#### **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 Institutional Official, Alan J. Silva.
  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 federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 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 Institutional Official, Alan J. Silva.
  5. Any minority views filed by members of the IACUC

*[Note: if there are no changes to report, provide written notification that there are no changes.]*

For further guidance on the OLAW Annual Report update, please refer to the following websites <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-109.html> and <https://olaw.nih.gov/resources/documents/annual-report.htm>.

- B. The IACUC, through the Institutional Official, 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.

## VII. Institutional Endorsement and PHS Approval

<b>A. Authorized Institutional Official</b>	
Name: Alan J. Silva	
Title: Executive Vice President & Provost	
Name of Institution: Marian University	
Address:  3200 Cold Spring Road Indianapolis, Indiana, USA, 46222	
Phone: 317-955-6010	Fax: 317-955-6010
E-mail: ajsilva@marian.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 5/20/2022
<b>B. PHS Approving Official</b> <i>(to be completed by OLAW)</i>	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Signature:	Date: 6/24/2022
Assurance Number: D21-01122	
Effective Date: 6/24/2022	Expiration Date: 6/30/2026

## VIII. Membership of the IACUC

Date: October 1, 2021			
Name of Institution: Marian University			
Assurance Number:			
<b>IACUC Chairperson</b>			
Name*: Jonathan W. Lowery			
Title*: Assistant Provost for Research & Scholarship, Associate Professor of Physiology			Degree/Credentials*: PhD
Address:  3200 Cold Spring Road, EC317E Indianapolis, Indiana 46222			
E-mail*: <a href="mailto:jlowery@marian.edu">jlowery@marian.edu</a>			
Phone*: 317-955-6621		Fax*: 317-955-6621	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Jonathan Lowery	PhD	Assistant Provost for Research & Scholarship and Associate Professor of Physiology	Scientist
Nancy Johnston	DVM	Attending Veterinarian	Veterinarian
Keely Szilagyi	DVM	Backup Veterinarian	Veterinarian
Julia Hum	PhD	Assistant Professor of Physiology & Pharmacology	Scientist
Loren Bertocci	PhD	Professor of Biochemistry	Scientist - Alternate
Matthew Sherman	PhD	Semler Chair for Applied Ethics	Nonscientist
Laura Cummings	MS	Science Department Chair, Indianapolis Classical Schools	Nonaffiliated* not a former or current lab animal user
Allyson Bradford	MSW	Medical Social Worker, Roudebush VA Medical Center	Nonaffiliated* not a former or current lab animal user - Alternate

## IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

<b>Contact #1</b>	
Name: N/A	
Title:	
Phone:	E-mail:
<b>Contact #2</b>	
Name:	
Title:	
Phone:	E-mail:

## X. Facility and Species Inventory

[illegible]

\*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.