

ANIMAL WELFARE ASSURANCE #A3481-01

MARQUETTE UNIVERSITY ASSURANCE OF COMPLIANCE WITH PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

Marquette University, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY

This assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

“Institution” includes the following branches and major components of Marquette University: College of Arts and Sciences, School of Dentistry, College of Engineering, College of Health Sciences, and College of Nursing.

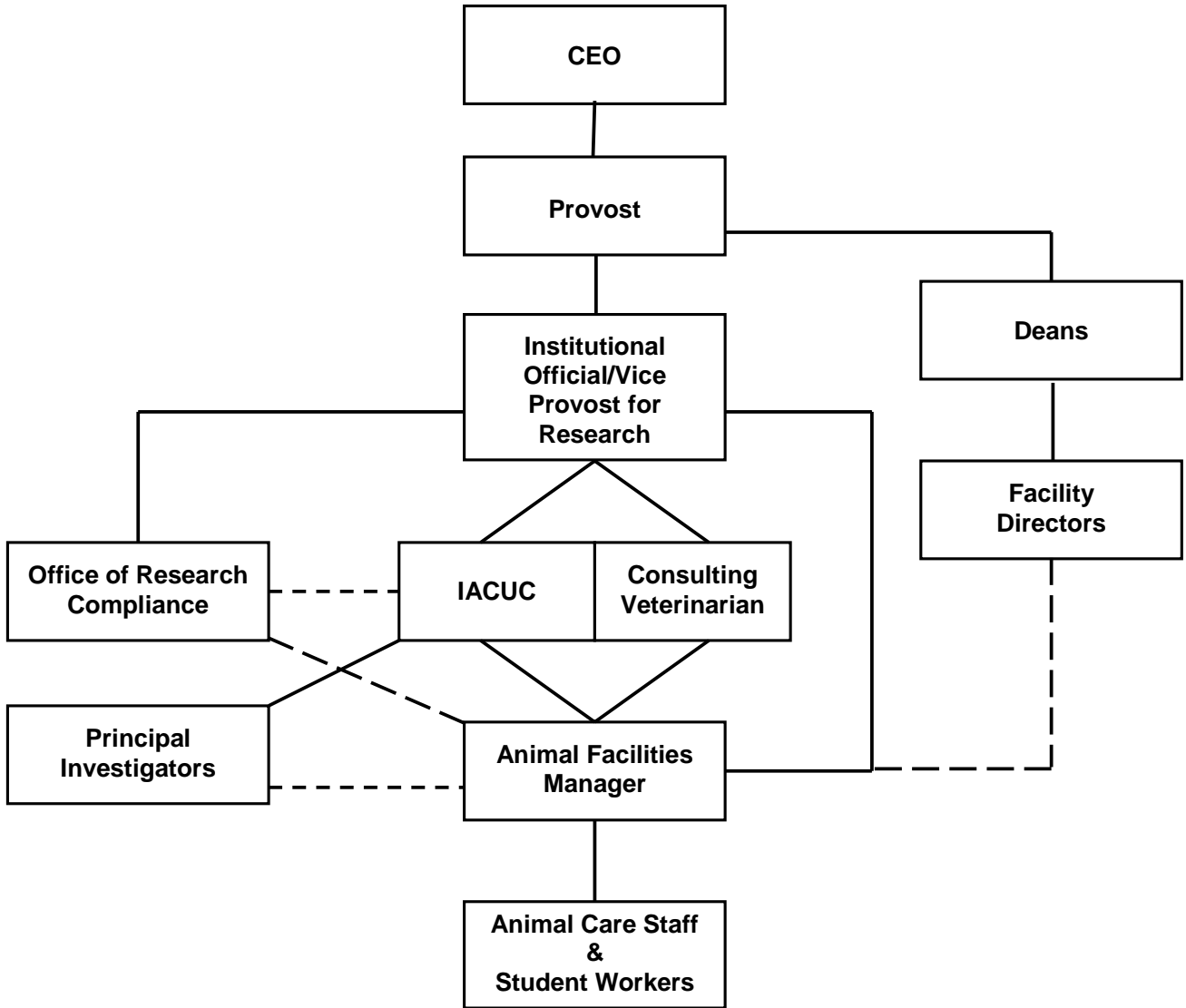
II. INSTITUTIONAL POLICY

- 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 make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as 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 in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are:



B. The qualifications, authority, and percent time contributed by the veterinarian who will participate in the program:

Dr. Beryl R. Forman is the Consulting Veterinarian. Dr. Forman is a licensed veterinarian (DVM), has a teaching certification in Broadfield Science, Biology, and Chemistry, and has twenty years of experience in laboratory animal medicine.

Dr. Forman monitors the health of the animals and the overall Animal Care at Marquette to ensure compliance with appropriate regulations. She spends approximately 10% of her time on the institution's animal care and use program. She conducts unannounced weekly inspections of the animal facilities, attends the monthly IACUC meetings, participates in semiannual facility inspections, and is available for consultation as needed. In addition to conducting inspections, she is called when medical intervention is deemed necessary by the Animal Facilities Manager. Dr. Forman ensures that animals having diseases are immediately isolated if required, the Animal Facilities Manager and Principal Investigator are notified, the animals are treated or euthanized unless the investigator has scientifically valid objections, and quarantine is maintained if required, while treatment measures are underway. Dr. Forman serves as a central resource person for information regarding use of controlled substances in animals. Dr. Forman also is available to provide specialized education and training programs for Principal Investigators and their staff.

Dr. Forman attends national and local veterinary and laboratory animal science meetings for continuing education, including national AALAS and local SWAALAS meetings. She is a member of ASLAP and LAMA.

Dr. Forman is an integral part of the Animal Care and Use Program at the institution. Her program authority encompasses direction of the facility management and animal welfare as a whole. She shares the responsibility of implementing the PHS Policy and recommendations of the Guide with the IACUC, the Animal Facilities Manager, and the Director of Research Compliance.

When Dr. Forman is out of town, contact information has been provided for her home phone and cell phone. Dr. Forman has also provided the institution with contact information for other laboratory animal veterinarians at other institutions in the area. In addition, a formal back-up arrangement has been established with local veterinarian James Henderson, Jr., DVM, who is also trained in laboratory animal medicine.

- C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS policy at IV.A.3.b. Attached is a list of the names, degrees, position titles, specialties, and institutional affiliations of the IACUC chairperson and members.
- D. The IACUC will:

1. Review at least once every six 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 evaluations require that two program evaluations be conducted, one at the end of the second quarter and one at the end of the fourth quarter of each year. The institution uses the OLAW Sample Semiannual Program and Facility Review Checklist as a guide for each review.
2. Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC's procedures for conducting semiannual facility inspections require that Semiannual Facility Reviews be conducted in the middle of the second quarter and in the middle of the fourth quarter each year. The institution uses the OLAW Sample Semiannual Program and Facility Review Checklist as a guide for each review. Facility inspections must be conducted by a minimum of two IACUC members for each facility.
3. Prepare reports of the IACUC evaluations as set forth in the PHS policy at IV.B.3. and submit the reports to William Wiener, Ph.D., Vice Provost for Research, Dean of the Graduate School, and Institutional Official. The IACUC process for developing reports and submitting them to the Institutional Official requires that the Office of Research Compliance, which provides all administrative support to the IACUC, compile the reports based on the OLAW sample format, submit the reports to the IACUC Chair for his/her approval and signature, and following this approval, the report is submitted to the Institutional Official.
4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are such that anyone from the public, facility personnel, or those using animals may report concerns regarding animal care or use. Reports of concern should be directed to either the ORC or the IACUC. The ORC and the IACUC will investigate the concern(s) and, if needed, action will be taken by the ORC and the IACUC to address the concern(s). A report of the original concern, the investigation, and the actions taken will be submitted to the Institutional Official. The Institutional Official will report any significant, ongoing non-compliance activity to PHS, APHIS (if applicable), and any federal agency funding the activity.
5. Make written recommendations to William Wiener, Ph.D., Vice Provost for Research, Dean of the Graduate School, and 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 that the IACUC will discuss recommendations in convened meetings and a written recommendation from the IACUC Chair will be forwarded to the Institutional Official.
6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in

the PHS policy at IV.C. The ORC assigns a protocol number to each new protocol, and the protocol is reviewed at the next scheduled meeting by a quorum of the IACUC. All IACUC members will receive a copy of the protocol prior to the meeting. A primary reviewer will be assigned to each protocol and will be responsible for presenting the protocol at the IACUC meeting. Prior to the meeting, the primary reviewer may contact the Principal Investigator to seek clarification and have questions answered regarding the protocol. The Principal Investigator is encouraged to attend the meeting, but will leave the room for any vote regarding the protocol. Upon completion of review of the protocol at the IACUC meeting, there will be a motion to approve, require modifications to, table, or disapprove. IACUC approval may be contingent upon receipt of specific modifications or clarifications. When contingent approval is granted, changes are handled administratively and verified by an assigned member of the IACUC, usually the IACUC Chair. A majority of the convened quorum voting in favor of the motion will pass the motion. Protocols will be approved for one year beginning with the date of approval. Annual review will occur at the end of the 1st and 2nd years. At the end of the third year, a new full protocol must be submitted. No study may begin before approval is granted. The following are examples of issues that will be considered in review: 1) rationale and purpose of the proposed use of animals, 2) justification for species and numbers of animals, 3) consideration of alternatives (e.g., in vitro, computer simulation), 4) unusual housing and husbandry requirements, 5) appropriateness of methods for sedation, analgesia, and anesthesia, 6) unnecessary duplication of experiments, 7) conduct of multiple major operative procedures, 8) criteria for intervention, removal, or euthanasia of animals from study, 9) appropriateness of euthanasia methods, and 10) safety of working environment for personnel. The investigator will be notified of the results of the review within one week of the meeting, and will receive written notification of all IACUC decisions. The ORC maintains files of all approved protocols. If funded, the ORC will send communication to Marquette University's grants office (ORSP); the ORSP Director is responsible for signing the agreements with all funding agencies. If requested, the ORC will send communication regarding an approved protocol directly to the funding agency.

Designated Review is a protocol review procedure that is not done by the full IACUC committee but by one or more reviewers appointed by the Chair. Examples of when the Designated Review may be used are 1) when a request is made by the Principal Investigator that a protocol (new or modification) be considered before the next scheduled IACUC meeting because significant disruption of a research or teaching program would result if delayed, and 2) when a previously approved protocol is being resubmitted with no or only minor changes because the grant application to which it is linked is being submitted to a different funding agency. The Chair will make the decision regarding whether a protocol is eligible for Designated Review. If eligible for Designated Review, the following procedures will be followed: 1) The protocol will be sent either electronically or via mail to all members of the IACUC; 2) IACUC members will have 5 days to respond as to whether the protocol may be reviewed by Designated

Review; 3) If a majority of the IACUC members respond affirmatively that the protocol may be done by Designated Review, then the Chair will designate a member of the IACUC to review the protocol. If any one IACUC member requests a full review, then the protocol will go to full review. The Designated Reviewer will either approve the protocol or recommend the protocol for full review. The Designated Reviewer must present the recommendation regarding the protocol to the IACUC at the next meeting.

Deferred Review is a review procedure for protocols from Marquette Principal Investigators that have been approved at another institution for work being conducted at the other institution. The Marquette IACUC does not need to review the protocol, but must keep the protocol and the other institution's approval letter on file. The Marquette IACUC must be informed of any problems encountered during the other institution's semi-annual inspections related to the protocol. The Marquette IACUC must be informed of the outcome of annual reviews of the protocol at the other institution. It will be the responsibility of Marquette University Principal Investigator to obtain these documents from the other institution and provide copies to the Office of Research Compliance.

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 as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are such that investigators must submit modifications of protocols by completing the Protocol Modification Form and submit it to the ORC. ORC will forward the modification request to the IACUC Chair or the Veterinarian, who will make the determination as to whether the change requested is a major or minor modification. All major modification requests will be reviewed by the IACUC at a convened meeting. Minor modifications will be reviewed and approved by the Chair or Veterinarian. Investigators are informed of the IACUC decision in writing.

The full IACUC will review all major (significant) changes to a protocol (as described by PHS and OLAW, Lab Animal Vol. 24 (9): 24-26, 1995). Some examples of major (significant) changes are 1) changes in the objectives of a study, 2) proposals to switch from non-survival to survival surgery, 3) changes in the degree of invasiveness of a procedure or discomfort to an animal, 4) changes in species or in the number of animals used by more than 10%, 5) changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia, and 6) changes in the duration, frequency, or number of procedures performed on an animal. The addition or deletion of project personnel is considered a minor change. The procedures for full committee review of major modifications are similar to those for new protocols. The Consulting Veterinarian will serve as a resource regarding drug dosage, euthanasia, etc.

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 as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review require that a member of the Office of Research Compliance document the official IACUC decisions. The ORC notifies the investigators in writing of the IACUC decisions.
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 in accordance with the PHS Policy at IV.C.1-4. at least once every three years.

Continuing review notices will be sent to investigators prior to the first and second anniversary dates of the original approval date. The IACUC procedures for conducting continuing review require that all protocols be reviewed at least once per year following initial approval. Each protocol is approved for a maximum duration of three years; therefore, two continuing reviews are required for each protocol within the three year period. The IACUC reviews Continuing Reviews at a convened meeting. Investigators are required to complete the Continuing Review Form and submit it to ORC prior to review. Continuing review will be done at the next scheduled meeting of the IACUC in a manner similar to that described for new protocols. To renew a protocol on the third anniversary date of the original approval date (3-year renewal), the Principal Investigator must complete and submit a new protocol form.

The following are examples of issues that will be considered in review: 1) rationale and purpose of the proposed use of animals, 2) justification for species and numbers of animals, 3) consideration of alternatives (e.g., in vitro, computer simulation), 4) unusual housing and husbandry requirements, 5) appropriateness of methods for sedation, analgesia, and anesthesia, 6) unnecessary duplication of experiments, 7) conduct of multiple major operative procedures, 8) criteria for intervention, removal, or euthanasia of animals from study, 9) appropriateness of euthanasia methods, and 10) safety of working environment for personnel. The investigator will be notified of the results of the review within one week of the meeting and will receive written notification of all IACUC decisions. The ORC will send appropriate communications to any grant funding agencies and maintain files of all approved protocols.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are: In the event of an animal health emergency, the veterinarian has the authority to euthanize an animal if necessary, and temporarily (until the IACUC convenes) suspend animal experimentation if animals are in distress. The IACUC can suspend a protocol with a majority vote of a convened quorum. Suspensions will

be reported to PHS, APHIS (if applicable), and any federal agency funding the activity.

The IACUC has the authority to suspend any activity involving animals if it determines that the activity is not being conducted in accordance with provisions of the Animal Welfare Act, the NIH Guide for the Care and Use of Laboratory Animals, and the MU Animal Care Manual. The Consulting Veterinarian may terminate an experiment if the activity is deemed egregious enough, until a quorum of the IACUC can meet to discuss the issue.

- E. The individuals authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals, are the Chair of the IACUC and a member of the Office of Research Compliance.
- F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is comprised of several components.

A Laboratory Animal Contact Health Questionnaire is provided to all institution staff working with animals. The questionnaire requests information regarding personal health history (including past animal exposure, immunization status and allergy status) and present health status. Completed questionnaires are evaluated by a qualified health professional, Tim Gengembre, PA-C, Chair of Physician Assistant Studies, and the staff member is asked to schedule an appointment with Mr. Gengembre to discuss the questionnaire. Institution staff are allowed to decline to participate in the questionnaire and sign a statement to this effect. Each year, staff are provided with an Annual Follow-Up Questionnaire. Tetanus vaccinations are strongly recommended for animal care personnel, including student workers and faculty. Workers must report any animal-related injuries to their supervisors. All personnel working with animals are required to read those portions of the Marquette University Animal Care Manual that relate to their role in the animal care and use program. In addition, staff working with animals receive a brochure providing basic information for Health and Safety in working with animals.

Use of hazardous agents with animals is required to be reviewed and approved by the IACUC. The appropriate University committee evaluates qualification for the use of these agents by the investigators. The Radioisotope Safety Committee must first approve use of radioactive substances, and the Institutional Biosafety Committee must approve use of recombinant DNA. If these agents are to be used, the caging is labeled appropriately and all personnel are notified of the procedures in use. If a principal investigator should require the use of hazardous agents, the IACUC would require the PI to devise and initiate a training program as appropriate for the hazardous material to be used, subject to review and approval by the university's safety officers.

Educational programs to inform persons about zoonoses, personal hygiene, and other considerations regarding occupational health are provided during employee orientation. All animal care handlers, professionals, technicians, and students are required to read the corresponding training sections of the Animal Care Manual and watch training DVDs for the appropriate species housed in the facility in which they will be working. The manual provides training on animal handling, zoonotic diseases, and preventive health measures. The Animal Facilities Manager may provide oral or written continuing education, as appropriate.

The animal facility is also equipped with safety advisory signs regarding proper lifting techniques. The ARC staff also take part in protocol review sessions every other month in which one PI discusses his/her active protocol(s) with the staff.

Workers are provided with lab coats, scrubs, and disposable shoe covers to wear when they are working with the animals and cleaning animal cages. Services for cleaning these garments are available through a commercial laundry service. A mobile, self-contained, waste disposal station is used in the animal facility's cage washer room to help control airborne allergens generated during the disposal of animal bedding and waste (Lab Products, Inc. Waste Management System, Model #59030). When dumping soiled bedding and around the cage washer, workers must wear gloves, masks, hairnets, scrubs/lab coats, and hearing protection. Rubber apparel, including gloves, aprons and boots, is available for protection, if needed.

Marquette University's Risk Management Office provides all employees with information about any toxic substances, infectious agents, and pesticides with which employees could come into contact. All employees may request such information at any time.

Animal care personnel are instructed to report any exposure to a hazardous agent to their supervisor, who will then complete an incident report. Once the severity of the problem is established, appropriate action can be taken by the employee's supervisor. According to Marquette University's Worker's Compensation policy, in the case of serious injury, the Department of Public Safety would be contacted and Risk Management notified, and appropriate action taken (e.g., transportation to local emergency room). In the case of an exposure to a radioisotope hazard, the principal investigator is contacted and the University Radiation Safety Officer is alerted. Once the nature of the exposure is established, the appropriate procedures are followed according to WIHFS guidelines.

Additional occupational health and safety training is provided to personnel during the initial and ongoing training sessions. Personnel are educated on the risk of developing allergies, possible zoonoses, infection due to bites and scratches, exposure to hazardous materials, and procedures for reporting injuries. In the event of injury, student workers report the injury to the Principal Investigator, and receive treatment from Marquette University Student Health Services. The Principal Investigator/Supervisor will report this occurrence to ORC and the Office of Risk

Management. Investigators, Faculty and Staff are required to complete an injury report for Worker's Compensation and file this report with the Office of Risk Management and ORC. Emergency medical treatment is available at Sinai Samaritan Medical Center, which is the closest full service hospital to Marquette University's campus.

Detailed information regarding risks to personnel is provided in the Marquette University Animal Care Manual. Prior to entering the animal facilities, all personnel will receive an orientation, which includes showing personnel the location of exits, emergency eye wash stations, and fire extinguishers.

- G. The gross number of square feet in each facility, the species of animals housed therein, and the average daily inventory of animals, by species, in each facility is provided in the attached table.
- H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is provided by the veterinarian and the Animal Facilities Manager. Laboratory Animal Training Association (LATA) videotapes are viewed by all personnel (species specific). The Animal Facility Manager provides hands-on training for the proper animal handling techniques and husbandry. The veterinarian assesses the qualifications of the personnel and provides specialized surgical training for scientists and technicians. The Marquette University Animal Care Manual provides detailed information regarding all aspects of animal care, including information on the use of analgesics, anesthetics, and acceptable methods of euthanasia. Training is required for all personnel prior to working with animals and administered on an as needed basis. Training records for all personnel are maintained by the Animal Resource Center (ARC).

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2., as Category 1, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All of this institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to 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 evaluations will be submitted to

William Wiener, Ph.D., Vice Provost for Research, Dean of the Graduate School, and Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

V. RECORD KEEPING REQUIREMENTS

A. This institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by 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 given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to William Wiener, Ph.D., Vice Provost for Research, Dean of the Graduate School, and Institutional Official.
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 three 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. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:

1. Any change in the status of the institution, any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
2. 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 William Wiener, Ph.D., Vice Provost for Research, Dean of the Graduate School, and Institutional Official.

- B. The IACUC, through the Institutional Official, will provide the OLAW promptly 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 shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: William Wiener, Ph.D.

Title: Vice Provost for Research, Dean of the Graduate School, and Institutional Official

Address: Marquette University
Graduate School, Holthusen Hall 305
P.O. Box 1881
Milwaukee WI 53201-1881

Phone: (414) 288-1532

Fax: (414) 288-1902

Signature: *A copy of this document with signature is available at the Office of Research Compliance.*

Date:

B. PHS Approving Official

Name:

Title:

Address: Office of Laboratory Animal Welfare
Division of Assurances
6570 Rockledge Drive-RKL1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Phone: (301) 496-7163

Fax: (301) 402-7065

Signature: A copy of this document with signature is available at the Office of Research Compliance.

C. Effective Date of Assurance:

D. Expiration of Assurance: