

University of Rochester
A-3292-01
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, Mark B. Taubman, M.D., as named Institutional Official for animal care and use at the University of Rochester, hereinafter referred to as the institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

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.

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, as well as all 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 as follows: The members of the University Committee on Animal Resources, hereinafter designated as UCAR (our Institutional Animal Care and Use Committee equivalent), are appointed by the Institutional Official (IO) of the Institution, Mark Taubman, M.D. The term of appointment of University Members of the Committee is one year with a three (3) year reappointment. The President/CEO has delegated responsibility and authority for compliance with this policy to Mark Taubman, M.D., Acting Senior Vice President and Acting Vice Provost for Health Affairs, Medical Center and Strong Health, CEO. The Acting Senior Vice President has the authority and responsibility of ensuring compliance with this policy as described below. The Attending Veterinarian reports to the Institutional Official.

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

Jeffrey D. Wyatt, DVM, MPH, ACLAM dipl.

Qualifications:

- Degrees: DVM, MPH, ACLAM dipl
- Training and/or experience in laboratory animal medicine: Dr. Wyatt is specialty board certified by the American College of Laboratory Animal Medicine (ACLAM), licensed to practice veterinary medicine in New York State and is accredited by the NYS Division of Animal Industry. Dr. Wyatt earned his DVM from The Ohio State University in 1982, completed a residency in laboratory animal medicine at the University of Rochester in 1986 and earned his MPH from the University of Rochester School of Medicine in 1995. Dr. Wyatt is a member of AAALAC, International Council and has twenty-eight years of experience in laboratory animal medicine.

Authority: Dr. Wyatt has direct program authority and responsibility for the Institution's animal care and use program. He is the Attending Veterinarian, Professor and Chair of Comparative Medicine and Executive Director of the Animal Resource. Dr. Wyatt is responsible for all aspects of the animal care program at the University of Rochester.

Time Contributed to Program: Dr. Wyatt is a full time employee who devotes 100% effort to the University of Rochester Program of Animal Care and Use. He is a voting member of UCAR.

Veterinarian #2

Qualifications:

- Degrees: DVM
- Training and/or experience in laboratory animal medicine: After three years in practice, she entered the residency training program in Laboratory Animal Medicine at the University of Rochester School of

Medicine in 1991. She completed the residency program in 1993, and joined the faculty. She is licensed to practice veterinary medicine in New York State, is accredited by the NYS Division of Animal Industry and is Associate Professor of Comparative Medicine.

Responsibilities: Responsible for the Animal Resource Quality Assurance & Regulatory Compliance program.

Time Contributed to Program: She is a full time employee and devotes 100% of her time to the University of Rochester Program of Animal Care and Use. She is a voting member of UCAR.

Veterinarian #3

Qualifications:

- Degrees: DVM
- Training and/or experience in laboratory animal medicine. She joined the Division of Laboratory Animal Medicine as Clinician and Instructor in November, 1997. She is licensed to practice veterinary medicine in New York State, is accredited by the NYS Division of Animal Industry and is Associate Professor in the Department of Comparative Medicine.

Responsibilities: She the clinical and preventive medicine program.

Time Contributed to Program: She is a full time employee and devotes 100% effort to the University of Rochester Program of Animal Care and Use.

Veterinary Resident

Qualifications:

- Degrees: DVM
- Training and/or experience in laboratory animal medicine: She graduated from AVMA accredited Veterinary Medical College in 2006.

Responsibilities: Clinical veterinary work.

Time Contributed to Program: She is a full time employee and devotes 100% effort to the program of veterinary care as a resident in the University's ACLAM recognized training program in comparative medicine.

Veterinary Resident

Qualifications:

- Degrees: DVM
- Training and/or experience in laboratory animal medicine: He graduated from AVMA accredited Veterinary Medical College in 2004.

Responsibilities: Clinical veterinary work.

Time Contributed to Program: He is a full time employee and devotes 100% effort to the program of veterinary care as a resident in the University's ACLAM recognized training program in comparative medicine.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the 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 five

members, and its membership meets the composition requirements set forth in the PHS Policy, Section 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 (Attachment A).

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 reviews are as follows: The Committee members review the written Assurance and Program Description. These documents become part of the package distributed to each UCAR member prior to the semi-annual inspection and are discussed at a convened meeting. At that meeting, the Vivarium director or attending veterinarian reviews the program and discusses any changes to the program. Reports are also submitted and discussed at this meeting from Environmental Health and Safety, Occupational Health and Security. Copies of the reports are kept in the UCAR office for reference by Committee members. Additionally, copies of Vivarium SOP's are kept in the Animal Resource Office for reference by Committee members.

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 procedures for conducting semiannual facility inspections are as follows: The facilities are inspected twice each year at approximately six month intervals. At least two voting members of the UCAR conduct each inspection. The results of the inspection are compiled and presented to the Committee at a special convened meeting of the full UCAR, at which all inspection findings are reviewed and discussed, and the program of animal care and use is reviewed and discussed. The review of the facilities is divided into 2 parts, review of the vivarium facilities, and review of laboratories to which animals are taken. Surgical facilities used for both USDA regulated species and non-regulated species are reviewed either as part of the vivarium facility in which they are located, or as part of the laboratory that supervises their use. Results of the inspections are compiled in a database together with plans and dates for resolution of problems found during the inspection and tracked by the Research and Training Coordinator.

3. Prepare reports of the IACUC evaluations as set forth in the 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: The report is prepared for review by the full Committee by the Research and Training Coordinator and the UCAR office staff. It is reviewed along with the inspection results at a convened meeting. Each member in attendance signs a sheet indicating the report is accurate. The report is then submitted to Mark Taubman, M.D.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: UCAR publishes widely to all animal users, via web site and newsletter notices, periodic emails, and signs in the facility and laboratories, the methods of registering concerns about the care and use of animals at the University of Rochester. UCAR investigates, reviews and evaluates all concerns brought to the attention of the IACUC by faculty, staff, students, or outside persons involving the care and use of animals at the University and reports its findings and recommendations, if any, to the IO, Mark Taubman, MD. The Committee's findings and recommendations are communicated in writing to the person or group originating the concern.

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 Institutional Official receives copies of minutes, semi-annual inspections and program reviews, and all written recommendations regarding any aspect of the Institution's animal program, facilities, or personnel training.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows: Animal Use Protocols must be submitted to the University Committee on Animal Resources for any use of vertebrate animals in research or teaching. There are several different forms used, depending on the animal model proposed for use and the type of protocol. Projects that will not be receiving scientific peer review from a funding agency or an established peer review committee must receive approval from the University of Rochester's internal Dean's Research Advisory Committee before they can be initiated.

All protocols must be submitted using our on-line protocol submission and review system.(Granite from Topaz Technologies Inc). When notice of a submitted protocol is received by the UCAR office, the office staff briefly reviews the protocol for obvious problems, then assigns the protocol to Committee Pre-review. Once a week a list of protocols for Committee Pre-review is sent by email to all committee members, requesting that they review the protocols to determine whether any should be reviewed at a meeting of the Full Committee. The committee members have access to the protocol from the time it is assigned until five (5) days after the notice is sent. The committee members may also enter review comments and questions at this time.

If any committee member requests full committee review for a protocol, it is placed on the agenda for the next meeting. Primary and secondary reviewers are assigned to present the protocol at the meeting. A notice is sent to committee members telling them that the protocol will undergo Full Committee Review, and requesting that they review it and submit any questions and

comments. All questions and comments submitted by reviewers are returned to the PI, who then has an opportunity to revise the protocol before the meeting. If a revision is submitted, it is assigned to Full Committee Review, and the committee members are notified that the protocol has been revised. The protocol and any responses from the PI are then discussed at the meeting. Additional questions or clarifications may be required by the committee. During the committee meeting, a quorum of the full committee may vote to:

- approve the protocol
- require modification(s) to obtain approval
- defer the protocol to the next meeting
- withhold approval

If the vote is to require modifications to secure approval, a quorum of the full committee may further vote to require the protocol to return for full committee review, or be assigned to designated member review. The information that the protocol has been assigned to designated member review will be available in the meeting minutes. Any member wishing to review the modified protocol may at any time request to see the revised protocol and will be added to the list of reviewers in the online review group, but they will not be considered designated reviewers. At any time, those members reviewing the protocol can call for it, or the modifications to it, to be reviewed at a meeting of the full committee.

All members of the committee have signed an agreement stating that protocols undergoing Full Committee Review can be subsequently assigned to designated review by a vote of a majority of a quorum of the Full Committee. New committee members will be informed of this policy and asked to indicate their acceptance in writing.

If no member of the committee requests full committee review during the five day period of Committee Pre-review, the protocol is assigned to the designated review process. Designated reviewers are assigned by the UCAR office staff, with advice from the UCAR Chair. Designated reviewers submit any questions or clarifications required from the investigator using the on-line review system. Reviewer comments and questions are summarized by the UCAR Chair or the UCAR office staff. The protocol is then returned to the PI with all the summarized comments and questions. The PI edits the protocol to address all issues that have arisen during the review, and resubmits the protocol. The resubmitted protocol is assigned for review to the original designated reviewers (and to any other committee member who wishes to see it). Designated reviewers can approve the protocol, request additional information, or request that the protocol be reviewed at a full committee meeting. Committee meetings are normally held once a month. A quorum must be met before voting on protocols or any other issues.

Members who have a conflict of interest with a protocol are not allowed to vote on the protocol at a meeting of the full committee and are not assigned to be a designated reviewer.

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 IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows: All proposed changes to protocols must be reviewed and approved by UCAR. To request a modification the investigator is required to submit a modified protocol to UCAR. Twice a week, a summary of each modification is distributed to all members of the committee, who then have two business days to request that the modification be reviewed by the full committee at a regular meeting. If full committee review is requested, it is handled in the same manner as full committee review and approval of protocols. If full review is not requested, UCAR has delegated review of the modification to the UCAR Chair and one other member of the committee designated by the chair. If the modification requires a change in invasive procedures, surgery, methods of euthanasia, pain level, or any other item requiring veterinary review, one of the committee veterinarians acts as the second reviewer. If there are no such changes (e.g. change in animal numbers), the Chair designates a second member of the committee to review the modification. The two reviewers can approve the modification, seek additional information from the investigator, or request full committee review of the modification.

For certain modifications that have been recommended by one of the veterinarians by a letter or email to UCAR, an expedited modification process may be used. After UCAR has received the recommendation of the veterinarian and a modified protocol, a special notice is sent to all committee members requesting that they respond within 8 business hours if they do not feel that the modification can undergo expedited review. If there are no responses within 8 hours, a designated review is chosen by the Chair, who is asked to review the modification as soon as possible. The designated review can approve the modification, request additional information or call for full committee review.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows: The Committee issues approval letters (titled Verification of Review and Approval) to the Principal Investigator. Letters are kept on file for review by the IO.

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 IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing

reviews are as follows: Annual reviews are conducted for each protocol before its anniversary date. The investigator is required to review the protocol, and submit a form confirming that the protocol is still active and all changes that have been made to the protocol have been reviewed and approved by UCAR. Annual protocol reviews also undergo an administrative review by the UCAR Office Staff. UCAR review and approval (or deferment to full committee review) of the annual protocol has been delegated to the UCAR Chair by UCAR. A list of all annual protocol reviews coming up for approval is distributed to all committee members at the monthly meeting. Any committee member may request to review the protocol or request a full committee review prior to the expiration date.

Full review of active animal care and use protocols is required every three years (36-month intervals) The PI must submit a protocol for 36 month review to the UCAR office (using the on-line system) at least two (2) months before the expiration date. Review is handled the same way for 36 month reviews and new protocols (see section 6 above). If a protocol for an active PHS grant is allowed to expire, UCAR notifies the University of Rochester Office of Research and Sponsored Programs, who notifies PHS. If there are any animals on the protocol at the time of expiration, they are moved to the DLAM holding protocol before the expiration date, and remain there until UCAR can determine what should be done with them. The PI does not have access to them, and no procedures other than those required for veterinary care or husbandry can be done on them.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows: All issues relating to the potential suspension are discussed at a meeting of the full UCAR. A majority vote of a quorum of the committee to suspend the protocol is communicated to the PI, the Department Chair, the University Council, and the IO, Dr. Taubman, in writing. The Institutional Official sends a letter with a copy of the report to OLAW.

E. The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows: The University of Rochester occupational health and safety program emphasizes hazard identification and risk assessment. The University of Rochester Risk Management and Environmental Safety (URMES) Department and University Health Service's Occupational Health Unit evaluate hazards and assess risk for people working with animals at the University of Rochester. The following people are enrolled in the occupational health program:

- Research staff
- Animal care staff
- Veterinary staff
- Facilities staff
- UCAR members
- Students participating in teaching labs

Level of involvement is dictated by hazard identification and risk assessment (e.g. Herpes B training and TB testing of employees working with macaques). All new employees (including research, animal care, veterinary and facilities staff and IACUC members) who may be in contact with laboratory animals receive an orientation to animal allergens, a tetanus update, evaluation by UHS plus information about zoonoses and animal allergens at the Animal Resource orientation. Student participants in teaching labs receive an orientation by the veterinary staff regarding allergen awareness and PPE required specific for the lab. URMES staff describe safe work practices for physical, chemical and protocol-related hazards. URMES staff have evaluated the vivarium workplace for physical hazards involved with moving and lifting heavy materials and equipment, cleaning chemical hazards in cagewash and the animal room, facility noise levels and anesthetic gas, formaldehyde and blood-borne pathogen exposure, proper disposal of sharps, maintenance of eyewash stations and use of fire extinguishers. URMES evaluates every UCAR animal use protocol involving hazardous agents and describes safe work practices and facility requirements for physical, chemical, infectious hazards and radioactive materials, for both research and animal care staff. The veterinary and vivarium supervisory staff train both research and animal care staff in safe animal handling techniques to avoid animal bites, scratches, kicks and related hazards. Incidents of workplace injuries (e.g. animal bites, scratches, scraped or bruised fingers) are tracked by URMES and workplace evaluations occur to decrease incidence of injuries.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

<p>Humane methods of animal maintenance & experimentation including:</p> <ol style="list-style-type: none"> 1. the basic needs of each species of animals 2. proper handling and care for the various species 3. proper pre- and post-procedural care 4. aseptic surgical 	<ol style="list-style-type: none"> 1. The Responsible Care and Use of Laboratory Animals UCAR Manual, available on-line for all employees, includes a chapter on "Laboratory Animal Biotechnology" describing manual and chemical restraint techniques, aseptic surgical technique, sample administration and collection, anesthesia, analgesia and euthanasia of laboratory animals. 2. Animal Resource Orientation (two hour meeting) and certification quiz are required for all new employees listed on UCAR approved
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<p>methods & procedures</p>	<p>protocols. At this time the Research and Training Coordinator identifies investigators requiring targeted training (e.g. nonhuman primate workers, mouse breeding colonies) as well as informs new staff about additional wet lab training opportunities offered by the veterinary staff.</p> <ol style="list-style-type: none"> 3. All new personnel are required to review The Collaborative Institutional Training Initiative (CITI) on-line program that includes courses for Researchers and staff; IACUC members, species specific for ten species; reducing pain & distress; and aseptic surgery. UCAR has additional training DVDs for ferrets and chickens. 4. Meeting with Attending Veterinarian is required for all new principal investigators to assess species-specific and procedural skills (e.g. aseptic surgical technique, anesthetic monitoring) and additional training requirements. 5. Animal Resource species-specific one-on-one training in anesthesia, surgery, euthanasia and sample administration or collection is available upon request. 6. Breeding Colony Management Training course is required for all staff approved to manage breeding colonies of mice. 7. Microisolator Technology training (Blackboard on-line and hands-on) is required for all staff handling mice housed in Microisolator barrier rooms. 8. On-line training and quiz is required for all staff euthanizing rodents by carbon dioxide inhalation. 9. "Safely Working with Nonhuman Primates" training CD viewing and quiz are required for all staff working with nonhuman primates as well as the CITI online training. 10. All personnel that administer anesthesia to primates are required to complete an "Primate Anesthetist" course offered by DLAM. 11. The UCAR Research & Training Coordinator visits all laboratories where surgeries occur at least every six months and assists research staff with accessing additional training
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	<p>opportunities.</p> <p>12. Laboratory Animal Biomethodology (LAM 402), a 1 credit course, is offered every year for researchers, technicians and graduate students interested in formal training in a lecture and wet lab setting learning laboratory animal techniques including anesthetic monitoring and aseptic surgical technique across all commonly used laboratory animal species.</p>
<p>The concept, availability, and use of research or testing methods which limit the use of animals or minimize animal distress</p>	<ol style="list-style-type: none"> 1. The Responsible Care and Use of Laboratory Animals UCAR Manual, available on-line for all employees, includes a chapter on “The Alternative Concept” describing techniques in replacement, refinement and reduction. 2. The Responsible Care and Use of Laboratory Animals UCAR Manual, available on-line for all employees, includes a chapter on “Biomethodology” describing the refinement in protocols including proper techniques for euthanasia, manual and chemical restraint, administration of anesthetics, analgesics, and sample administration and collection. 3. Laboratory Animal Biomethodology (LAM 402), a 1 credit course, is offered every year for research technicians and graduate students interested in formal training in a lecture and wet lab setting. The course requires each student complete a “mock” UCAR protocol addressing all sections including the alternative concept. The students formally review each other’s protocols, functioning as an IACUC using the PHS Guide guidelines and Animal Welfare Act regulations as basis for protocol review, approval or modification.
<p>Proper use of anesthetics, analgesics and tranquilizers</p>	<ol style="list-style-type: none"> 1. The Responsible Care and Use of Laboratory Animals UCAR Manual, available on-line for all employees, includes a chapter on “Laboratory Animal Biomethodology” describing manual and chemical restraint techniques, aseptic surgical technique, sample administration and collection, anesthesia, analgesia and euthanasia of laboratory animals. 2. “Aseptic Surgery” and species specific

	<p>training courses through the CITI Lab Animal Welfare online program are required for all staff involved with laboratory animals and who perform surgery and basic animal handling.</p> <ol style="list-style-type: none"> 3. Meeting with Attending Veterinarian is required for all new principal investigators to assess species-specific and procedural skills (e.g. proper use of anesthetics, analgesics and tranquilizers) and additional training requirements. 4. The UCAR Research & Training Coordinator visits all laboratories where surgeries occur at least every six months and assists research staff with accessing training opportunities especially as new methods of anesthesia and analgesia become available. 5. Animal Resource species-specific one-on-one training in anesthesia, analgesia and euthanasia is available upon request. 6. Laboratory Animal Biomethodology (LAM 402), a 1 credit course, is offered every year for research technicians and graduate students interested in formal training in a lecture and wet lab setting learning laboratory animal techniques across all commonly used laboratory animal species.
<p>Methods whereby deficiencies in animal care and treatment are reported, including deficiencies reported by any employee of the facility.</p>	<ol style="list-style-type: none"> 1. The UCAR Research & Training Coordinator distributes instructional cards for posting in animal labs offering methods for anyone to report concerns about animal welfare at the university. The card offers options for reporting concerns including web site reporting, anonymous reporting or confidential reporting where feedback may be provided by the UCAR. 2. The UCAR website includes information about methods for reporting concerns about animal welfare. 3. All new staff (research and animal care) are required to attend the Animal Resource orientation during which instructions are given for reporting deficiencies.
<p>Utilization of services (e.g. National Agricultural Library, National Library of Medicine) available to provide</p>	<ol style="list-style-type: none"> 1. All new staff (research and animal care) are required to attend the Animal Resource orientation where the alternative concept, including techniques in refinement,

<p>Information on appropriate methods of animal care and use, on alternatives to the use of live animals in research, unintended and unnecessary duplication of research involving animals and the intent and requirements of the Animal Welfare Act.</p>	<p>replacement and reduction, is described. Instructors and the certification quiz describe the availability of the National Agricultural Library (NAL) and Animal Welfare Information Center (AWIC) as information sources useful for documenting the consideration of alternatives to the use of live animals and avoidance of unintended and unnecessary duplication of research involving animals.</p> <ol style="list-style-type: none"> 2. The UCAR guidelines offer guidance about how to satisfy the requirement to document consideration of alternatives including availability of a Medical School reference librarian. The librarian has special training in searching for alternatives, and will assist in defining search parameters. The UCAR web site includes a “how to do” literature search set of instructions written by the Medical School reference librarian who is a voting UCAR member. 3. Laboratory Animal Biomethodology (LAM 402), a 1 credit course, is offered every year for researchers, technicians and graduate students interested in formal training in a lecture and wet lab setting. The course requires each student complete a “mock” UCAR protocol addressing all sections including familiarity with the availability of NAL and AWIC for addressing the alternative concept.
<p>Training of UCAR members</p>	<ol style="list-style-type: none"> 1. New members are required to take CITI training for UCAR members. 2. New members are provided an orientation to the Animal Use Protocol and how it should be reviewed by the Chair. 3. All members are encouraged to attend IACUC 101 and IACUC 201, and other PRIMN&R or SCAW training offered. 4. All members are encouraged to attend Webinars available from OLAW.

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 six

months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the 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 "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 One (1)—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.

V. RECORDKEEPING REQUIREMENTS

- A. This Institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto, 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 given or withheld.
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Mark B. Taubman, M.D.
 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. This Institution's reporting period is January 1 through December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31st, of each year. The 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), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide 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 the Institutional Official, Mark B. Taubman, M.D.

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 sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.