

University of Rochester

D16-00188 (#A3292-01)

Animal Welfare Assurance for Domestic Institutions

I, **Mark B. Taubman, MD** as named Institutional Official for animal care and use at University of Rochester, 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, NSF and/or NASA. This Assurance covers only those facilities and components listed below.

- A. The following branches and components over which this Institution has legal authority, included are those that operate under a different name: University of Rochester (including: River Campus, Strong Memorial Hospital Campus). These two campuses are adjacent to each other separated by Elmwood Ave.
- B. The following are other institution(s), or branches and components of another institution: None

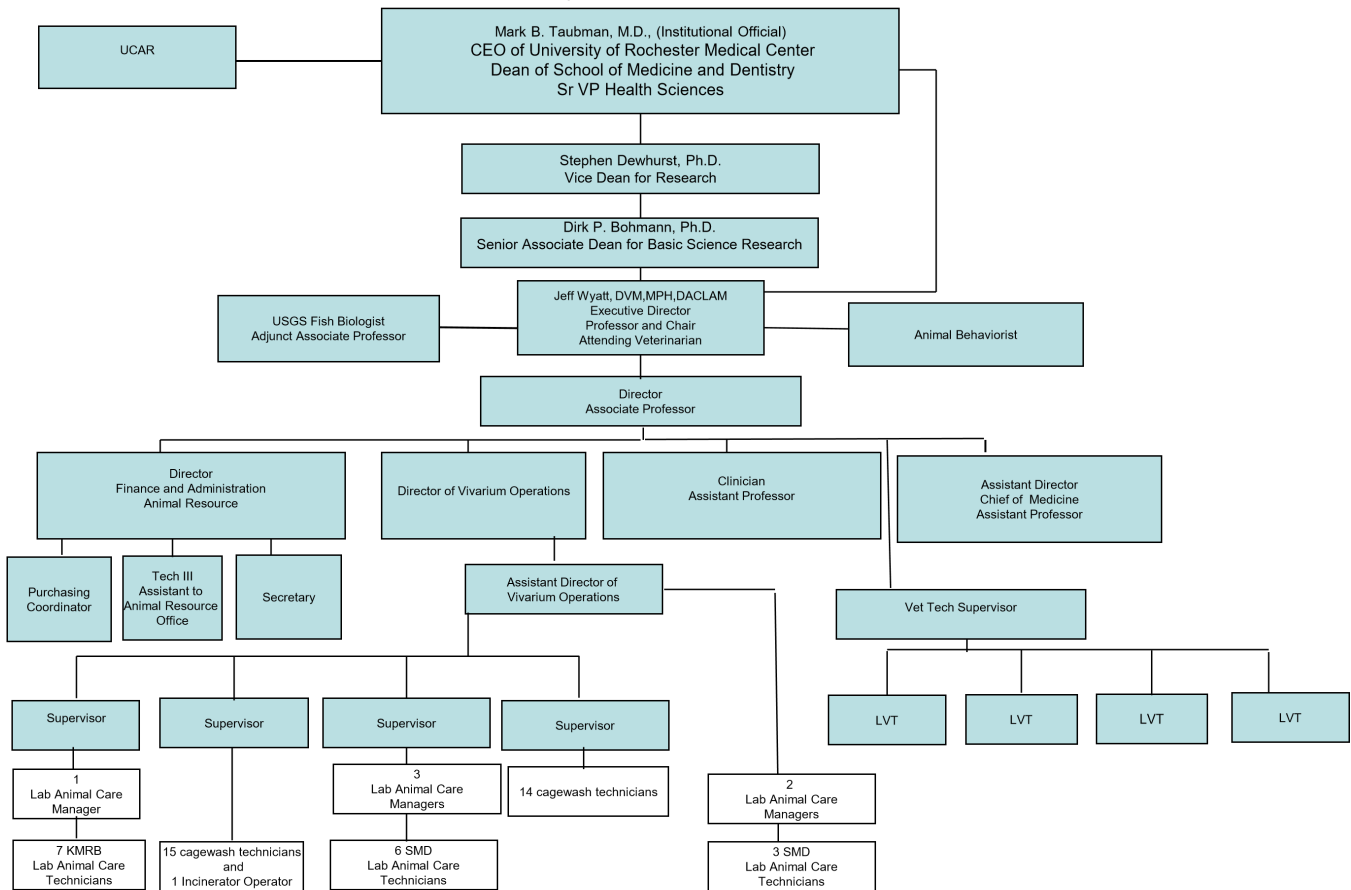
II. Institutional Commitment

- 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:

**Organizational Chart
University of Rochester - Animal Resource**



December 2021

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

1) Name: Jeffery D. Wyatt

Qualifications

- Degrees: DVM, MPH, ACLAM Diplomate
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Wyatt is a specialty board certified by the American College of Laboratory Animal Medicine (ACLAM-1986), licensed to practice veterinary medicine in New York State and is fully 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 has over 41 years of experience in laboratory and comparative animal medicine.

Authority: Dr. Dr. Jeffrey D. Wyatt has direct program authority and responsibility for the Institution's Animal Care and Use Program including access to all animals. He is the Attending Veterinarian for the University of Rochester's Animal Care and Use Program.

Time contributed to program: Full time employee

2) Name: [REDACTED]

Qualifications

- Degrees: DVM, CPIA

- Training or experience in laboratory animal medicine or in the use of the species at the institution:

[REDACTED]

Responsibilities:

[REDACTED] is the Director of Regulatory Compliance and Quality Assurance of the Animal Resource and clinical veterinarian.

Time contributed to program: Full time employee

- 3) Name: [REDACTED]

Qualifications

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

[REDACTED]

Responsibilities:

[REDACTED] is a clinical veterinarian and Assistant Director of the Animal Resource.

Time contributed to program: Full time employee

- 4) Name: [REDACTED]

Qualifications

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

[REDACTED]

Responsibilities:

[REDACTED] is a clinical veterinarian in the Animal Resource.

Time contributed to program: Full time employee

- 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.

(see Part VIII.).

- 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:

During the Semiannual Program Evaluation meeting reports are provided that discuss the various parts of the Program of Animal Care and Use, and highlight any changes. These include discussions of:

- **IACUC** (membership, responsibilities including reporting, protocol review procedures and considerations, policies and departures from the Guide for the Care and Use of Laboratory Animals (*Guide*)).
- **Veterinary Care Program** (including activities of the Department of Comparative Medicine (DCM))
- **Environmental Enrichment**
- **Training Program** (including training of IACUC members)
- **Occupational Health and Safety Program.** These reports include reports from Environmental Health & Safety (EH&S) Concerning use of hazardous substances (chemical, biological and radioactive), proper PPE, nonhuman primate bite and scratch incidents, other injuries, and from the University Health Service that includes compliance with requirements for health screening and health updates.
- **Public Safety.** , including a report from the Animal Resource Security Committee about security issues.
- **Disaster Planning**
- **Animal Welfare Concerns**, including a report of animal welfare concerns that have been investigated during the previous 6 month period, and their resolution.
- **Drug storage and control** (administered by the University Pharmacy)
- **Inspection of the Animal Housing Facility**, Satellite facilities and Surgeries, including a summary of the previously reviewed inspection findings.
- **Inspections of laboratories** to which live animals are taken (less than 24 hours for mice and rats, 12 hours for other species).

Following these reviews, the OLAW checklist (Semiannual Program Review and Facility Inspection Checklist) is reviewed to make sure our Program and Facility is in compliance with PHS Policy and the PHS Guide. This review also serves to provide a review for the IACUC members of the requirements of PHS Policy and the Guide. Any deficiencies are identified as minor or significant, and any changes in the program are identified. Exemptions that have been granted by the IACUC are separately noted. A copy of this checklist is included in the IACUC report to the Institutional Official.

Copies of the reports are kept in the UCAR office for reference by Committee members. Additionally, copies of Vivarium and Department of Comparative Medicine SOP's are kept in the Animal Resource Office for reference by Committee members.

- 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 facilities are inspected twice each year at approximately six months intervals. Upcoming inspection dates are announced at UCAR meetings, and an email is sent to all UCAR members listing the dates of inspections and the facilities to be inspected. The email requests that each member sign up for one or more of the inspections. At least two voting members of the IACUC conduct each inspection. Additionally, the IACUC may include the Flexibilities for conducting semiannual facilities inspections for areas housing non-Animal Welfare Act (AWA)-regulated species as described in the 21st Century Cures Act by using as few as one qualified individual or ad hoc consultant, who need not be an IACUC member or institutional employee, to conduct the facility inspections. Qualified individuals will have training and a working knowledge of the PHS Policy, and the *Guide* to appropriately evaluate the facilities and identify deficiencies and animal welfare issues. The results of the inspection are compiled and presented to the Committee at a special convened meeting of the full IACUC, at which all inspection findings are reviewed and discussed. The review of the facilities is divided into two 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 resolutions of problems identified during the inspection and tracked by the Research and Training Coordinator and Assistant Research and Training Coordinator.

Currently, the University of Rochester has field research activities which are described in a protocol so that the committee can consider potential risks to personnel and/or impact on study subjects. The protocol is reviewed and approved as described in III. D. 6. so the research activities are in accord with the *Guide*.

- 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:

- After the completion of the institution's program review and facilities inspection, a full report is prepared by Research & Training Coordinators and UCAR office.
- Reports are submitted to the IACUC by Environmental Health & Safety, University Health Services, Pharmacy and U of R Public Safety departments.
- The report includes a determination of whether the program meets standards or has deficiencies, defined as either minor or significant, as well as suggestions for corrective action to be taken.
- The report contains a list of IACUC approved departures from the PHS Policy, Guide, and the reasons for the departures. If there are not departures the report will state none.
- The report includes an excel spreadsheet that lists items found during the inspection of the facility and satellites. The deficiencies are categorized as minor or significant, identifies the party responsible for correction and assigned a reasonable timeline for correction.
- The report may contain recommendations for improvements in any aspect of the Institution's animal care and use program, facilities and/or personnel training.

- Reports are reviewed by and may be revised by the Committee prior to and during the special convened meeting. The final report will be signed by a majority of the IACUC members and will include any minority opinions.
 - The final report contains a description that the Institution adheres to the *Guide* and the PHS Policy.
 - The final report includes the Institution's AAALAC accreditation status.
 - The final report, along with a cover letter identifying the dates of the inspections, the date the Committee reviewed all reports, along with assurances that the inspections were performed in accordance with PHS policy, Animal Welfare Regulations and the Guide and any recommendations by the IACUC, is submitted to the Institutional Official.
 - A copy of the report will be maintained by the UCAR office for a period of three years.
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The IACUC publishes widely to all animal users, via website and, periodic mailings through Listserve™ email lists to specific user groups, and signs in the facility and laboratories, the methods of registering concerns about the care and use of animals at the University of Rochester. The IACUC investigates, reviews and evaluates all concerns brought to the attention of the Committee 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 if known.

All information related to reporting animal welfare concerns is posted on the IACUC/UCAR website. Additionally, animal welfare concern signage is posted in laboratories and vivarium spaces. The animal welfare concern sign includes the following information: "Any concerns about animal welfare or security should be reported (you will remain anonymous) to one of the following: URMCI Integrity Hotline phone number, UCAR Hotline number (goes to voice mailbox), UCAR office phone number, University Veterinarian phone number and/or Animal Resource office phone number"; No employee will be retaliated against or subject to reprisals for reporting violation of any regulation or standards under PHS policy, the *Guide* or USDA Animal Welfare Act or Regulations. The UCAR Hotline number is monitored by our Training and Compliance Coordinator. Additionally, there is an animal welfare/noncompliance form posted on the website which can also be submitted anonymously via secure drop boxes located outside the UCAR office door, or the office of our Training and Compliance Coordinator.

These protections are in accordance to the university's published whistleblower policy, which is part of the university's overall [Code of Conduct](#) ensures that any person regardless of their background (e.g., age, sex, race, religion, orientation) making a report in good shall not suffer retaliation:

"No Trustee, Officer, employee, student, or volunteer of the University who in good faith reports any action or suspected action taken by or within the University that is illegal, fraudulent, or in violation of any adopted policy of the University shall suffer intimidation, harassment, discrimination, or other retaliation or, in the case of employees, adverse employment consequence. Any person, regardless of position or title, who has been determined to have engaged in retaliation in violation of this Code will be subject to appropriate disciplinary action, up to and including termination of employment or other separation from the University. Reports of retaliation may be made to any person or office identified in Section IV.1 , above, and such reports will be investigated and acted upon in the same manner as reports of other types of violations of this Code."

- 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 care and use program, facilities, or personnel training.

- 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:

Animal Use Protocols must be submitted to the University Committee on Animal Resources (The University's IACUC) 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 (Topaz Elements 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. As directed by the UCAR Chair, the UCAR office staff will assign the protocol for 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.

Committee meetings are normally held once a month either in person or through tele- or videoconferences. Documents (for discussion) are provided to members in advance. A quorum must be met before voting on protocols or any other issues. Written minutes of the meeting are maintained in the IACUC Office for three years. Remote meetings adhere to the NIH Guidance on Telecommunications for IACUC Meetings ([NOT-OD-06-052](#)).

If any committee member requests full committee review (FCR) for a protocol, it is placed on the agenda for the next 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, the revised protocol is assigned to FCR 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 majority vote of the quorum present may vote to:

- Approve the protocol
- Require modification(s) to obtain approval
- FCR at the next meeting
- Withhold approval

If the vote is to require modifications to secure approval, a unanimous vote of the quorum

present may further vote to return the protocol to DMR. However, if any one committee member votes to keep the protocol in FCR, it will do so until approved, or the full quorum unanimously votes to return it to DMR.

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 unanimous vote of the quorum present. 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 member review process (DMR).

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. Other members, including the veterinarians, can review the protocol and provide comments and questions. However, they are not considered designated reviewers, and may not approve or require modification to obtain approval. The designated reviewers can see the veterinarian's questions and comments and take them into consideration during the designated review.

The procedure at the University for Designated Member Review requires that the UCAR Chair appoint two UCAR members to review each protocol. The protocol cannot be approved unless both designated reviewers agree to its approval. If either designated reviewer requests full committee review, the DMR process is suspended until full committee review takes place. If either designated reviewer requests modifications to obtain approval, the resubmitted, modified protocol must be reviewed by both designated reviewers, who again, can approve, request full committee review, or require modification to secure approval. This procedure continues until either the protocol is reviewed by the full committee, or both designated reviewers agree to approve the protocol as written. Note that the copies of the protocol being reviewed are always identical because they are submitted in our on-line protocol review system.

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. The IACUC Chair and/or Vice Chair with assistance from the UCAR office ensure that a quorum of the members is maintained during the voting 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:

Review and approval of significant changes will be handled in the same manner as new protocol (see Part III, D.6 above).

Examples considered to be significant include changes, but not limited to:

- the objective of a study or Principal Investigator
- from non-survival to survival;
- resulting in greater pain/discomfort or in a greater degree of invasiveness;
- in housing and or use of animal in a location that is not part of the animal program overseen by the IACUC;
- in the species or in approximate number of animals used;
- anesthetic agent(s) or the use or withholding analgesics;
- in the duration, frequency, or number of procedures performed on an animal;
- in impact to personnel safety, and
- any changes deemed significant by one or more reviewers;

Twice weekly, 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.

Veterinary Verification and Consultation (VVC) process for specific significant changes in a previously approved IACUC protocol based on Notice Number: NOT-0D-14-126 is also used at the University. The consulting veterinarian will provide documentation of the VVC to UCAR. UCAR has approved specific reference documents to support the VVC process. These reference documents consist of various previously approved lists (for example the formulary) and procedures that form the basis for (and limit) the significant changes that a veterinarian is allowed to verify using the WC procedure. They are used by the veterinarian to determine whether the requested modification is within the scope of UCAR approved policies. VVC is not allowed outside of the areas covered by these reference documents. The approved VVC policy specifically authorizes all University of Rochester veterinarians to perform VVC within the limits of the specifically named reference documents listed in the VVC Policy. A veterinarian will refer amendments to FCR or DMR if a requested change is not within the scope of the IACUC-approved VVC policy. VVC changes are limited to: a. anesthesia, analgesia, or sedation; b. euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and c. duration, frequency, type, or number of procedures to be performed on an animal as long as those procedures are either approved in the protocol or are approved UCAR or DCM SOPs

- 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:

The Committee issues notifications via email informing the Principal Investigator of the IACUC decision of modifications required (to secure approval).

The Committee notifies the investigator in writing of protocol approval, once the protocol, or its amendment is approved by the committee. Letters are kept on file for review by the IO.

The Committee notifies the investigator in writing of any decision to withhold approval. The Investigator would have the opportunity to address the Committee to provide clarification of the study. Additionally, the Investigator could modify the protocol to secure approval from the Committee.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

Post Approval Monitoring (PAM)

Post approval monitoring is ongoing and addressed by the Research and Training Coordinator and an assistant (RTCs) who meets with investigators and their staff to review current approved protocols and view hands-on procedures. While not necessarily required by policy, the UCAR Chair, a veterinarian, or any other committee member may be present at the visit. Additionally, the RTCs visit the vivaria and/or research laboratories to monitor research activities including: food/water provisions by investigators/or their associates; post-operative care; and hazard posting. These examples are not exhaustive. If there are deficiencies determined during a PAM visit, they are brought to the attention of the PI and their staff, the Chair and, if necessary, a veterinarian for corrective action. All findings are discussed at the next monthly UCAR meeting.

36 Month Reviews (all species)

A de novo review of active animal care and use protocols is required every 36-month intervals, and is to be completed by the previous approval date. 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. At this point, the 36-month review is handled in the manner as a new protocol (see Part III.D.6 above). If a protocol for an active PHS grant is allowed to expire, the UCAR office staff 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 handled by the UCAR holding protocol beginning at the expiration date, and remain under that holding protocol until UCAR can determine what should be done with them. During this time, the PI does not have access to the animals assigned to the expired protocol, 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 according to 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 UCAR to suspend the protocol is communicated to the PI, the Department Chair, the University Council, and the Institutional Official, in writing. The Institutional Official reviews the reasons for the suspension and the corrective actions recommended by the UCAR, and in consultation with the UCAR, ensures that any necessary corrective actions are taken. A report of the suspension and corrective actions is then prepared by UCAR, and an electronic letter with a copy of the report is sent to OLAW by the IO. Preliminary reports to OLAW may be made by telephone

- 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:

The University of Rochester Occupational Health and Safety Program (OH&S) emphasizes hazard identification and risk assessment based on job duties and level of exposure to the type of animal species and chemical, biological or environmental risks. The program is directed by a University of Rochester MD and nurses; supplemented by members of the Environmental Health & Safety (a certified Industrial Hygienist), the Institutional Biosafety Officer (a DVM), the Radiation Safety Officer, and the Veterinary staff.

The OH&S Program is a risk based, confidential personnel health screening and monitoring program. The following people are enrolled in the occupational health program:

- Research staff
- Animal care staff
- Veterinary staff
- Facilities/Maintenance Staff
- Courier staff
- UCAR members
- Students participating in teaching labs
- Campus Public Safety

All new employees (including research, animal care, veterinary, facilities staff, and paid-students) or volunteers (including non-paid students) entering animal rooms and/or in contact with laboratory animals, or their soiled cages receive a pre-placement one-on-one health assessment and health history as well as an orientation to animal allergens. In addition, information about zoonoses and animal allergens is presented at the Animal Resource Orientation and at Animal Resource "all staff" meetings for the employees working in the vivaria.

IACUC members who are not already regular users of animals are informed of risks of allergy prior to entering the vivarium or exposure to animals. They are also escorted by IACUC staff (Chair, Training and Compliance Coordinator, or vivarium veterinary staff) when in the vivarium. If these members are to enter rooms where nonhuman primates are housed/present, the IACUC member would first need to be enrolled in a health surveillance program which would include verification of an annual PPT/TB test and tetanus update.

Ongoing risk-based employee (including Facilities Department staff, UCAR members, UR Courier services, and laboratory staff) health surveillance is accomplished at a frequency based upon risk; annually for people working with higher risk species (e.g. primates with higher zoonotic potential), or triennially if working with lower risk species (e.g. lab reared SPF rodents with allergen potential). Allergen awareness is promoted throughout the year during UCAR research lab visits which include employee sign off of allergy awareness fact sheets and, UHS brochures and web site updates. The occupational health nurse elevates employee awareness about allergies especially taking into consideration their health history during occupational health visits (including annual PPD/TB tests and tetanus updates) of all Animal Resource staff. Student participants in teaching labs using rats or frogs receive an orientation by the veterinary staff regarding allergen awareness including distribution of the UHS "Animal Allergy" brochure and information on seeking medical guidance.

Animal Use Protocols identify all substances, including chemicals, biologicals, and radiation hazards, that will be used on animals. Each protocol is reviewed by the appropriate safety groups (see above) to determine whether the use of hazards has been proposed. If a substance is determined to present a hazardous, the appropriate safety group(s) notifies the PI, the Animal Resource, and UCAR in writing of the risk of the agent and what precautionary measures need to be followed for its safe use and notification of others who may come in contact with the exposed animals. A copy of this letter is attached to the Animal Use Protocol for reference.

As part of the requirements for use of any of these hazardous substances in the Animal Resource, the PI must submit a "Notification of Intent to Use Hazards" form to the Animal Resource before using the substance. This form is maintained by the Animal Resource, a notice of the hazard (nature of risk, e.g., Chemical Risk, Biosafety Level, etc.) agent is posted on the animal room door (ABSL2 agents), and cage cards are labeled with the hazard. ABSL1 or chemical hazards cage cards are also labeled with the hazard.

Specific hazards posed by use of certain species of animals are evaluated by the Occupational Health Unit of the University Health Service and by the Biosafety Officer, who set the standards for health monitoring of users, and track injuries. Staff members who interact with animals receive species specific training in PPE and handling.

Employees are trained on precautions to be taken during routine work with animals, including

proper PPE, handling, notification of use of hazards and reporting of accidents during the initial training that they receive before they are allowed any contact with animals. This includes information on precautions to be taken during pregnancy, illness, decreased immunocompetence or any other health issues of concern, and includes recommendations for them to address these issues with the University Health Service Occupational Health Unit or their personal physicians. Additional information about allergies is provided to each laboratory that uses animals, in multiple places in the Animal Resource, and is discussed by the Research and Training Coordinators during laboratory visits and inspections. In addition, 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 UHS and EHS who perform workplace evaluations occur to decrease incidence of injuries.

In the case of injury or chemical/biological exposure, the affected individual has been informed through training to contact University Health Services, or if necessary to go to the Emergency Department to seek treatment. A report is made by the staff member to University Health Service's Employee Health Group of all workplace injuries.

In case of accidents or injury afterhours, the person is instructed to contact Campus Security and if necessary seek medical treatment at Emergency Department at Strong Memorial Hospital, or University Health Services (River Campus). Important contact numbers are provided in quick access flipbook that the university places adjacent to telephones.

All staff who have contact with animals also receive training about work place hazards and accidents/injuries during their initial orientation provided by UCAR, and then during their mandated annual laboratory refresher training that is managed by Environmental Health & Safety.

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

(see Part X)

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

<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 methods & procedures 	<ol style="list-style-type: none"> 1. Animal Resource Orientation (one hour meeting) and certification quiz are required for all new employees listed on UCAR approved protocols. At this time, the Research and Training Coordinators identifies investigators requiring targeted training (e.g. nonhuman primate workers, mouse breeding colonies) as well as informs new staff about additional hands-on training opportunities offered by UCAR and the veterinary staff. 2. 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. 3. All new personnel are required to review The Collaborative Institutional Training Initiative (CITI) on-line program that includes courses for researchers, staff and students; IACUC members, species specific training (fish to nonhuman primates); reducing pain & distress in the laboratory mouse and rat; and aseptic surgery. The UCAR office has additional
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	<p>training for birds, ferrets, working safely with nonhuman primates, mole rats and degus.</p> <p>4. Rodent Breeding Colony Management Training on-line course is required for all staff approved to manage breeding colonies of mice and rats. Completion of a quiz is required.</p> <p>5. Microisolator Technology training (on-line) is required for all staff handling mice and/or rats housed in Microisolator barrier rooms. Completion of a quiz is required.</p> <p>6. Carbon dioxide inhalation on-line training is required for all staff euthanizing rodents using (CO₂). Completion of a quiz is required.</p> <p>7. All personnel who perform recovery surgery (rodents & birds) are required to complete the "Rodent Survival Surgery Workshop" offered by the UCAR staff and/or the Department of Comparative Medicine.</p> <p>8. All new hires with no experience working with rodents must attend a hands-on workshop designed to cover sexing, handling and injections.</p> <p>9. Animal Resource species-specific one-on-one training in anesthesia, surgery, euthanasia and sample administration or collection is available through DCM upon request.</p> <p>10. The UCAR Research & Training Coordinators visits all laboratories where surgeries occur at least every six months and assists research staff with accessing additional training opportunities.</p> <p>11. 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.</p> <p>12. If an individual fails any component of the IACUC required training or as the result of non-compliance within the Vivarium or a laboratory, UCAR will require that the Principal Investigator assign a mentor to assist in the training for a time period determined by the Committee before vivarium access is granted.</p>
<p>The concept, availability, and use of research or testing methods which limit the use of animals or minimize animal distress</p>	<p>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.</p> <p>2. The Responsible Care and Use of Laboratory Animals UCAR Manual, available on-line for all employees, includes a chapter on "Biotechnology" describing the refinement in protocols including proper techniques for euthanasia, manual and chemical restraint, administration of anesthetics, analgesics, and sample administration and collection.</p>
<p>Proper use of anesthetics, analgesics and tranquilizers</p>	<p>1. The Responsible Care and Use of Laboratory Animals UCAR Manual, available on-line for all employees, includes a</p>

	<p>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.</p> <p>2. "Aseptic Surgery" and species specific 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> <p>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.</p> <p>4. The UCAR Research & Training Coordinators 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.</p> <p>5. Animal Resource species-specific one-on-one training in anesthesia, analgesia and euthanasia is available upon request.</p>
<p>Methods whereby deficiencies in animal care and treatment are reported, including deficiencies reported by any employee of the facility.</p>	<p>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 without fear of reprisals and feedback may be provided by UCAR.</p> <p>2. The UCAR website includes information about methods for reporting concerns about animal welfare.</p> <p>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>
<p>Utilization of services (e.g. National Agricultural Library, National Library of Medicine) available to provide 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>1. All new staff (research and animal care) are required to attend the Animal Resource orientation where the alternative concept, including techniques in refinement, 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> <p>2. 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.</p>
<p>Training for IACUC Members</p>	<p><i>1. New Members are required to take CITI on-line training for IACUC members.</i></p> <p><i>2. All Community members are required to take on-line CITI IACUC Community Member.</i></p> <p><i>3. New members are provided an orientation to the Animal Use Protocol and how it should be reviewed by the Chair.</i></p> <p><i>4. All members are encouraged to attend IACUC 101 and IACUC 201, and other PRIM&R or SCAW training offered.</i></p>

	<p>5. All members are encouraged to attend Webinars available from OLAW, USDA and NABR.</p> <p>6. New members are given a PDF (or hard copy) of the following documents for review:</p> <ul style="list-style-type: none"> • <i>Guide for the Care and Use of Laboratory Animals, 8th ed.</i> • <i>PHS Policy on Humane Care and Use of Laboratory Animals</i> • <i>Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research</i> • <i>OLAW IACUC Guidebook</i> • <i>AVMA Guidelines for Euthanasia of Animals: 2020 Edition</i> • <i>Animal Welfare Act and Regulations 2017</i> • <i>University of Rochester PHS Assurance</i> • <i>University of Rochester AAALAC Program Description</i> • <i>List of important websites (including OLAW, USDA/APHIS)</i>
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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 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 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, **Mark B. Taubman, MD**.
 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, Mark Taubman, MD.
 - 5. Any minority views filed by members of the IACUC

- 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.