

UNIVERSITY OF ROCHESTER
ASSURANCE RENEWAL - A-3292-01

Animal Welfare Assurance for Domestic Institutions

I, Mark B. Taubman, M.D., as named Institutional Official for animal care and use at the 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. 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, 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

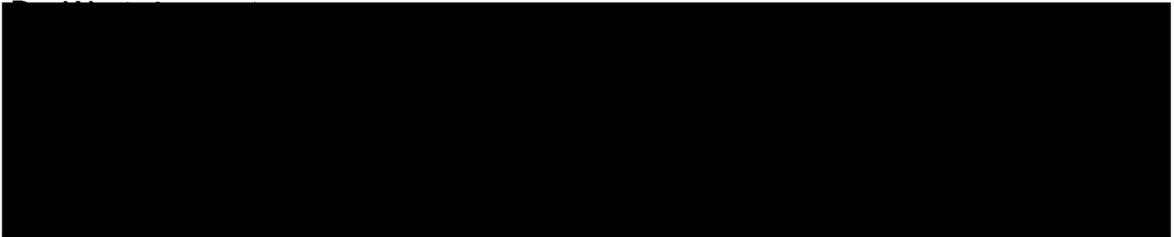
- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are shown in the attached organizational chart. The Attending Veterinarian reports directly to the Institutional Official for all regulatory purposes, including animal welfare, OLAW, USDA, or AAALAC concerns. Likewise, the IACUC, through the IACUC chair reports directly to the Institutional Official.
- B. Veterinary care is provided by a staff consisting of the Attending Veterinarian and the 3 additional full time veterinarians listed below. During regular hours of operation at least one veterinarian is always available for consultation and emergency care. After regular hours there is always a veterinarian on-call who can be contacted by pager. The pager number is posted on the door of each animal room and is also available on the Animal Resource answering machine.

The Attending Veterinarian is routinely available for consultation by cell phone or email, even if he is not physically present at the University. If the Attending Veterinarian is unavailable, Dr. Moorman-White, Director of Regulatory Compliance & Quality Assurance, or another veterinarian appointed by Dr. Wyatt for that purpose, would fill his regulatory role. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: Jeffrey D. Wyatt

Qualifications

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



Authority: 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.

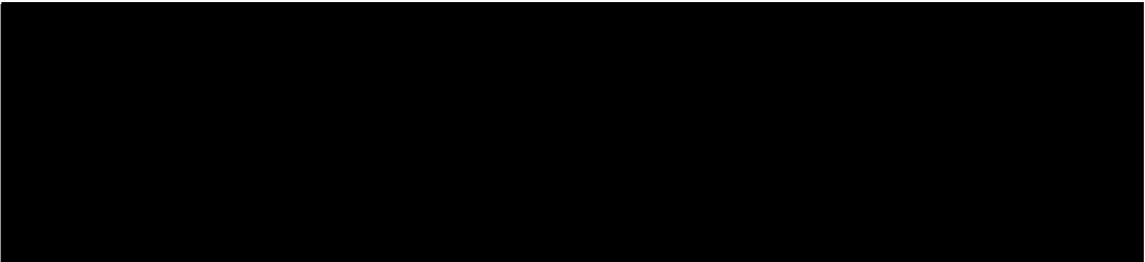
Time contributed to program: Full time employee

2) Name:



Qualifications

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



Responsibilities: [Redacted] is the Director of Regulatory Compliance & Quality Assurance of the Animal Resource and clinical veterinarian.

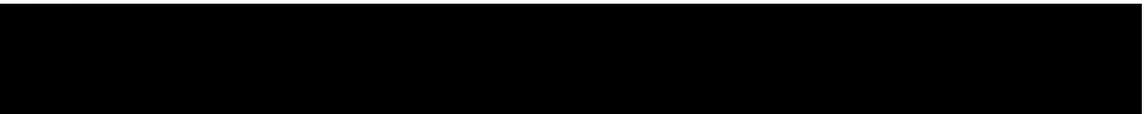
Time contributed to program: Full time employee

3) Name:



Qualifications

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





Responsibilities: [REDACTED] the Chief of Small Animal Medicine & Research and clinical veterinarian.

Time contributed to program: Full time employee

4) Name: [REDACTED]

Qualifications

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



Responsibilities: [REDACTED] is the Chief of Large Animal Medicine & Research and clinical veterinarian.

Time contributed to program: Full time employee

C. The IACUC (called the University Committee on Animal Resources or UCAR) 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. It is composed of 18 voting members, including the Attending Veterinarian, one additional veterinarian, 12 scientists who have experience with animal research, 2 non-scientists, and 2 Community (public) members who are not laboratory animal users and have no affiliations with the University. The IACUC and its membership meet the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and degrees, professions, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1) The IACUC at a convened meeting, will review at least every six months the Institution's Program for Human 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 Semiannual Program Evaluation reviews all areas of the Animal Care and Use Program. The structure of the meeting is based on the OLAW checklist. Before the meeting, all members of the IACUC receive a copy of the Assurance, the Guide, PHS Policy, and a spreadsheet providing the complete findings of the facility inspections done for the 6-month period being reviewed.

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 guidelines, exemptions to either IACUC policies and guidelines, or to the Guide, granted by the IACUC to investigators)
- **Veterinary Care Program** (including activities of the Department of Laboratory Animal Medicine (DLAM))
- **Environmental Enrichment**
- **Training Program** (including training of IACUC members)
- **Occupational Health and Safety Program.** These reports include reports from University of Rochester Risk Management and Environmental Safety (URMES) 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.
- **Security**, 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 Laboratory Animal Medicine SOP's are kept in the Animal Resource Office for reference by Committee members.

- 2) The IACUC will inspect at least once every six months all the institution's animal facilities, including satellite facilities, using the Guide as a basis for the evaluation. 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 IACUC meetings, and an email is sent to all IACUC 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. 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.

- 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 Coordinator and UCAR office.
 - Reports are submitted to IACUC by University of Rochester Risk Management and Environmental Safety (URMES), University Health Services and U of R Security 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, 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 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 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. 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.

- 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 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 Protocols 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 IACUC Chair, the UCAR office staff will assign 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.

Committee meetings are normally held once a month. A quorum must be met before voting on protocols or any other issues.

If any committee member requests full committee review (FCR) 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 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 quorum of the full committee 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 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 member review process (DMR).

Designated reviewers are assigned by the UCAR office staff, with advice from the IACUC 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 IACUC 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 their questions and comments and take them into consideration.

The procedure at the University for Designated Member Review requires that the IACUC chair appoint 2 IACUC 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 re-submitted, 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. 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.

- 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:

- In 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 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; and
- any changes deemed significant by one or more reviewers

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, the IACUC has delegated review of the modification to the IACUC 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 the IACUC, an expedited modification process may be used. The expedited review process is only used to review modifications that, in the opinion of the IACUC chair and a veterinary reviewer, require a quick response. Examples of such modifications might include substitution of an anesthetic or euthanasia agent due to the unavailability of the approved agent, or the recommendation of a veterinarian that specialized care be provided for all animals undergoing a specific procedure. As with all other modifications, the decision for approval by the designated reviewers is listed in the IACUC meeting minutes for the next meeting.

After the IACUC 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 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 approval letters (titled Verification of Review and Approval) to the Principal Investigator. 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

Post approval monitoring is addressed by the Research and Training Coordinator who meets with investigators and their staff to review current approved protocols and view hands-on procedures.

Protocol Audits (all species)

Protocol Audits are performed regularly by the veterinary staff or animal care staff. The Protocol Audit Form with an investigator's name and protocol number along with a description of an observation at the cage level (staples, clipped fur, compound administered, etc.) is submitted to the IACUC. The UCAR staff verifies that the information matches the protocol or, if it does not,

informs the investigator (in writing) of any mismatches between the observation and the protocol. All Protocol Audits are discussed at monthly IACUC meetings.

Annual Reviews (all species)

Annual reviews are conducted for each protocol before its anniversary date, and are conducted in the same manner for all species, including species regulated by the USDA. 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 the IACUC. Annual protocol reviews also undergo an administrative review by the UCAR office staff. IACUC review and approval (or deferment to full committee review) of the annual protocol has been delegated to the IACUC Chair by the Committee. 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.

36 Month Reviews (all species)

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 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 Department of Laboratory Animal Medicine holding SOP beginning at the expiration date, and remain under that SOP until the IACUC 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 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 IACUC. A majority vote of a quorum of the IACUC 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 IACUC, and in consultation with the IACUC, ensures that any necessary corrective actions are taken. A report of the suspension and corrective actions is then prepared by the IACUC, 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 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. Several Occupational Health Professionals are involved in both planning and monitoring the program. Members of the University of Rochester Risk Management and Environmental Safety (URMES) Department that are directly involved include a Biosafety Officer (who is also a DVM), a Chemical Safety Officer who is a Certified Industrial Hygienist, and Radiation Safety Officer who is a Certified Health Physicist. The Director of the University Health Service's Occupational Health Unit is an MD.

Animal Use Protocols identify all substances, including chemicals, biologicals, and radiation hazards, that will be used on animals. Each protocol is reviewed by University of Rochester Risk Management and Environmental Safety (URMES) to determine whether the use of hazards has been proposed. If a substance is determined to present a hazard, the protocol is reviewed by a specialist, or in the case of biological hazards, by the Institutional Biosafety Committee, and the requirements for use of any of these hazards are provided in writing to the investigator, the Animal Resource and the IACUC. A copy 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 an "Intent to Use Hazard" form to the Animal Resource before using the substance. This form is maintained by the Animal Resource, a notice of the hazard is posted in the animal room, and cage cards are 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.

The following people are enrolled in the occupational health program:

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

Level of involvement is dictated by hazard identification and risk assessment (e.g. *Macacine herpesvirus 1* 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 cage-wash 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 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.

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. All these issues are addressed in the required Animal Resource Orientation, and are discussed in more detail in species specific training required for work with

each animal species. 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 Coordinator 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 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 there 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 for animal care technicians includes attending Animal Resource Orientation and they are provided with on the job training by senior animal care technicians. Animal Care technicians may participate in an in-house training course for AALAS technician certification (ALAT, LAT, LATG).

The training or instruction available to scientists, research 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. 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 IACUC approved 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. 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 for ten species; reducing pain & distress; and aseptic surgery. The UCAR office 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 and rats. 7. Microisolator Technology training (Blackboard on-line and hands-on) is required for all staff handling mice housed in Microisolator barrier rooms.
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	<ol style="list-style-type: none"> 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 a "Primate Anesthetist" course offered by the Department of Laboratory Animal Medicine. 11. All personnel who perform recovery surgery (rodents & birds) are required to complete the "Rodent Survival Surgery Workshop" offered by the UCAR staff and the Department of Laboratory Animal Medicine. 12. The UCAR Research & Training Coordinator visits all laboratories where surgeries occur at least every six months and assists research staff with accessing additional training opportunities. 13. 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. 14. If an individual fails any component of the IACUC required training or as the result of non compliance within the Vivarium or a laboratory, the IACUC 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>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" Animal Use Protocol 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.

	<ol style="list-style-type: none"> 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. 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 IACUC. 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 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>	<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, 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. 2. The IACUC 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 IACUC 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” Animal Use Protocol addressing all sections including familiarity with the availability of NAL and AWIC for addressing the alternative concept.
Training of IACUC members	<ol style="list-style-type: none"> 1. New members are required to take CITI training for IACUC members. 2. All Community members are required to take CITI “IACUC Community Member”. 3. New members are provided an orientation to the Animal Use Protocol and how it should be reviewed, by the Chair. 4. All members are encouraged to attend IACUC 101 and IACUC 201, and other PRIMN&R or SCAW training offered. 5. All members are encouraged to attend Webinars available from OLAW, USDA and NABR. 6. New members are given PDF or hard copies of the following documents for review: <ul style="list-style-type: none"> • Guide for the Care and Use of Laboratory Animals, 8th ed. • PHS Policy on Humane Care and Use of Laboratory Animals • Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research • OLAW/ARENA IACUC Guidebook • AVMA Guidelines for Euthanasia of Animals: 2013 Edition • Animal Welfare Act and Regulations “Blue Book” September 2013 • USDA Animal Welfare Inspection Guide • University of Rochester PHS Assurance • University of Rochester AAALAC Program Description • List of important websites (including OLAW and USDA/APHIS)

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.

- (1) 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 Taubman, M.D., Ph.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 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

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

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official
Name: Mark Taubman, M.D. Ph.D.
Title: Senior Vice President for Health Sciences, CEO of Medical Center and Strong Hospital

Name of Institution: University of Rochester	
Address: <i>(street, city, state, country, postal code)</i> University of Rochester 601 Elmwood Avenue, PO Box 706 Rochester, NY 14642	
Phone: [REDACTED]	Fax: [REDACTED]
E-mail: Mark_Taubman@urmc.rochester.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 05/09/2014
B. PHS Approving Official <i>(to be completed by OLAW)</i>	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

VIII. Membership of the IACUC

Date: 05/07/2014	
Name of Institution: University of Rochester	
Assurance Number: A-3292-01	
IACUC Chairperson	
Name*: Suzanne Y. Stevens	
Title*: Associate Professor of Neurobiology & Anatomy	Degree/Credentials*: Ph.D.
Address*: <i>(street, city, state, zip code)</i> University of Rochester, UCAR Dept 601 Elmwood Avenue, Box 674 Rochester, New York 14642	
E-mail*:suzanne_stevens@urmc.rochester.edu	

Phone* [REDACTED]

Fax* [REDACTED]

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
1 Jeffrey Wyatt	DVM, MPH, DACLAM	Executive Director, Professor and Chair of Comparative Medicine	Attending Veterinarian, V
15 Suzanne Stevens	Ph.D.	IACUC Chair, Assoc. Prof. of Neurobiology and Anatomy	Scientist, V
2	DVM, CPIA	Assoc. Prof. of Comparative Medicine, Director of Regulatory Compliance and Quality Assurance	Veterinarian, V
Mark Taubman	M.D.	Dean, School of Medicine and Dentistry, IO	Ex-officio, N
4	Ph.D.	Asst. Prof. of Pediatrics	Scientist, V
5	B.S., M.S.	Outside Member, Retired Teacher, Monroe #1 BOCES	Community (public) member, V
7	Ph.D.	Professor, Biochemistry and Biophysics	Scientist, V
8	B.S., LVT, LATG, CPIA	Compliance Analyst Trainer/UCAR Research & Training Coordinator	Nonscientist, V
12	Ph.D.	Asst. Prof., Biomedical Genetics, Oral Biology	Scientist, V
13	Ph.D.	Assoc. Prof., Surgery	Scientist, V
16	Ph.D.	Asst. Prof., Obstetrics and Gynecology, IACUC Vice-Chair	Scientist, V
17	Ph.D.	Prof., Environmental Medicine and Radiation Oncology	Scientist, V
18	Ph.D.	Res. Assoc. Prof., Environmental Med.	Scientist, V
20	Ph.D.	Asst. Prof., Otolaryngology	Scientist, V
23	DVM	Senior Instructor, Chief of Large Animal Medicine and Research, Alternate for #1 or #2, voting as	Veterinarian, V (as alternate only)

		alternate only	
24	Ph.D.	Assoc. Prof., Neurobiology and Anatomy	Scientist, V
25	Ph.D.	Research Asst. Prof., Brain and Cognitive Sciences, Alternate for #25, voting as alternate only	Scientist, V (as alternate)
26	Ph.D.	Professor, Brain and Cognitive Sciences, Alternate for #25, voting as alternate only	Scientist, V (as alternate)
27	---	Outside Member, Retired Teacher	Community (public) member, V
28	DVM	Assoc. Prof., Chief of Small Animal Medicine and Research, Alternate for #2, voting as alternate only	Veterinarian, V (as alternate)
29	M.D., Ph.D.	Asst. Prof., Orthopaedics	Scientist, V
30	M.S.L.S.	Biomedical Sciences Librarian	Nonscientist, V
31	Ph.D.	Asst. Prof., Eastman Dental Center	Scientist, V

IX. Other Key Contacts (optional)

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

X. Facility and Species Inventory

Date:12/2/2013			
Name of Institution: University of Rochester			
Assurance Number: A-3292-01			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
1V	53,587	Frogs	1
		Mouse cages	8677
		Rat cages	70
		Canaries	750
		Rabbits	42

		Cats	16
		Dogs	3
		Rhesus macaques	34
		Cynomolgus macaques	7
		Squirrel Monkeys	4
		Pigs	1
		Turtles	2
		Gerbils	1
		Sheep	4
		Calves	1
		Parakeets	10
2V	17,713	Mouse cages	8840
3V	3,560	Mouse cages	167
		Rats cages	16
4V	23,000	Mouse cages	2185
		Rats cages	12
		Frogs	10
7V	2,748	Rhesus macaques	16
		Rats	55 (spring only)
8V	900	Mouse cages	8
11S	410	Frogs	1300
14S	300	Naked Mole Rats	100
15S	300	Mice	5
16S	300	Mice	30
17S	200	Blind Mole Rats	6

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