

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 and/or NSH. This Assurance is applicable to all research and covers only those facilities and components listed below.

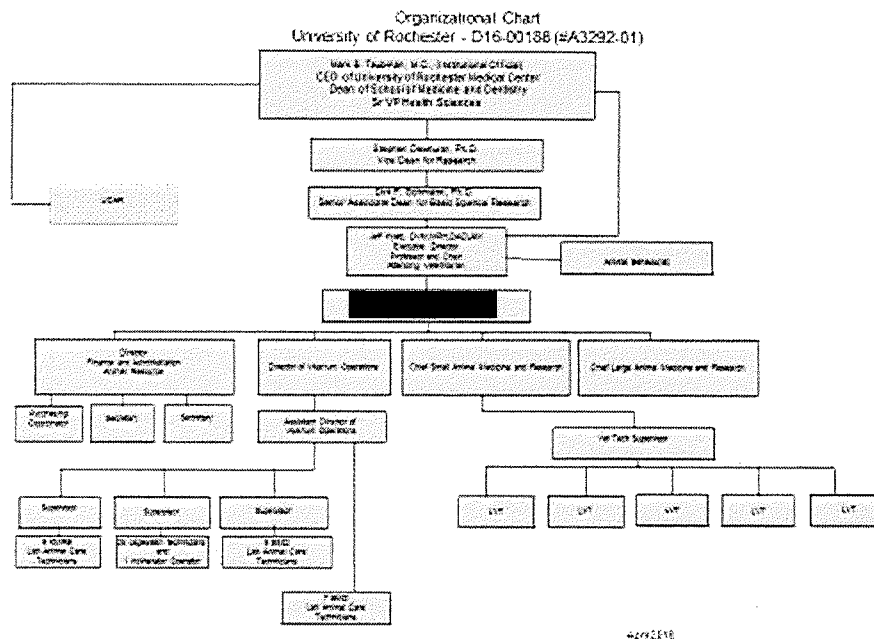
- A. This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by PHS, NSF or any other agency.

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 three 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 business 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, [REDACTED] 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:

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 35 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:



Responsibilities:

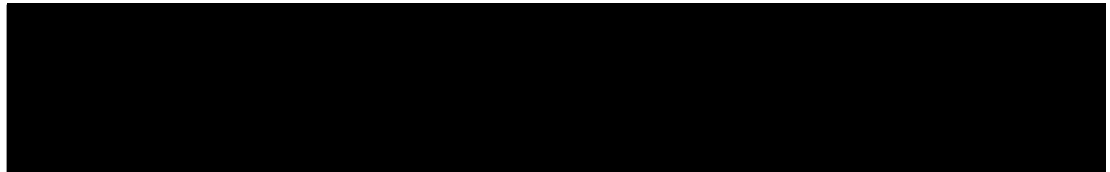
[REDACTED] is the Director of Regulatory Compliance and Quality Assurance of the Animal Resource and clinical veterinarian.

Time contributed to program: Full time employee

3) Name: [REDACTED]

Qualifications

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



Responsibilities:

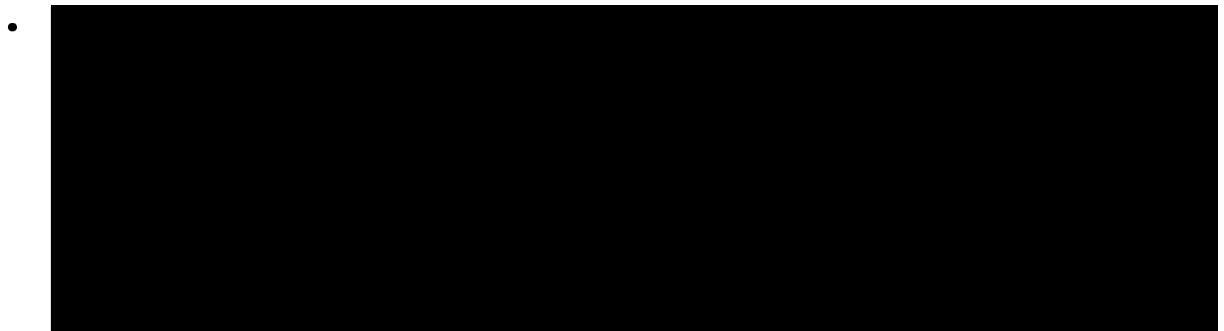
[REDACTED] is the Chief of Small Animal Medicine and Research and clinical veterinarian.

Time contributed to program: Full time employee

4) Name: [REDACTED]

Qualifications

- Degrees: DVM



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

Time contributed to program: Full time employee

- C. The IACUC (referred to as 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 22 voting members, including the Attending Veterinarian, three additional veterinarians (2 serve as alternates), 13 scientists who have experience with animal research (1 serves as an alternate), 2 nonscientists, 3 members (1 serves as an alternate) and 1 Community (public) member who is not a laboratory animal user and has no affiliation 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.

(see Part VIII.)

- D. The IACUC will:

- 1) The IACUC at a convened meeting, will review at least every six months the Institution's Program for Humane Care and Use of Animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The 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 Comparative Medicine (DCM))
- **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.
- **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) The IACUC will 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. 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 UCAR by University of Rochester Risk Management and Environmental Safety (URMES), University Health Services 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, 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 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. The UCAR Chairperson appoints/selects one or more qualified UCAR members to serve as the designated reviewer(s).

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).

The UCAR Chairperson appoints/selects one or more qualified UCAR members to serve as the designated reviewer(s). 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 2 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. If a member has a conflict of interest or recuses themselves from the vote, the UCAR decision is made by a vote of a simple majority (51%) of the quorum.

- 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 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-OD-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 VVC 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.

- 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 (PAM)

Post approval monitoring is ongoing and addressed by the Research and Training Coordinator and an assistant 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 will often be present at the visit. 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.

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 (e.g., staples, clipped fur, compound administered, etc.) is submitted to UCAR. 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 UCAR 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 UCAR. 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 UCAR 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)

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 Division of Comparative Medicine's holding SOP beginning at the expiration date, and remain under that SOP 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 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 UCAR. 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 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
- UCAR 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 UCAR 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.

(see Part X.)

- 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. Animal Resource Orientation (two hour meeting) and certification quiz are required for all new employees listed on UCAR 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 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; reducing pain & distress in the laboratory mouse and rat;
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	<p>and aseptic surgery. The UCAR office has additional training for ferrets.</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.</p> <p>5. Microisolator Technology training (on-line and hands-on) is required for all staff handling mice and/or rats housed in Microisolator barrier rooms.</p> <p>6. Carbon dioxide inhalation on-line training and quiz is required for all staff euthanizing rodents using (CO₂).</p> <p>7. "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.</p> <p>8. All personnel that administer anesthesia to primates are required to complete a "Primate Anesthetist" course offered by the Department of Laboratory Animal Medicine.</p> <p>9. 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 Comparative Medicine.</p> <p>10. All new hires with no experience working with rodents must attend a hands-on workshop designed to cover sexing, handling and injections.</p> <p>11. Animal Resource species-specific one-on-one training in anesthesia, surgery, euthanasia and sample administration or collection is available upon request.</p> <p>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.</p> <p>13. 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>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, 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>
The concept, availability, and use of research or testing methods which limit the use of animals or minimize animal distress	<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 "Biomethodology" describing the refinement in protocols including proper techniques for euthanasia, manual and chemical restraint, administration of anesthetics, analgesics, and sample administration and collection.</p>
Proper use of anesthetics, analgesics and tranquilizers	<p>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.</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 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.</p> <p>5. Animal Resource species-specific one-on-one training in anesthesia, analgesia and euthanasia is available upon request.</p>
Methods whereby deficiencies in animal care and treatment are reported, including deficiencies reported by any employee of the facility.	<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>
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>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</p>

	set of instructions written by the Medical School reference librarian who is a voting UCAR member.
Training for IACUC Members	<ol style="list-style-type: none"> 1. New Members are required to take CITI on-line training for IACUC members. 2. All Community members are required to take on-line 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 PRIM&R or SCAW training offered. 5. All members are encouraged to attend Webinars available from OLAW, USDA and NABR. 6. New members are given a PDF or hard copy 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 IACUC Guidebook • AVMA Guidelines for Euthanasia of Animals: 2013 Edition • Animal Welfare Act and Regulations "Blue Book" November 2013 • USDA Animal Welfare Inspection Guide • University of Rochester PHS Assurance • University of Rochester AAALAC Program Description • List of important websites (including OLAW, 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. 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:	University of Rochester 601 Elmwood Ave. PO Box 706 Rochester, NY 14642
Phone:	[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:

Mark Stodgell

Date:

4/30/18

B. PHS Approving Official (to be completed by OLAW)

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) 451-5672

Signature:

Date:

Assurance Number:

Effective Date:

Expiration Date:

VIII. Membership of the IACUC

Date: 12/1/2017

Name of Institution: University of Rochester

Assurance Number: D16-00188 (#A3292-01)

IACUC Chairperson

Name*: Christopher J Stodgell

Title*: Assoc. Prof., Obstetrics and Gynecology

Degree/Credentials*: Ph.D.

Address*:

University of Rochester, UCAR Department
601 Elmwood Ave, Box 674
Rochester, New York 14642

E-mail*: Chris_Stodgell@URMC.Rochester.edu

Phone*: [REDACTED]

IACUC Roster

Name of Member/
Code**

Degree/
Credentials

Position Title***

PHS Policy Membership
Requirements****