DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
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Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

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Division of Assurances
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October 21, 2011

Reference: Renewal Assurance **#A3414-01**

James Trempe, Ph.D.
Vice President for Research
University of Toledo
3000 Arlington Avenue
Toledo, Ohio 43614

Dear Dr. Trempe:

I am pleased to inform you that The Office of Laboratory Animal Welfare (OLAW) reviewed and approved the renewal of your institution's Animal Welfare Assurance (Assurance) that was submitted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), as revised August 2002.

Your Assurance renewal, number **A3414-01**, became effective on **October 21, 2011** and expires on **October 31, 2015**. This Assurance supersedes all previously issued Assurances—both for previous Assurances 3414-01 and 3264-01; the latter is inactive effective today. Please include the Assurance number in all correspondence to OLAW. A copy of the Assurance signature page is enclosed.

The Assurance is a key document in defining the relationship of your Institution to the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that a Report to OLAW is required at least once every 12 months. The reporting period, unless requested otherwise in writing, is the calendar year. Reports, for the previous calendar year, are due **January 31**.

If we may be of further assistance, please do not hesitate to contact me or Dr. Parlett.

Thank you for your attention in these matters.

Sincerely,

Venita B Thornton

for Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare, NIH

Enclosure

cc:
Dr. Andrew Beavis
Dr. Phillip Robinson

A3414-01

ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, Dr. James Trempe, Vice President for Research, as named Institutional Official (IO) for animal care and use at The University of Toledo (UT), hereinafter referred to as 'Institution', by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

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

"Institution" includes the following branches and major components of The University of Toledo: All components (Colleges, Schools, Centers, Departments, etc) that are physically located on the University's Main Campus and Health Science Campus. Both Campuses are located in Toledo, Ohio. The distance between the two campuses is approximately 4 miles. Institution also includes the University's Lake Erie Center for Great Lakes Studies, which is located 10 miles NE of the Main Campus. There are no other off-campus satellite facilities and/or other covered components.

II. INSTITUTIONAL COMMITMENT

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

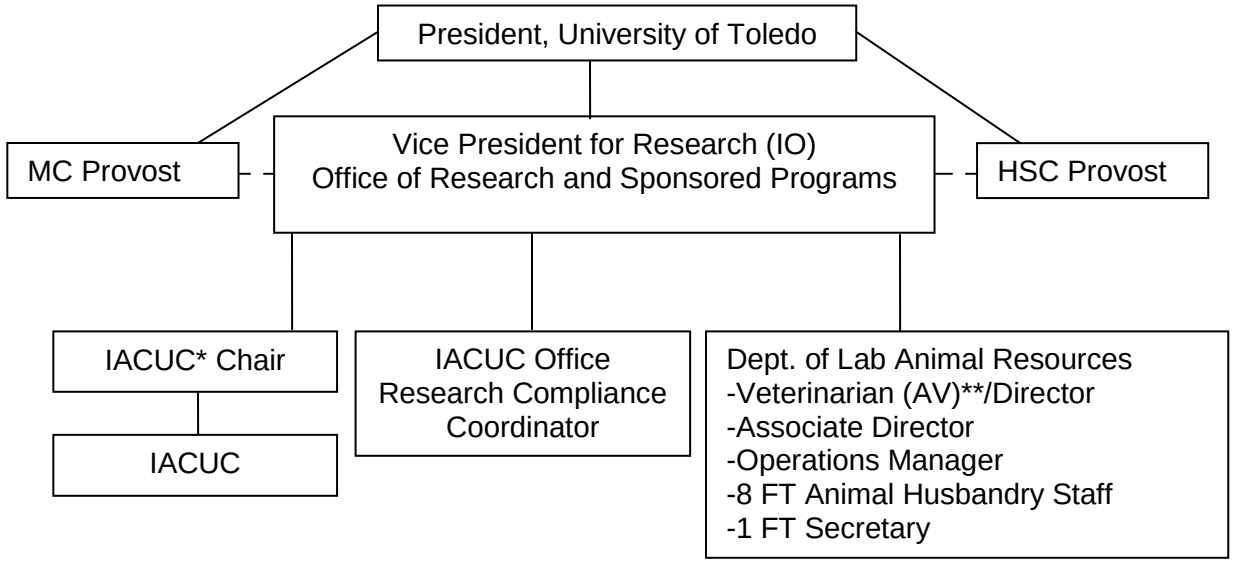
B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals in accordance with the "Guide for the Care and Use of Laboratory Animals" ("Guide").

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

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



MC = Main Campus
HSC = Health Science Campus
* Institutional Animal Care and Use Committee
** Attending Veterinarian

Note: As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.

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

Name: Phillip T. Robinson, DVM, Director, Dept. of Laboratory Animal Resources (DLAR)
Qualifications:

- Degrees: BS, MS, DVM
  Board Certification: Diplomate, American College of Zoological Medicine
- Training and/or experience in laboratory animal medicine: Dr. Robinson completed a veterinary internship in zoological medicine at the San Diego Zoo where he served on the staff as Associate Veterinarian and Director of Veterinary Services for a total of 15 years. He then was a laboratory animal veterinarian at the University of California, San Diego for ten years, where he also served for ten years as Director of Veterinary Services and Animal Resources. From 1998-2008 he was a research

veterinary consultant and clinical companion/exotic animal veterinarian in private practice. Since 2008, he has been Attending Veterinarian and Director of Laboratory Animal Resources at The University of Toledo. Dr. Robinson has published over 100 articles on veterinary medicine and animal biology.

Authority: Dr. Phillip T. Robinson has direct program authority and responsibility for the Institution's animal care and use program, including the authority to implement the PHS Policy and the recommendations of the "Guide", and is the designated Attending Veterinarian (AV)

Time Contributed to Program: Dr. Robinson is a full-time employee of the University. Approximately 100% percent of his time is contributed to the animal care and use program.

Name: Timothy A. Reichard, DVM

Qualifications:

- Degrees: MS, DVM
- Training and/or experience in laboratory animal medicine: Dr. Reichard completed an internship in zoological medicine at the San Diego Zoo and San Diego Wild Animal Park in California before joining the staff of the Toledo Zoo in 1983, and remained there as chief veterinarian until 2007. He has been a consulting veterinarian to private non-domestic animal facilities, and directs the animal health technology program at Stautzenberger College in Toledo, OH. Dr. Reichard is experienced in the medical and husbandry care of a wide range of non-domestic animal species, including small mammals, primates, swine and ruminants. In the past he has served as a consultant to the University of Toledo IACUC. He has provided on-call veterinary service to the UT animal care and use program in the past.

Responsibilities: Provides relief and emergency animal care to research animals at the University in the absence of the Attending Veterinarian.

Time Contributed to Program: Time as an independent contractor varies according to the schedule of the Attending Veterinarian and any special needs in the animal research program.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The President, as Chief Executive Officer (CEO), has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing.

The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations (**Attachment A**).

D. The IACUC will:

1. Review at least once every six months the Institution's program for humane care and use of animals, using the “Guide” as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

Program review is conducted by a subcommittee of the IACUC consisting of at least 3 members. All other IACUC members are apprised of the inspection schedule and are invited to participate; no member will be willfully excluded from participating in any portion of the reviews. The Committee uses the “Guide” and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee uses the OLAW program review checklist. The evaluation will include, but not necessarily be limited to a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care; d) Assessment of Personnel Qualifications; e) Occupational Health and Safety; and f) disaster planning. In addition, the evaluation will include a review of the Institution’s PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to health and safety of animals or personnel.

2. Inspect at least once every six months all of the Institution’s animal facilities, including satellite facilities, using the “Guide” as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

All IACUC members are apprised of the inspection schedule and welcomed to participate; no member will be willfully excluded from participating in any portion of the inspections. The inspection involves visual evaluation of physical spaces related to storage areas, procedure areas, and laboratories where animal surgical manipulations are conducted. Equipment used for confining and transporting of the animals is also inspected. The Committee uses the “Guide” and other pertinent resources, e.g., PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee uses the OLAW sample checklist. If deficiencies are noted, the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one which, consistent with PHS Policy, and in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health and safety of the animals. In addition, the inspection team audits a sample of active IACUC protocols that include potentially painful or distressful procedures (e.g., UT Pain or Distress Category B or C, i.e., USDA pain category D and E). These protocol audits are a face-to-face discussion with the investigative staff in facilities significant to animal use (e.g., the laboratory). Protocol audits encompass protocols from all three pain and discomfort categories each 6 months. The facilities and audit inspection commentary are made available to the entire IACUC at a subsequent convened meeting.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

A written report of the program evaluation, facilities inspection, and the audited protocols will be prepared by the evaluation team(s). Improvements will be noted. The reports will contain a description of the nature and extent of the Institution's adherence to the "Guide" and the PHS Policy, identify specifically any departures from the provisions of the "Guide" and the PHS Policy, and state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the Institution's facilities are accredited by AAALAC International the report will identify those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. The completed reports will be submitted to the Institutional Official within 90 days following the completion of the evaluation. The Institutional Official will be notified of significant deficiencies identified within 15 days.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

Concerns regarding animal care, use/abuse, etc. reported by an individual are addressed. The institution has an Academic and Scientific Misconduct Policy, Policy # 3364-70-21 and a UT Anonymous Reporting Line and website provided by Ethics Point. Furthermore, a statement encouraging any person to report animal care, use/abuse, etc. including a statement protecting the "whistleblower" identity is permanently posted on the Animal Research section of the UT Research and Sponsored Programs (RSP) website, in addition to being posted within each animal facility. Reported concerns may initially be directed to a subcommittee of the IACUC established to investigate these concerns. The subcommittee is made up of at least two IACUC members without a conflict of interest. Typically, the subcommittee includes the IACUC Chair and the Attending Veterinarian. The subcommittee will perform an investigation to determine if the concern has merit, and, if possible, may resolve the matter. However, all reported concerns, whether or not the subcommittee determined the concern to have merit and/or whether the subcommittee resolved the concern, will be brought to the attention of the full Committee. If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to, as warranted, the Institutional Official and OLAW.

5. Make written recommendations to the IO regarding any aspect of UT's animal program, facilities or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

Recommendations regarding any aspect of the Institution's animal program or facilities are discussed and developed by the Committee. The Committee's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter. Such documents are reviewed and approved by the Committee and then submitted to the IO.

6. Review and approve, require modifications in (to secure approval) or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for activities involving animals (protocols) are as follows:

The IACUC will meet at least once per month if any protocol applications are presented for review. If no protocols are presented for review, the IACUC may meet to discuss animal-related matters at the request of any member of the IACUC.

a. Protocol applications are submitted to the IACUC through the Research Compliance Coordinator in the office of the Vice President for Research. Prior to each convened meeting, IACUC members receive a list and a copy of protocol applications to be reviewed. A quorum must be present to discuss and vote on any protocol or issue. Primary and secondary reviewers are assigned to each protocol. The primary reviewer presents the protocol in detail, giving his/her comments and recommendations; the secondary reviewer adds his/her comments and recommendations. Following further committee discussion and deliberation, the protocol is either: 1) approved as submitted; 2) modifications and or clarifications are required to secure approval; 3) the protocol is deferred for major revisions; or 4) approval is withheld. If the primary and/or secondary reviewer is unable to attend the convened meeting, but provides his/her comments in writing, they may be read by any of the other IACUC members. However, if the committee believes that the protocol cannot be given adequate and fair review due to the absence of the primary and/or secondary reviewers, the review of the protocol is deferred until a future meeting.

b. Required modifications subsequent to full-committee review (FCR). When the IACUC requires modifications (to secure approval) of a protocol, such modifications are reviewed as follows:

1) FCR or designated-member review (DMR) following the procedures delineated above (FCR) and below (DMR).

2) DMR if approved unanimously by all members at the meeting at which the required modifications are developed, delineated AND if the entire current Committee has previously approved, in advance and in writing, that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

3) Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

c. Protocols may be handled based on the provisions for expedited review by a designated member review as set forth in Section IV, C.2 of PHS Policy. The protocol is sent to all IACUC members. If full committee review is requested by any member of the IACUC, the review of the protocol follows the procedures stated in section 6a. If no member requests full committee review, at least one member of the IACUC, designated by the Chair and qualified to conduct the review, reviews the protocol and has the authority to approve or require modifications (to secure approval) in the protocol, or request full committee review. Other IACUC members may provide the designated reviewer with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the designated-member review (DMR) method may not be conditioned. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

d. On occasion, consultants may be asked to assist in the review of complex issues in accordance with the provisions set forth in PHS Policy IV.C.3.

e. A member of the IACUC may not participate in the IACUC review or approval of an animal use protocol in which the member has direct or perceived conflict of interest except to provide information requested by the IACUC. A member of the IACUC who has a conflicting interest is recused from the meeting before deliberations on actions begin, is absent for the vote, and does not contribute to the quorum.

f. Protocols that have been approved by the IACUC may be subject to further appropriate review and approval by officials of UT. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

g. In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act, insofar as it applies to the activity, and that the protocol is consistent with the "Guide", unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

1) Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

2) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

3) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

4) The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

5) Medical care for animals will be available and provided as necessary by a qualified veterinarian.

6) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

7) Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

7. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C.

The written significant change (amendment) will be copied and distributed to the entire committee prior to the convened monthly meeting. The review will be handled according to the review process described in section III.D.6 above.

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

a. in the objectives of a study
b. from non survival to survival surgery;
c. resulting in greater discomfort or in a greater degree of invasiveness;
d. in the species or in approximate number of animals used[1];
e. in Principal Investigator;
f. in anesthetic agent(s) or the use or withholding of analgesics;
g. in the method of euthanasia; and
h. in the duration, frequency, or number of procedures performed on an animal

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC

procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

a. If a protocol is approved with no modifications, the original protocol will be officially endorsed by the IACUC Chair, or Chair designee, including approval and expiration dates and then forwarded to the investigator. If modifications are required or if a protocol is deferred, the investigator is informed in writing of the decision and any requested protocol modifications including a deadline for required modification to be submitted.

b. All actions on protocols are entered into the Research and Sponsored Programs database following a convened meeting. All approvals are also reported to DLAR.

c. The Institutional Official is notified by virtue of ready access to the IACUC meeting minutes.

9. Conduct continuing review of each previously approved, ongoing activity covered by this Policy at least once every 12 months, including a complete review in accordance with PHS Policy and IV.C. 1-4 at least once every three years. The IACUC procedures for conducting continuing review are as follows:

Protocol annual renewals are reviewed by the IACUC via the DMR process; all members are notified monthly of the specific protocols scheduled for renewal review, and one or more members evaluate the list of responses provided by the PI which are the basis for renewal review process. Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee (see also section D.2). Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the original IACUC approval date. If the PI wishes to continue the animal work beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6. above.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC may suspend an activity that it previously approved (e.g. if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the “Guide”, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy). The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the “Guide”, or the Institution's Assurance, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

E. The occupational health and safety program for personnel working in laboratory animal facilities or that have frequent contact with animals is as follows:

1. Administration/management. The UT Director of Safety and Health is responsible for the overall management (development, implementation, monitoring, etc) of the Occupational Health and Safety Program for Personnel involved in the care and/or use of laboratory animals.

2. Scope. The program covers all personnel involved in laboratory animal care and/or use at the University of Toledo. Participation in the program is mandatory. An "Exposure Profile" form must be submitted prior to approval of the protocol or Personnel Amendment. Some additional staff members are identified via their employment role at UT (safety personnel and facility management workers). They are supplied training materials appropriate for their Institutional role via the Laboratory Safety Program in the Safety and Health Department.

3. Hazard Identification and Risk Assessment. The program is based on hazard identification, risk assessment, and developing and implementing measures to minimize identified hazards and risks.

Potentially hazardous agents are identified during the IACUC protocol/amendment review process. Information regarding the agent is submitted to either the Institutional Biosafety Committee (IBC), the Radiation Safety Committee, or to Safety & Health for risk assessment. The IACUC office and DLAR office are notified of the results of the assessment. The appropriate precautions are then taken prior to working with the agent.

4. Health Histories and Evaluations. Animal research personnel enter the occupational health program through one of two avenues. Most participants are enrolled via their inclusion on IACUC protocol applications. IACUC approval of those applications is withheld until all personnel file an "Exposure Profile". Some additional staff members are identified via their employment role at UT (safety personnel and facility management workers). They are supplied training materials appropriate for their Institutional role via the Laboratory Safety Program in the Dept. of Safety & Health.

All personnel are then requested to complete a health history questionnaire. Each questionnaire along with an applicable individual hazard identification and risk assessment form are evaluated by the Occupational Medicine group. This process is completed initially and updated/repeated at least annually. The health history forms are maintained by the Occupational Medicine group.

5. Common Identified Hazards and Risks. Allergic reactions are among the most common conditions that adversely affect the health of personnel working with laboratory animals. Major sources of allergens include rodent urine and saliva.

6. Procedures in Place to Alleviate Hazards and Minimize Risks. Measures taken to minimize exposure include the following: education, protective clothing, gloves, and hand washing. To reduce aerosol exposure, the use of bedding dump stations, appropriate hoods or laminar flow benches/cabinets, and/or other respiratory protection, e.g., N95 masks, are worn when performing cage changing and/or handling dirty bedding.

7. Immunizations. Vaccination against tetanus is required. Individuals who decline vaccination must do so in writing. To date, less than 1 percent of covered personnel have declined vaccination.

8. Precautions taken during pregnancy, illness or decreased immunocompetence. Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals. If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/her health care professional, human resources, etc.

9. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used.

Personnel who are not involved in animal care and/or use, but who need to enter areas where animals are housed or used are also under the oversight of the UT Dept. of Safety & Health. Such personnel are also provided necessary training by DLAR to assure that their activities are compatible with facility work flow and practices.

The housekeeping staff is not routinely allowed access to the animal facilities. In situations where housekeeping, maintenance, or other non-animal care and use personnel must access the animal rooms, they are briefed on appropriate precautions and provided any appropriate PPE and are then permitted in for a limited amount of time. A member of the animal care staff will be available for escort if needed. If there is extensive or prolonged work to be done the animals are removed prior to the individuals being allowed into the room.

10. Availability and procedures for treatment in the event of bites, scratches, illness or injury. All Staff and students have free access to the health center in the event of an animal related injury, or bite. Treatment is free and records are maintained by the Health Center. If required, treatment is also available at the local hospital: The University of Toledo Medical Center located 1/8th or 5 miles away depending on research facility location.

11. Procedures/program for reporting and tracking injuries and illnesses. Occupational injuries are monitored by the Dept. of Safety & Health office. Report of all work-related illness and/or injury is mandatory. This requirement is covered and during OS & H training and Animal Care & Use Training. This program is referred to as the Occurrence Reporting System. The procedures involve filing a report and receiving medical

attention as appropriate. The Occurrence Report is then reviewed by the UT Safety & Health Committee for potential correction of unsafe practices or conditions. Needle stick injuries are also reported to the State of Ohio via a Sharps Injury Form Needlestick Report.

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

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

IACUC Training - Each IACUC member will be provided with a copy of the following:

1. The PHS Policy for the Humane Care and Use of Laboratory Animals;
2. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
3. The ARENA/OLAW IACUC Guidebook;
4. The AVMA Guidelines on Euthanasia;
5. A copy of this Assurance.

All members of the IACUC are required to complete the Essentials for IACUC Members Curriculum located at the American Association for Laboratory Animal Science website, www.aalaslearninglibrary.org or the Collaborative Institutional Training Initiative website, www.citiprogram.org

IACUC members regularly receive informational articles about animal welfare and research technologies that are distributed by the IACUC Chair and AV. All IACUC members visit the OLAW website at least annually and complete the IACUC tutorial module (initial visit) and familiarize themselves with the other pertinent modules and information, e.g., OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources.

Animal Research Personnel – The training or instruction available to scientists, and other personnel involved in animal research is as follows:

All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol. Adescription of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review. Any person needing additional protocol-specific training is identified during the review process and such required training will be a condition of approval of the protocol.

All persons involved in animal research will be required to attend an orientation seminar given by the IACUC Chair, Veterinarian, or other qualified individual(s), which covers the laws and regulations covering laboratory animal care and use with an emphasis on the

contents of the NRC Guide and the 3R's. The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). Specifically, training and instruction of personnel must include guidance in at least the following areas:

1. Humane methods of animal maintenance and experimentation, including:

    a. The basic needs of each species of animal;
    b. Proper handling and care for the various species of animals used by the facility;
    c. Proper pre-procedural and post-procedural care of animals; and
    d. Aseptic surgical methods and procedures;

2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:

    a. On appropriate methods of animal care and use;
    b. On alternatives to the use of live animals in research;
    c. That could prevent unintended and unnecessary duplication of research involving animals; and
    d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

Training of personnel involved in the animal research program involves small group and individual didactic and hands-on sessions and a locally produced "Information Manual for Investigators Using Animals". On-line training may be used and accepted in lieu of in-house training. Any use of on-line training to fulfill training requirements must be approved by the IACUC. Approval and completion of on-line training will be documented.

Specialized Training: Training in experimental methods, i.e., specific animal manipulations and techniques and in the care of new and nontraditional laboratory animal species, will be conducted based on the types of research being conducted and the species being used at the institution.

Note: For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu of some Institutional required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

Oversight of training adequacy is an on-going process. Assessments of problem areas are made by the DLAR staff based on the appearance of animals and associated records. In the event of procedural complications, gross necropsy assessments are available to investigatory staff. The IACUC conducts laboratory/protocol audits as a component of the semi-annual inspections. These target protocols that involve procedures with greater potential for pain or distress.

Animal Husbandry Personnel – In addition to the training provided to research staff, hands-on training is conducted and documented for the animal technician staff. This involves review and discussion of standard operating procedures, research animal anatomy wet labs, vendor demonstrations, CDs, and demonstrations and observations by senior staff and managers. The UT Safety and Health department provides safety information through presentations and via the intranet. The information covers such things as: UT's safety program, emergency preparedness, medical equipment safety, life safety, security management, infection control, and hazardous materials. The DLAR husbandry staff is also encouraged to obtain AALAS certification.

IV. INSTITUTIONAL STATUS

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the "Guide." Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category One (1)—accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. RECORDKEEPING REQUIREMENTS

A. UT will maintain for at least three years:

1. A copy of this assurance and any modification thereto, as approved by PHS.

2. Minutes of IACUC meetings, including records of attendance, activities of the committee and committee deliberations.

3. Records of applications, proposals and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, the Vice President for Research Administration.

5. Records of accrediting body determinations.

B. UT will maintain records that relate directly to applications, proposals and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. This Institution's reporting period is January 1 – December 31. After the end of the reporting period, the IACUC, through the Institutional Official, will submit an annual report to OLAW no later than **January 31**. The report will include:

1. Any change in the status of UT (e.g., if UT's AAALAC accreditation is revoked), any change in the description of UT's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, UT will submit a letter to OLAW stating that there are no changes.

2. Notification of the date that the IACUC conducted its semiannual evaluations of UT's program and facilities (including any satellite facilities) and submitted the evaluations to the Institutional Official, the Vice President for Research.

B. The IACUC, through the Institutional Official, will provide OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.

2. Any serious deviations from the provisions of the "Guide".

3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A.2. and VI.B above shall include any minority views filed by members of the IACUC

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: James Trempe, Ph.D.

Title: Vice President for Research

Name of Institution: University of Toledo

Address: 3000 Arlington Avenue, Toledo, OH 43614

Phone: 419 383 4252

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E-mail: james.trempe@utoledo.edu

Signature: James Trempe

Date: October 18, 2011

B. PHS Approving Official

for **Eileen M. Morgan**
Director, Division of Assurances, OLAW
National Institutes of Health
RKL1, Suite 360-MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Signature: Venita B Thornton am, MSL

Date: 10/24/11

C. Effective Date of Assurance: 10/21/11

D. Expiration Date of Assurance: 10/31/15

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