Animal Welfare Assurance

I, Dr. William S. Messer, Jr., Vice President for Research, as named Institutional Official (IO) for animal care and use at The University of Toledo (UT), 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 the National Science Foundation (NSF). This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: 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 four 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.

B. The following are other institution(s), or branches and components of another institution: None. Not Applicable.

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 (sub-award) 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 this Policy are as follows:

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:

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

   Qualifications:
   - Degrees: BS, MS, DVM, Michigan State University
   - Board Certification: Diplomat, 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) with unfettered access to all of the animals.

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.

2. Name: Timothy A. Reichard, DVM

Qualifications:
- Degrees: MS, DVM, Washington State University
- 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: In the absence of the Attending Veterinarian, provide emergency / back-up veterinary care to research animals at the University.

Time Contributed to Program: As needed. 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 IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The 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 of PHS Policy IV.A.3.b. Part VIII is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

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 two members.
• All other IACUC members are apprised of the program review schedule and are invited to participate; no member will be involuntarily 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. Institutional and Individual Responsibilities
  b. IACUC Membership and Functions;
  c. IACUC Experience and Training
  d. IACUC Records and Reporting Requirements;
  e. Husbandry and Veterinary Care;
  f. Assessment of Personnel Qualifications;
  g. Occupational Health and Safety,
  h. Emergency and Disaster Planning, and
  i. Security

• In addition, the evaluation may periodically 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 and animal surgical sites, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

• At least once every six months at least two voting members of the IACUC will inspect all of the institute’s animal facilities and animal surgical areas.

• All IACUC members are apprised of the inspection schedule and welcomed to participate; no member will be involuntarily excluded from participating in any portion of the inspections.

• The areas inspected include, but are not necessary limited to the following: Any and all buildings, room, area, enclosures, or vehicles, including satellite facilities, used for animal confinement, transportation, maintenance, breeding, or experiments inclusive of surgical manipulation.

• 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. These protocol audits are a face-to-face discussion with the investigative staff in facilities significant to animal use (e.g., the laboratory).

• The facilities and audit inspection commentary are made available to the entire IACUC.

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:

• 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.

• The reports identify specifically any departures from the provisions of the “Guide” and the PHS Policy, and state the reasons for each departure. If there are no departures the reports will so state.

• Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.

• Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such, i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.

• 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.

• The final reports that will be submitted to the IO will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
- The completed reports will be submitted to the Institutional Official in a timely manner following the completion of the evaluation.

- The Institutional Official will be notified of significant deficiencies identified within 15 days.

- Deficiencies will be tracked by the Research Compliance Officer and reported in the following semi-annual report, to ensure that they are appropriately resolved.

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 in writing to the Institutional Official and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate document. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally.

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:

- 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 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:

Submission, Pre-review, and Distribution

- Protocol applications are submitted to the IACUC through the Research Compliance Officer in the Research and Sponsored Programs office under the Vice President for Research. Protocols are submitted/received by email. When a database system becomes available, protocols will be uploaded by the submitting PI.

- IACUC members may be contacted for questions prior to submission.

- An administrative screening is performed that includes verification of form version and inclusion of a progress report for renewal applications.

- Protocol packets are distributed to the committee prior to the meeting, or accessed on the secure server when that system comes on line (see above)

IACUC Review

- 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.

- 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. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review by full-committee review (FCR) or designated-member review (DMR) 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:

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

b. 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.

c. 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.

d. 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 with training and experience in the proper care, handling, and use of the species being maintained or studied.

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

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

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

- 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.

**Full-Committee Review (FCR)**

- For full-committee review, primary and secondary reviewers are assigned and may communicate with the PI prior to the committee meeting to resolve questions which could lead to protocol deferral.

- The IACUC generally meets at least once per month to review protocol applications. 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.
Prior to each convened meeting, IACUC members receive a list and a copy of protocol applications to be reviewed.

IACUC meetings are generally conducted in person.

A properly constituted quorum must be present to discuss and vote on any protocol or issue.

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.

The primary reviewer presents the protocol in detail, giving his/her comments and recommendations; the secondary reviewer adds his/her comments and recommendations.

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.

The voting process follows Roberts Rules of Order with vote by show of hands. Abstentions are recorded.

The possible outcomes of FCR are as follows:

a. approved as submitted;
b. modifications and or clarifications are required to secure approval; or
c. approval is withheld.

Review of required modifications subsequent to FCR. When the IACUC requires modifications (to secure approval) of a protocol, such modifications are reviewed using one of the options listed below:

a. FCR or DMR following all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

b. DMR if all members of the IACUC are present at a meeting, the committee may decide by unanimous consent to have the required modifications to secure approval reviewed and approved by designated member review (DMR)

c. 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 (e.g., a documented policy), that the quorum of members present at a convened meeting may decide by unanimous consent 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.
If DMR is used, the approval date is the date that the final revised protocol is approved by the designated reviewer.

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

**Designated-Member Review (DMR)**

- The protocol is sent to all IACUC members and any member of the IACUC may obtain, upon request, full committee review (FCR) of the protocol.

- If FCR is requested, approval of the protocol 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. That is, the review of the protocol must follow the FCR procedures described above.

- If no member requests full-committee review within four full working days, 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.

- Records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.

- 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.

- After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all designated reviewers for review and approval.

- If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.

- The possible outcomes of DMR are either:
  a. Approval, by unanimous agreement
  b. Require modifications to secure approval
  c. Referral for FCR.

  "Withhold approval" is not a possible outcome of DMR.

**Special or expedited Reviews**

- There are no procedures for special or expedited review. All protocols are reviewed using FCR or DMR as described above.
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:

- Other than the specific exceptions delineated in OLAW Guidance, Notice NOT-OD-14-126, and August 26, 2014 and as delineated below and in IACUC approved policies, review and approval of significant changes will be handled in the same manner as new protocols. See Part 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 housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
  e. in the species
  f. in Principal Investigator;
  g. that impact personnel safety;
  h. in anesthetic agent(s) or the use or withholding of analgesics;
  i. in the method of euthanasia;
  j. in the duration, frequency, or number of procedures performed on an animal
  k. in approximate number of animals use

- Review and approval of items a. – g. must be by FCR or DMR. See Part III.D.6. above.

- Review and approval of items h. – j. may also be handled administratively in consultation with a University of Toledo veterinarian who is authorized by the IACUC and as described in an IACUC approved written policy(ies) that is compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will include specific evaluation criteria, e.g., published drug formularies, AVMA Guidelines for the Euthanasia of Animals, allowable blood draw data/charts, etc. Such policies will also address possible negative impacts on animal welfare

- Review and approval of item k. may also be handled administratively, but without requiring additional veterinary consultation, as described in an IACUC approved written policy(ies) that is compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will address the rational for the original number of animals used, approved study objectives, the rational for the additional animals, and possible negative impacts on animal welfare.

- All such aforementioned policies related to administrative review will be adopted by formal action by the IACUC using FCR or DMR.

- All authorizations of individuals by the IACUC to handle changes administratively will be specific (by name or positional title and change(s) authorized to handle) and in writing.
• All such aforementioned policies and authorization of individuals related to administrative review may be approved for a maximum of 36 months only. That is, all such policies expire no later than the three-year anniversary of the IACUC approval.

• If the IACUC wishes to continue the procedures/policies and/or authorizations beyond the expiration date, prior to expiration of the policy, the existing or a new policy must be reviewed and adopted by formal action by the IACUC using FCR or DMR.

• All approved changes will be documented in the associated protocol file.

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:

• If a protocol is approved as submitted, 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 to secure approval the investigator is informed in writing of the decision, listing the specific required modifications and providing an opportunity to respond in writing.

• If the IACUC’s decision is to withhold approval, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

• All actions on protocols are recorded in the IACUC meeting minutes and are entered into the Research and Sponsored Programs database following a convened meeting. All approvals are also reported to DLAR.

• 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 PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every three years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

Post-approval Monitoring

• The IACUC conducts PAM as part of the semi-annual facility inspections (see also section III.D.2).

Continuing Protocol Review
USDA Regulated Species –

a. Protocols involving USDA regulated species are reviewed by a member or members of the IACUC at least annually.

b. Investigators are required to submit and annual progress report. The report must include any unexpected adverse events.

c. The investigator's annual report is included as part of the IACUC's annual review.

Non-USDA Regulated Species – Protocols involving only non-USDA regulated species are reviewed annually using the same procedures as described above of USDA-regulated species.

Annual protocol reviews are recorded in the IACUC meeting minutes and the IACUC meeting minutes are reviewed and approved by the Committee.

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, prior to expiration of the original or preceding protocol, 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 according to PHS Policy 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 in writing to OLAW. Preliminary reports may be made verbally.

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:

1. Administration/management.
The Director of the Department of Environmental Health and Radiation Safety is responsible for the overall management of the Occupational Safety and Radiation Safety program components for personnel involved in the care and/or use of laboratory animals.

The Medical Director for Occupational Health is responsible for review of medical surveillance information, making recommendations for any significant risk identified.

Notification of clearance for work with animals must be received by DLAR before any individual can begin work.

2. Scope.

All personnel that are involved in the direct care of animals and their living quarters and those individuals who have direct contact with animals (live or dead), their viable tissues, body fluids or wastes are included. This description is not limited to UT faculty and staff. Students, volunteers, and anyone else with animal or animal material contact are included.

Animal research personnel enter the occupational health program through one of two avenues.

a. Most participants are enrolled via their inclusion on IACUC protocol applications. IACUC approval of those applications is withheld until all personnel file an "Occupational and Medical History for Research Animal Contact Form", described below.

b. 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. Health Histories and Evaluations.

All participants are given an Occupational and Medical History for Research Animal Contact Form. The form is completed by each individual and reviewed by a health care provider at Occupational Health. The procedures are compliant with HIPAA regulations. This is a survey to further assess the need for medical surveillance. When evaluated at Occupational Health, additional discussions and examinations with medical staff are scheduled as needed.


The assessment of individual risk is determined by frequency of contact, intensity of exposure, hazards associated with the animals being handled, hazardous properties of agents used in research, the susceptibility of individual employees, the hazard-control measures available, and the occupational history of individual employees.
Potential hazards are identified on the protocol and assessed by the applicable University committee.

a. Recombinant DNA and Biohazardous/infectious agents must be approved by the Institutional Biosafety Committee
b. Radioactive isotopes must be approved by the Radiation Safety Committee
c. Potentially hazardous chemical use must be reviewed by Environmental Health and Safety

Approval from each of the above committees, if involved, must be obtained to receive final approval of the IACUC protocol.

Risk associated with animal exposure is assessed upon clinician review of the health profile and planned exposure outlined by the protocol. When indicated, individuals are directed to Department of Safety and Health for respirator fitting.

Individuals at exposure risk are required to complete a Respirator Medical Evaluation Questionnaire for clinical review. On approval, respirator fit assessment is carried out by personnel in the Department of Health and Safety.

In addition, the IACUC considers possible hazards and risks during protocol review and during its semiannual program reviews and facility inspections.

The most common hazards and risks that have been identified are allergies, respiratory conditions and ergonomic injury.

5. Procedures in Place to Alleviate Hazards and Minimize Risks.

The central core of the program is an "Occupational and Medical History for Research Animal Contact Form". This is a simple survey used to make a general assessment of the risk factors to which each animal user is exposed. Based on the information supplied in the Occupational and Medical History for Research Animal Contact Form, the user is assigned a "Category".

Each Category has a general management plan and training materials associated with it. Frequency of renewal of the Occupational and Medical History for Research Animal Contact Form is based on risk assessment, but the user may also modify it at any time.

The program relies on education of the users about the main identified risk factors and how to lessen or avoid those risk factors.

Standard safety practices are also key components of the occupational health and safety program. DLAR supplies scrub uniforms, safety-toe work shoes and laboratory coats for the animal husbandry staff. These protective clothing items remain at work and are laundered on-site.

The staff receives training in personal hygiene and proper use of protective equipment. Appropriate protective clothing and safe behavior in working with animals is described in the previously mentioned training materials. Also, a locally produced document "Information Manual for Investigators Using Animals" is supplied to all laboratories.
• These practices are supplemented with signage in the animal housing areas. The UT Safety and Health department provides training and information through seminars and via the intranet, which covers such topics as UT’s safety program, emergency preparedness, medical equipment safety, life safety, security management, infection control, and hazardous materials.

• A description of hazardous agent use is required in the IACUC protocol. Final approval of the protocol is dependent upon review and approval of the material and animal handling procedures by an associated safety committee/department (e.g. Institutional Biosafety Committee, Radiation Safety Office and/or Safety and Health Department). Respiratory protection is managed under a Safety and Health Department program consistent with OSHA requirements.

• Biohazard designated projects have notices posted on door entries and work conditions reviewed and stipulated by Health & Safety staff. The ABSL3 facility within DLAR has specific standard operating procedures in conformance with NIH requirements for this level of work. The Institutional Biosafety Committee (IBC) provides project specific oversight of animal work involving biohazardous agents.

6. Immunizations.

• The immunization of personnel for tetanus is required at appropriate intervals and managed through the Safety & Health compliance database.

7. 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.

• Individuals experiencing pregnancy or decreased immunocompetence obtain special counseling and instructions on work behaviors based on their exposure potential. This activity is managed by the Dept. of Safety & Health, who determines permitted exposure and provide case-specific oversight.

8. 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.

• University personnel, i.e. facilities maintenance, are fully informed of the risks associated with working in and around an active animal facility. These employees are given the same training and Occupational Health Services as those personnel involved in animal care and/or use.

• When non-university personnel, e.g., outside maintenance or service contractors, equipment sales reps and service personnel, visitors, etc., must access the animal...
facility, they are briefed on potential hazards or risks and any necessary precautions, and provided appropriate PPE.

- A member of the animal care staff will be available for escort if needed.
- If there are extensive or prolonged repairs, installation, or construction, to be done the animals are removed prior to the individuals being allowed into the room.

9. Availability and procedures for treatment of bites, scratches, illness or injury.

- First-aid kits are maintained in the animal facility.
- If more than first-aid is required, treatment is available at University of Toledo Medical Center.
- Personnel are advised during training that in cases of serious injury (threat to life or limb) to immediately call 911.

10. Procedures/program for reporting and tracking injuries and illnesses.

- The Safety and Health and the Risk Management departments manage a program for monitoring, evaluating and establishing trends of any events that threaten physical safety and well-being of people at UT. 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 and 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.

11. Other Pertinent Information Regarding the OH&S Program.

- Proposed use of species that might require special procedures and precautions would be reviewed for additional risk. At the present time, no species which pose additional security or vaccination requirements are maintained or used.

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 Part X., Facility and Species Inventory

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

1. IACUC Members

- 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. A link to the AVMA Guidelines on Euthanasia;
5. A link to this Assurance.

- All members of the IACUC are required to complete the Essentials for IACUC Members Curriculum located at 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.

2. Animal Research Personnel

- Everyone that completes DLAR orientation will be informed that all animal care and/or use must follow PHS policy as outlined in this Assurance. If desired, a current copy is available for review in the DLAR office.

- 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.

  - A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be available for IACUC review.

  - Any person needing additional protocol-specific training is identified during the review process and such required training must be completed prior to any participation on 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, as applicable, 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.

- 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.

3. Animal Husbandry Personnel

- New personnel are informed that all animal care and/or use must follow PHS policy as outlined in this Assurance. If desired, a current copy is available for review in the DLAR office.

- 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 Environmental Health and Radiation Safety 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 Program Evaluation and Accreditation

A. 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 reevaluated by the IACUC at least once every six 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.

B. 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 three 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, the Vice President for Research Administration

5. Records of accrediting body determinations

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

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

VI. Reporting Requirements

A. 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, the Vice President for Research Administration

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: William S. Messer, Jr., Ph.D.
Title: Vice President for Research
Name of Institution: University of Toledo
Address: (street, city, state, country, postal code)
3000 Arlington Avenue
Toledo, Ohio 43614
Phone: 419 383 4252    Fax: 419 383 4262
E-mail: william.messer@utoledo.edu

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature:  
Date: 10/8/15

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) 915-9465

Signature:  
Date:  

Assurance Number:  

Effective Date:  
Expiration Date:  

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VIII. Membership of the IACUC

Date: October 2015
Name of Institution: University of Toledo
Assurance Number: A3414-01

IACUC Chairperson

Name*: Keith Crist
Title*: Associate Professor
Degree/Credentials*: PhD
Address*: (street, city, state, zip code)
3000 Arlington Avenue
Toledo, Ohio 43614
E-mail*: keith.crist@utoledo.edu
Phone*: 419 383 3992
Fax*: 419 383 3216

IACUC Roster¹

<table>
<thead>
<tr>
<th>Name of Member/Code</th>
<th>Degree/Credentials</th>
<th>Position Title***</th>
<th>PHS Policy Membership Requirements****</th>
</tr>
</thead>
<tbody>
<tr>
<td>George Cicila</td>
<td>Ph.D.</td>
<td>Associate Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Kathryn Eisenmann</td>
<td>Ph.D.</td>
<td>Assistant Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Steve Korn</td>
<td>B.A.</td>
<td>Pastor</td>
<td>Nonscientist and Non-affiliated Member</td>
</tr>
<tr>
<td>Viviana Ferreira</td>
<td>D.V.M., Ph.D.</td>
<td>Assistant Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Katherine Goans</td>
<td></td>
<td>Associate Director, DLAR</td>
<td>Member</td>
</tr>
<tr>
<td>Sadik Khuder</td>
<td>Ph.D.</td>
<td>Associate Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Guofa Liu</td>
<td>Ph.D.</td>
<td>Associate Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Nikolai Modyanov</td>
<td>Ph.D.</td>
<td>Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Phillip Robinson</td>
<td>M.S., D.V.M., DACZM</td>
<td>Director, DLAR</td>
<td>Veterinarian</td>
</tr>
<tr>
<td>Youssef Sari</td>
<td>Ph.D.</td>
<td>Associate Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Zahoor Shah</td>
<td>Ph.D.</td>
<td>Associate Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Stanislaw Stepkowski</td>
<td>D.V.M., Ph.D.</td>
<td>Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Frederick Williams</td>
<td>Ph.D.</td>
<td>Associate Professor</td>
<td>Scientist</td>
</tr>
</tbody>
</table>

¹ No more than three members, including the Chair, are from the same administrative unit, e.g., academic department.
This information is mandatory.

Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not “community member” or “retired”).

**PHS Policy** Membership Requirements:

- **Veterinarian** veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

- **Scientist** practicing scientist experienced in research involving animals.

- **Nonscientist** member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

- **Nonaffiliated** individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

All members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.

**IX. Other Key Contacts** (optional)

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

<table>
<thead>
<tr>
<th>Contact #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Phillip T. Robinson, DVM</td>
</tr>
<tr>
<td>Title: Director, DLAR</td>
</tr>
<tr>
<td>Phone: 419-383-4310</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Title:</td>
</tr>
<tr>
<td>Phone:</td>
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</tbody>
</table>
### X. Facility and Species Inventory

**Date:** October 2015  
**Name of Institution:** University of Toledo  
**Assurance Number:** A3414-01

<table>
<thead>
<tr>
<th>Laboratory, Unit, or Building</th>
<th>Gross Square Feet [include service areas]</th>
<th>Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]</th>
<th>Approximate Average Daily Inventory</th>
</tr>
</thead>
</table>
| Department of Lab Animal Resources, Health Education Building, Health Science Campus | 36,921 | Mice\(^1\), Rats\(^1\), Swine, Rabbits, Zebra Fish | 5,720  
4,085  
<1†  
<1†  
60 |
| BSL3, Health Education Building, Health Science Campus | 812 | Mice, Rats | <1†  
<1† |
| Fish Laboratory, Block Health Science Building, Health Science Campus | 369 | Fish (Parrot Fish) | <1† |
| Department of Lab Animal Resources, Wolfe Hall, Main Campus | 8881 | Mice\(^1\), Rats\(^1\), Zebra Fish | 250  
12  
<1† |
| Psychology Laboratory, University Hall, Main Campus | 1618 | Rats\(^1\), Budgerigars | 24  
2 |
| Kinesiology Laboratory, Health and Human Services Building, Main Campus | 670 | Mice\(^1\) | 150 |
| Fish Laboratory, Lake Erie Center for Great Lake Studies | 1816 | Fish (Yellow Perch, Round Goby, Walleye, Minnow Species) | <1† |

†These animals are obtained in very low numbers (<100/year) and are typically kept for very short periods (2 days – 2 weeks)

\(^1\)Mice and Rats means mice of the genus mus and rats of the genus rattus that are purposely bred for research.