

3364-70-10 Laboratory animal welfare, care and use.**(A) Policy statement**

The university of Toledo “UT” acknowledges and accepts responsibility for the care and use of animals involved in all research and educational activities conducted within the institution. UT will comply with all applicable provisions of the animal welfare act and animal welfare regulations. UT abides by the public health service “PHS” policy and United States government principles for the utilization and care of vertebrate animals used in testing, research, and training. UT has established and will maintain a program for activities involving animals in accordance with the guide for the care and use of laboratory animals “the Guide.” UT also conforms to other applicable federal, state, and local statutes and regulations relating to animal care and use.

(B) Purpose of policy

This policy summarizes UT requirements for conducting research or educational activities involving the use of animals.

(C) Scope

This policy applies to all UT faculty, students, research participants and staff using animals in research or educational activities.

(D) Definitions:

- (1) Animal facility – Any room or area where UT laboratory animals are housed for more than twelve continuous hours. The UT institutional animal care and use committee “IACUC” requires that the care of all animals (warm- and cold-blooded vertebrates and higher invertebrates, such as squid, octopus, lobsters, and crabs) housed in UT animal facilities must be approved by and remain under the oversight of that committee.**
- (2) Department of laboratory animal resources “DLAR” – DLAR is the principal department responsible for animal research facilities, animal husbandry, and veterinary care of animal research subjects.**

- (3) Institutional animal care program – UT has a centralized animal care program, with one IACUC, United States department of agriculture “USDA” research facility registration, office of laboratory animal welfare “OLAW” assurance, and association for assessment and accreditation of laboratory animal care international “AAALAC” accreditation that covers all UT faculty animal research activities regardless of UT campus/location. The office of research and sponsored programs administers the animal care program.
 - (4) IACUC – The university of Toledo has one IACUC which oversees all animal research activities on all UT campuses and offsite locations. The IACUC will be properly constituted according to the animal welfare regulations with UT faculty, staff and at least one unaffiliated and one non-scientist member. UT may also choose to utilize the services of an external IACUC at its discretion.
 - (5) OLAW – The office within the national institutes of health responsible for the administration and oversight of federal policy on the use of animals in research.
 - (6) Satellite facility – An animal facility as defined above located outside of a DLAR facility and managed by a UT department/investigator. These facilities must be reviewed and approved in advance by the IACUC. DLAR will oversee the animal care activities and provide veterinary care to all satellite facilities. Satellite facilities are inspected by the IACUC semi-annually and are included in the post-approval monitoring program.
 - (7) UT-related research and instructional activities – Research and instructional activities conducted by or under the direction of UT faculty, students, and other employees in connection with their university responsibilities either on- or off-campus (including other states or countries) and all research and instructional activities involving animals which utilize UT facilities.
- (E) Lines of authority and responsibility: The lines of authority and responsibility for administering the program and ensuring compliance are

as follows.

(1) Institutional official

The vice president for research serves as the institutional official “IO” with authority to legally commit UT resources to meet federal regulatory guidelines. This authority is delegated by the president of the university. The IO is responsible for appointing members to the IACUC. The IO is the signatory authority for the public health service “PHS” assurance.

(2) Attending veterinarian

The attending veterinarian “AV” is a voting member of the IACUC and has authority to implement the regulatory requirements of the public health service and animal welfare act. The AV provides veterinary care and protocol consultation. The AV works closely with the principal investigator for animal care issues, especially if unexpected complications arise from experimental procedures. In the case of a pressing health problem, if the investigator is not available, or if the investigator and the AV cannot reach consensus on treatment, the AV has the authority to treat the animal, remove it from the experiment, institute appropriate measures to relieve pain or distress, or perform euthanasia if necessary.

(3) Research compliance

The IACUC administrator is responsible for maintaining regulatory records and reports, participates in inspections, and performs post-approval monitoring of IACUC protocols.

(D) Compliance

(1) UT has established an IACUC, appointed by the institutional official, to implement the policies for protection of animals used in research and education.

(2) UT has an animal welfare assurance on file with the national institutes of health “NIH” OLAW covering all research, research training, experimentation, and biological testing and

related activities involving live, vertebrate animals and higher invertebrates, such as squid, octopus, lobster, and crabs, and includes the duties and procedures of the IACUC.

- (3) PHS/NIH regulations and the UT animal welfare assurance require that all UT-related research and instructional protocols which involve the use of animal subjects must be approved by and remain under the oversight of the IACUC. All UT-related research and instructional activities as described in (D)(2) in this rule, involving animal subjects must receive prior UT IACUC review and approval before any project can begin. In the case of customized antibody production using animals by an outside company, investigators must assure that the company has an active IACUC and an NIH animal welfare assurance. The office of research and sponsored programs has information on this process.

UT-related research involving animal subjects that occurs solely at another institution may not require prior UT IACUC review and approval, but does require a formal memorandum of understanding “MOU” between the institutions that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight. UT IACUC review requirements are determined on a case-by-case basis.

(E) Processes and procedures

The office of research and sponsored programs is responsible for developing and maintaining processes and procedures to implement this policy and for operating the UT animal care program in accordance with all applicable federal regulations, in consultation with the IACUC and DLAR.

- (1) The responsible party (a/k/a IACUC protocol principal investigator) for UT-related research and instructional protocols submitted to the IACUC for approval must be a salaried UT faculty member. The IACUC protocol principal investigator must be in a position to provide direct, personal, day-to-day oversight of activities and personnel associated with the IACUC protocol. Any exceptions to the above criteria regarding the eligibility of an individual to serve as the PI of an IACUC

protocol must be approved by the vice president for research.

- (2) The PI or a co-investigator on any research grant, agreement or contract requiring IACUC approval must be the PI on the IACUC protocol(s) supporting the work described in the research grant, agreement or contract. In the case of a fellowship, the faculty sponsor/mentor for the trainee applicant must be the PI on the regulatory protocol(s) supporting the work described in the application, and the trainee applicant must be among the authorized personnel on the same regulatory protocol(s).
- (3) The IACUC is responsible to ensure that all animal activity for extramurally funded research awards are congruent with active and approved IACUC protocol(s) and are consistent with PHS policy on humane care and use of laboratory animals (IV.C. 1.) and OLAW animal welfare assurance. All procedures described in extramural funding proposals must be approved in or amended to IACUC protocols before any "just in time" documentation will be released or animal research activities allowed. The PI is solely responsible for ensuring that all procedures are approved at the appropriate time for all proposal applications. The IACUC will only assess IACUC protocol congruency with proposed research plans when notice of award is received or "just in time" documentation is requested.
- (4) Prior approval must be granted by the IACUC for all modifications to previously approved activities and addition of personnel. Significant changes must be reviewed and approved by the IACUC. Significant modifications, as identified by OLAW include but are not limited to changes: in usage of potentially hazardous materials; in the objectives of a study; proposal switch from non-survival to survival surgery; in the degree of invasiveness of a procedure or discomfort to an animal; in species or in the approximate number of animals used; in principal investigator involved in animal procedures; and in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia. Additional factors may involve changes in the duration, frequency, or number of procedures performed on an animal.
- (5) Only laboratory personnel who have been approved by the IACUC to work on a specific protocol may handle and perform

the experimental procedures on the animals covered by the protocol. All personnel who have contact with animals are required to complete training and instruction regarding humane animal research as required by the IACUC. Information on training is provided by the DLAR.

- (6) All personnel with expected animal contact are required to be enrolled in the occupational health program for animal users as defined by the UT department of environmental health and radiation safety.
- (7) Research animals must be obtained from an appropriate source, such as commercial breeding facilities or another university/institution. Obtaining animals from any other source must be approved in advance by the IACUC. All animal orders must be processed through DLAR in order to verify that there is an approved IACUC protocol and reconcile inventory of the total number of approved animals with the approved protocol. The UT office of technology transfer administers material transfer agreements.
- (8) Any animal that has been housed in UT animal care facilities cannot be guaranteed to be free of any hazardous conditions or agents. Therefore, to assure protection of others from such unknown conditions, the adoption or transfer of any such animal to any private individual or non-research organization is not permitted without prior documented approval of the IACUC.
- (9) In advance of housing any animal at UT treated with hazardous substances, the PI must provide written notification to UT DLAR that includes the name, dose, and dates during which precautions must be taken for hazardous substances. All animals treated with hazardous substances must be housed appropriately and signage with the name of the substance (abbreviations are unacceptable) and the type of hazard (e.g., carcinogen) must be posted.

(F) Resources/references

Animal welfare act - 1966 animal welfare act "AWA" and its amendments, codified at 7 U.S.C. 2131, et. seq. and C.F.R. title 9

https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa/ct_awa_program_information

https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_FINAL_NAL_2017_508comp.pdf

Health research extension act of 1985

<https://olaw.nih.gov/policies-laws/hrea-1985.htm>

Public health service “PHS” policy on humane care and use of laboratory animals (policy)

<https://olaw.nih.gov/policies-laws/phs-policy.htm>

National institutes of health “NIH” office of laboratory animal welfare “OLAW”

<http://grants1.nih.gov/grants/olaw/olaw.htm>

U.S. government principles

<https://olaw.nih.gov/policies-laws/gov-principles.htm>

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