



**Title:** When is an Animal Protocol Required?

**Policy Number:** 032

**Policy Intent:** Approved animal protocols are generally, but not always required. Certain uses of animals do not fall under the purview of the IACUC. This policy clarifies the situations when a protocol is or is not required at Texas Tech University.

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### 1. Purpose

- A. The purpose of this policy is to provide a framework for the Institutional Animal Care and Use Committee (IACUC) and its committee members in determining the need for requiring an IACUC approved Animal Use Protocol (AUP).

### 2. Background

- A. University policy and federal law require review and approval of proposed activities related to the humane care and use of animals. It wasn't until 1985 that two laws at the national level were passed requiring an IACUC. These laws were the Health Research Extension Act (HREA) and key amendments to the Animal Welfare Act (AWA). Both laws led to statutory requirements for the composition and responsibilities of the IACUC. For the AWA, responsibility lies with the US Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care; the rules promulgated by USDA Animal Care are commonly referred to as the AWA regulations (AWARs). In the case of the HREA, responsibility lies with the Office of Laboratory Animal Welfare (OLAW) in the Department of Health and Human Services, and the rules are articulated in the "Public Health Service Policy for the Humane Care and Use of Laboratory Animals" (PHS Policy).
- B. Some institutions using animals are not covered by either set of regulations, meaning that the institution itself must set policy about the roles and responsibilities of an IACUC. Many, if not most, institutions have judged that a coherent policy requires applicability to all animals regardless of funding source. In addition to procedural decisions, many institutions have judged it important to demonstrate a higher level of accountability by voluntarily participating in accreditation by AAALAC International. This nonprofit organization now accredits companies, universities, hospitals, government agencies and other research institutions worldwide.
- C. IACUC's are sometimes criticized within their institution for inconsistency and over-interpretation of the regulations. It is, however, the nature of the regulations that local interpretation is necessary. The IACUC has federally mandated responsibilities that, if not executed properly, can result in sanctions. These may include fines and loss of federal research funding.

### 3. Policy



## Institutional Animal Care and Use Committee™

- A. IACUC approval must be obtained before initiating any research, teaching or demonstration project that involves the use of live vertebrate animals (including mammals, birds, fish, amphibians and reptiles), whether purchased or wild caught, including:
  - 1) Activities that are to be conducted with animals owned or leased by TTU.
  - 2) Activities conducted on property owned, leased or managed by TTU.
  - 3) Activities conducted by TTU faculty, staff or students.
  - 4) Field research activities that include observation, capture, handling, behavior modification, sedation, etc.
  - 5) Animals purchased or euthanized for the sole purpose of obtaining tissues
- B. Research or teaching conducted in collaboration with another institution or organization, including commercial entities, must be approved by an IACUC. When a protocol has been reviewed and approved by another institution's IACUC, the TTU IACUC may not require additional review and approval. However, the PI must inform the TTU IACUC of the activity and must have documentation from the collaborating institution before an acceptance decision can be made.
- C. An animal protocol is not required for activities including:
  - 1) Activities ordered and/or performed by the Attending Veterinarian or designee that involve only standard veterinary or emergency procedures necessary to ensure animal welfare.
  - 2) Research and teaching activities using cadavers or tissues from dead animals UNLESS the cadavers or tissues are to be acquired from animals specifically purchased or euthanized for the activity.
  - 3) Tissues obtained from an abattoir or market,
  - 4) Unused tissues from another Investigator
  - 5) Removal of vertebrate vermin.
  - 6) Non-research, non-teaching or non-demonstration activities involving privately owned animals, where the activity is an exhibition activity.

#### 4. References

- Guide for the Care and Use of Laboratory Animals, 8th Edition
- AWA Section 2141; 9 CFR, Part 2, Sections 2.38(g), 2.35(b), 2.50, 2.75(a )