

Institutional Animal Care and Use Committee		UNTHSC
Title: Annual Review of Protocols		
Document #: 003	Version #: 10	
Approved by IACUC Date: March 13, 2025		

#### **A. BACKGROUND**

- a. The Animal Welfare Act states, “The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually” (9CFR §2.31(d)(5)).
- b. On November 24, 2021, the USDA APHIS (Animal and Plant Health Inspection Service) issued a final rule, effective December 27, 2021. The ruling, in response to the 21<sup>st</sup> Century Cures Act, stated: “We proposed to amend §2.31(d)(5) by removing the continuing review requirement and adding the requirement for a complete review of activities at appropriate intervals as determined by the IACUC, but not less than every 3 years.” This change harmonizes the timeline for the complete review process with the NIH OLAW requirement. As such, UNTHSC IACUC will no longer require the annual review of protocols, regardless of species.

#### **B. RESPONSIBILITIES**

- a. The IACUC at the University of North Texas Health Science Center has the responsibility to assure that all animal use activity meets federal law mandates, Public Health Service policy, the Guide recommendations and all accreditation expectations.
- b. Principal Investigators (PI) are responsible to comply with the requirements set forth by UNTHSC IACUC to meet the federal regulations for all animal use activities.

#### **C. PROCESURES**

- a. Annual reviews are no longer required, regardless of species, in accordance to the updated ruling by the USDA APHIS in response to the 21<sup>st</sup> Century Cures Act.
- b. Amendment review, semi-annual inspections, and increased post-approval monitoring audits provides a more in-depth continuing review process for these activities.
- c. All protocols undergo a complete *de novo* review every three years in accordance to the Animal Welfare Act and PHS Policy.

#### **D. REFERENCES**

- a. [Animal Welfare Act, Public Law 89-544 as amended; codified at 7 U.S.C. 2131-2159.](#)
- b. [USDA Animal Welfare Act Regulations and Standards, 9 CFR Parts 1, 2, 3 and 4.](#)
- c. [PHS Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised 2015.](#)
- d. [Health Research Extension Act of 1985, Public Law 99-158, November 20, 1985, “Animals in Research.” Available from OLAW, National Institutes of Health, RKL1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982](#)
- e. [Guide for the Care and Use of Laboratory Animals, Eighth Edition. National Academy Press, Washington, D.C. 2011.](#)
- f. [https://www.federalregister.gov/documents/2021/11/24/2021-25614/awa-research-facility-registration-updates-reviews-and-reports.](https://www.federalregister.gov/documents/2021/11/24/2021-25614/awa-research-facility-registration-updates-reviews-and-reports)