Institutional Animal Care and Use Committee		UNTHSC
Title: Guidelines for Pilot Studies		
Document #: 033	**Version #:** 03	
Approved by IACUC Date: February 12, 2020		

A. BACKGROUND INFORMATION

Protocols may include procedures that have not been previously encountered or that have the potential to cause pain or distress that cannot be reliably predicted or controlled. If little is known about a specific procedure or when information for an alternative endpoint is lacking, the use of a pilot study may be appropriate (*Guide*, pages 26, 28).

B. RESPONSIBILITIES

a. It is the responsibility of the principal investigator (PI) to propose a pilot study when including a new procedure or alternative endpoints for which pain or distress may occur.
b. It is the responsibility of the PI to communicate to the IACUC the results of any pilot study completed.
c. It is the responsibility of the IACUC to request a pilot study, when deemed necessary.
d. It is the responsibility of the IACUC to assure that the number of animals used in an animal use protocol is appropriate.

C. PROCEDURES

a. For any new technique or new endpoints, a PI may need to show that it can work on a small number of animals before requesting a larger number of animals.
b. An Animal Use Protocol Application must be completed and submitted to the IACUC office for review and approval following *009 Protocol Submission Process.*
c. A pilot study may be requested by the IACUC during protocol review.
d. For new procedures:
    i. If little is known about a specific procedure, the IACUC may approve and oversee a pilot study designed to assess both the effect of the procedure on the animals and the skills of the research team.
    ii. The PI must report to the IACUC, in writing, the findings of the pilot study.
    iii. If the study will continue as a larger study, a new Animal Use Protocol Application must be submitted to the IACUC office for review. The new

protocol will not be approved by the IACUC until the results of the pilot study are known.

e. For alternative endpoints:
    i. The use of a pilot study is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC and veterinarian.
    ii. For such studies, a report must be made, in writing, to the IACUC during and after the study. Based on the report, the IACUC will determine if the alternative endpoints can be used on a larger scale.

D. REFERENCES

a. Institute of Laboratory Animal Resources (2011). *Guide for the Care and Use of Laboratory Animals*. National Academies Press, Washington, D.C.
b. IACUC Guideline *009 Protocol Submission Process*