



IACUC Guidance:	TAMU-G-030	Title:	Guidelines for Performing Pilot Studies
	Location	Effective Date	Review By
	College Station/Dallas/Galveston/Kingsville	05/01/2024	04/30/2027
	Houston	06/01/2024	04/30/2027

1. PURPOSE

- 1.1. To standardize the procedures for performance and reporting of pilot studies to the IACUC and Office of the Attending Veterinarian.

2. SCOPE

- 2.1. This applies to AUPs which include a pilot study on a small cohort of animals to determine conditions for the remainder of the study.
- 2.2. Does not include protocols in which the entire AUP is a pilot study.
- 2.3. Pilot studies should not be used to test hypotheses about the effects of an intervention, but rather, to assess the feasibility/acceptability of an approach to be used in a larger scale study.

3. RESPONSIBILITY

- 3.1. The **AWO Staff** is responsible for collection and distribution of pilot study progress reports from PIs and/or research personnel.
- 3.2. The **PI** is responsible for proposing a pilot study and for communicating the results to the IACUC by providing a report of pilot study progress.
- 3.3. **IACUC Members** are responsible for reviewing pilot study progress reports. The IACUC may request a pilot study in the course of protocol review.

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.2. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfil the regulatory role of AV. May also describe veterinary staff who report directly to, and have delegated authority from, the AV.
- 4.3. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.4. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.5. **iRIS:** Web-based compliance submission system
- 4.6. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.7. **Pilot Study:** A small-scale test of the methods and procedures to be used on a larger scale.

5. GUIDELINES OR PROCEDURE

- 5.1. Examples of pilot studies include, but are not limited to:
 - 5.1.1. To determine the humane endpoint for novel studies in which information and alternatives are lacking. Consensus among the PI, IACUC and Attending Veterinarian should be reached as to the performance of the pilot study. See TAMU-G-001 for guidance regarding choosing appropriate endpoints.
 - 5.1.2. To perfect a technique
 - 5.1.3. To assess effect on animals
 - 5.1.4. To assess the skills of the research team
 - 5.1.5. Demonstrate feasibility
 - 5.1.6. To estimate variability
 - 5.1.7. Dose tolerance studies where toxicity profiles are unknown



- 5.2. A pilot study may be requested by the IACUC during protocol review or proposed by the PI.
- 5.3. Pilot Study Summary
 - 5.3.1. The Pilot Study Summary is due 6 months after AUP approval, or after pilot study is completed but before the main study commences, whichever comes first.
 - 5.3.1.1. An email notification prompting the submission of the Pilot Study Summary will be sent to the PI via iRIS or directly from AWO staff.
 - 5.3.2. The Pilot Study Summary report is submitted via an Amendment submission in iRIS, or by an alternate mechanism as directed by AWO staff.
 - 5.3.3. The summary must be completed by the PI, submitted to and approved by the IACUC, before commencing with the main study.
 - 5.3.4. The summary must be submitted in a timely manner to identify the best study methods and procedures, thereby minimizing the effect on animal welfare.
 - 5.3.5. When received, the summary will be reviewed by the IACUC and outcome communicated to the PI.
- 5.4. Adverse events or unanticipated outcomes related to the performance of a pilot study may be reported at any time to the IACUC. See TAMU-G-015 for more information.

6. RECORDS

- 6.1. Research records, including pilot study records, must be maintained consistent with Texas A&M University Standard Administrative Procedures (SAPS) 15.99.03.M1.03. and 29.01.03.M0.01.

7. EXCEPTIONS

- 7.1. The PI may request an exception to the above standards by describing the departure in the AUP.

8. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

8.1. References

- 8.1.1. Definition of pilot study, Porta, *Dictionary of Epidemiology*, 5th edition, 2008
- 8.1.2. NIH, National Center for Complementary and Integrative Health, “Pilot Studies: Common Uses and Misuses”, https://nccih.nih.gov/grants/whatnccihfunds/pilot_studies
- 8.1.3. *The Guide for the Care and Use of Laboratory Animals*, (Eighth Edition, 2011, ILAR, NCR, p. 28)

8.2. Resources

8.2.1. Texas A&M University SAPs:

- 8.2.1.1. [15.99.03.M1.03](#) The Responsible Stewardship of Research Data
- 8.2.1.2. [29.01.03.M0.01](#) Security of Electronic Information Resources

8.2.2. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)

- 8.2.2.1. TAMU-G-001 Guidelines on Choosing Appropriate Endpoints
- 8.2.2.2. TAMU-G-015 Guidelines for Reporting Animal Concerns, Unanticipated or Adverse Events, and Potential Noncompliance

8.3. Acknowledgements

- 8.3.1. This document was partially adapted using materials obtained from Boston University and the University of Kentucky.

9. HISTORY

Effective Date	Version #	Description
10/17/2019	000	College Station/Galveston: New Document
09/01/2020	001	Houston/Kingsville: New Document; reviewed and approved via email
09/15/2020	002	Dallas: New Document
08/02/2021	003	College Station/Galveston: Renewal document; updated definitions and references; reviewed and approved via email



09/01/2021	004	Houston/Kingsville: Renewal document; updated definitions and references; reviewed and approved via email
09/21/2021	005	Dallas: Renewal document; updated definitions and references
03/24/2022	006	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	007	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
05/01/2024	008	College Station/Dallas/Galveston/Kingsville: Renewal; updated definition and reference sections, addition of records and exceptions sections. Reviewed and approved via TEAMs.
06/01/2024	009	Houston: Renewal; updated definition and reference sections, addition of records and exceptions sections.