IACUC REQUIRED PILOT STUDY POLICY

Background:

The Guide for the Care and Use of Laboratory Animals states that when novel studies are proposed or information for an alternative endpoint is lacking (i.e., the state, degree, or possibility that it can be achieved or is reasonable) the use of pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the Principal Investigator (PI), Institutional Animal Care and Use Committee (IACUC), and Attending Veterinarian (AV). A system for communication with the IACUC should be in place both during and after such studies (Guide, p 26 & 28). This policy defines the process for requiring, reviewing, approving, and following up on pilot studies that the IACUC requires before proposed activities can be initiated. This policy applies only to pilot studies required by the IACUC as a condition of approval, modification, or continuation of animal activities. PI-initiated pilot studies are outside of the scope of this policy but remain subject to all applicable IACUC review and approval requirements before animal activities begin.

For this policy, a pilot study is a small-scale, preliminary study that has been required by the IACUC to evaluate the feasibility of proposed testing, refine procedures, assess drug dosing, support training or technique development, validate equipment, determine expected variability of outcome variables, assess potential effects on animal welfare, establish humane endpoints, and collect preliminary data before initiating a larger study. The IACUC expects each pilot study to clearly define the number of animals, study duration, personnel training, procedures, objectives, and humane endpoints to be evaluated. When required by the IACUC, the pilot study will be reviewed as the initial approved phase of the same protocol through the standard protocol review process in eCompliance. Any expansion beyond the approved scope of the study requires prior IACUC approval.

Policy:

Pilot studies are subject to the same requirements for IACUC review and approval, scientific merit review, and animal welfare standards as other animal activities.

The IACUC may require pilot studies prior to a full-scale study whenever it determines that pilot data are necessary to evaluate scientific feasibility, personnel proficiency, humane endpoints, refinement measures, or potential animal welfare concerns, including but not limited to the following circumstances:

- The PI or research team has limited experience or background with the proposed model, procedure, or technique;
- The proposed model, procedure, or technique may involve significant pain, distress, morbidity, mortality, or other animal welfare concerns;
- Other circumstances identified by the IACUC or attending veterinarian as warranting a pilot study.

The IACUC Chair, AV, or convened IACUC may identify the need for a pilot study during review. If it is determined that a pilot study is necessary, the basis of that determination will be

communicated to the PI during the protocol review process. Any required protocol modifications or limitations would be implemented through the standard IACUC review process.

The protocol must describe:

- The purpose and objectives of the pilot study,
- The limited scope of work,
- The justification for the number of animals requested,
- The study duration and procedures,
- The monitoring plan,
- Humane endpoints, and
- Criteria for veterinary intervention or euthanasia, as applicable.

The protocol will undergo the normal protocol review process in eCompliance and must be approved prior to initiating any animal activities. Protocols initially approved as pilot studies will be designated accordingly in eCompliance by IACUC staff to ensure that all required post-approval monitoring and reports are reviewed.

Pilot studies involving novel procedures, uncertain outcomes, or alternative endpoints must include appropriate monitoring plans, humane endpoints, and criteria for veterinary intervention or euthanasia.

The monitoring plans must specify, as applicable, the personnel responsible, the frequency of observations, the behavioral parameters to be assessed, the scoring criteria or assessment forms, where records will be kept, the notification thresholds for veterinary contact, after-hours coverage, and the required actions when humane endpoints or intervention criteria are met.

Unexpected morbidity, mortality, adverse events, or significant animal welfare concerns that occur during a pilot study must be reported promptly in accordance with the UMKC adverse event reporting requirements.

Approval of a pilot study does not constitute approval of the full-scale study unless the full-scale activities are specifically approved by the IACUC. The PI may not proceed beyond the approved pilot scope until the IACUC has reviewed and approved the required amendment or modification. Before proceeding beyond the approved pilot study activities, the PI must submit a follow-up amendment in eCompliance summarizing:

- Pilot study outcomes,
- Animal welfare observations,
- Procedural feasibility,
- Humane endpoint findings, if applicable,
- Any unexpected or adverse events, and
- Proposed next steps.

The amendment will be reviewed in accordance with normal amendment review processes. The IACUC may invite the PI and/or research staff to attend an IACUC meeting to discuss pilot study outcomes, animal welfare observations, procedural feasibility, humane endpoints, or proposed next steps. Based on review of pilot outcomes, the IACUC may approve an amendment for progression to the next phase, request additional information, require modifications, require

additional pilot work, impose additional monitoring or reporting requirements, restrict the scope of activities, or withhold approval of further work. Following IACUC approval of the amendment, the pilot study designation may be removed from the protocol, and the research may proceed in accordance with the approved protocol. All significant changes to animal activities, unexpected morbidity or mortality, adverse events, unanticipated pain/distress, or significant welfare concerns must be submitted for review or reported to the IACUC in accordance with IACUC policies.

Applicable To:

All UMKC faculty, staff, students, employees, and personnel involved in the care or use of animals owned by the UMKC.

Revisions to the Policy:

This policy is intended to be flexible and readily adaptable to changes in regulatory requirements. The UMKC IACUC has the authority to amend this policy as needed. The UMKC IACUC has reviewed and approved this policy.

Reference:

The Guide for the Care and Use of Laboratory Animals, Eighth Edition:
https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf
UMKC IACUC Adverse Event Reporting Policy.
AVMA Guidelines for the Euthanasia of Animals, current edition