132.1 PURPOSE

This document establishes policies and provides guidelines for the oversight of pilot studies the University of Kentucky.

132.2 BACKGROUND

The Guide for the Care and Use of Laboratory Animals states “If little is known about a specific procedure, limited pilot studies, designed to assess both the procedure’s effects on the animals and the skills of the research team and conducted under IACUC oversight, are appropriate” (Guide page 26).

Furthermore the Guide also states “When novel studies are proposed or information for an alternative endpoint is lacking, the use of pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC, and veterinarian. A system for communication with the IACUC should be in place both during and after such studies” (Guide page 28).

132.3 Definition

The IACUC defines a pilot study as one that is designed to: 1) explore the feasibility of performing a specific procedure, 2) the potential effects of a procedure on animals or 3) the skills of research team members on conducting a new procedure. Dose finding studies where several doses are initially approved for eventual selection of the one that produces the best results is not considered a pilot study in the context of this policy.

132.4 Procedures

The University of Kentucky IACUC believes that pilot studies are appropriate under certain conditions (e. g. feasibility studies).

Under certain conditions, the IACUC may require pilot studies be conducted before full scale experiments are undertaken. Some instances where the requirement of pilot studies may be appropriate include, but are not limited to: when conducting novel procedures, when little is known about a procedure and its potential outcome, when establishing endpoints.

PIs should propose pilot studies as deemed necessary to ensure future studies will be likely to achieve proposed goals. When pilot studies are proposed the PI must communicate results to the IACUC in writing before engaging in using larger number of animals.
REFERENCES:


Approved and Adopted by the Institutional Animal Care and Use Committee
November 9, 2016