

Policy on Pilot Studies

This document establishes the policy of the IACUC regarding pilot studies when used for work involving research animals at the University of Kentucky.

Policy

The IACUC defines a pilot study as one that is designed to explore: 1) the feasibility of performing a specific procedure, 2) the potential effects of a procedure or drug on animals or 3) the development of skills as it relates to a new animal procedure. Dose finding studies in which several dosages of a compound are initially approved for eventual selection of the one that produces the best results are not considered pilot studies.

PI-Proposed Pilot Studies

PIs should propose pilot studies as deemed necessary to ensure future studies will be likely to achieve proposed goals. Some instances where the requirement of pilot studies may be appropriate include but are not limited to the following: 1) conduct of novel procedures, 2) when little is known about a procedure or drug and its potential outcome, or 3) when establishing endpoints.

IACUC-Required Pilot Studies

Under certain conditions, the IACUC may require pilot studies be conducted before full scale experiments are undertaken. When pilot studies are required by the IACUC, the PI must include the following statement in the IACUC protocol at the end of the pilot project description of the Methodology section:

Following completion of the pilot experiment(s), results (including outcomes and adverse events) will be reported back as an amendment to the IACUC for review and approval prior to progressing further with the protocol.

Once any required pilot experiments have been completed, the PI must provide an update on the results/outcomes and any adverse events that were noted via an amendment in Cayuse. This amendment must be approved by the IACUC prior to moving on to any other related experiments or aims in the protocol.

REFERENCE:

Institute of Laboratory Animal Resources (U.S.). 2011. *Guide for the Care and Use of Laboratory Animals*. Washington, D.C.: National Academy Press.

Approved and Adopted by the IACUC:
November 9, 2016

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October 16, 2024