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 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.

PIs should propose pilot studies as deemed necessary to ensure future studies will be likely to achieve proposed goals. 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 the following:1) conduct of novel procedures, 2) when little is known about a procedure and its potential outcome, or 3) when establishing endpoints.

When pilot studies are required by the IACUC, the PI must communicate results to the IACUC Chair in writing. Such communications should detail completion of the required pilot studies, including any adverse events or complications encountered, and are a prerequisite prior to the initiation of a larger study.

REFERENCE:

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

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