

University Animal Care Committee Standard Operating Procedure		
Document No: UACC 1.10	Subject: Pilot Studies	
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Location: Queen's University

Purpose: The purpose of this Standard Operating Procedure (SOP) is to describe the procedures surrounding pilot studies.

- 1. Introduction and Definitions:** Both the CCAC and the UACC encourage the use of pilot studies when new approaches, methods or products are being tried, before approving new, large-scale protocols.

Pilot studies are defined as AUPs where the outcome of what is being proposed is generally unknown. This could include the determination of a half-life of a compound; a new procedure/animal model to the University/Lab; or an evaluation of a new procedure against a known procedure. Pilots are conducted to support the future methodological decisions needed to progress with a full study. A pilot should contain the minimum number of animals to define statistical variability which will enable a power analysis for a more robust study, if warranted. The results of the study should also help define the humane intervention points as well as the experimental endpoints for any future studies.

Abbreviations: University Animal Care Committee **UACC**, Principal Investigator **PI**, Animal Use Protocol **AUP**, Canadian Council on Animal Care **CCAC**

2. Procedures:

Submitting a pilot project for review entails the same process as submitting a new protocol. When completing the protocol, it must be labelled as a pilot within the title.

At time of renewal, regardless of whether the study is to continue, a pilot progress report must be completed. If further work is to be undertaken following the pilot, a new protocol also must be submitted however the pilot progress report should be reviewed and approved prior to the review of the new protocol.

Pilot extensions of up to 1 year are available if nothing is changing within the application and little or no progress was made during the initial 1-year period.

PIs must report on the results of pilot studies, regardless of whether they wish to pursue the study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not.

Additional peer review for scientific merit is not required if the purpose of the pilot study is to develop or evaluate a new method within the context of a peer-reviewed research

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program. Standalone peer review is however required if the pilot study explores a new research direction that is not covered within the context of an existing peer-reviewed research program.

Notes:

References:

SOP Revision History:

Date	New Version
Sept 2023	SOP Created & Approved