

IACUC SOP # 3
Effective Date: April 18, 2013

Title: Pilot Studies – Continuing Review

Purpose:

This SOP describes the continuing review procedures for AUPs that were approved as pilot studies.

Pilot studies may be appropriate to determine the technical feasibility of larger studies, determine potential variability, refine procedures, or to make initial assessments of the effect of procedures on animals (*Guide* [pages 26, 28](#)). Whether proposed by investigators or required by the IACUC, pilot studies require review and approval by the IACUC in accordance with the PHS Policy.

Procedures:

Annual Review (AR)

- 1.) The following must be provided when considering and AR of an approved pilot study:
 - a) Specific accomplishments of the past year
 - b) Validation from the PI that the AUP should remain a pilot study
- 2.) When the AR is submitted through the automatic submission process, the manager will forward the AR to the attending veterinarian (AV); the AV will forward the AR to the PI with instructions to provide the two items listed above. This documentation **MUST** appear in the designated text box, not the revision comments box.

Modifications

- 1) A PI request for significant modification of an approved pilot study will require validation of continued pilot status.

Third Year Renewal

- 1) It may be necessary to extend a pilot study if the original goals were not met.

IMPORTANT FACTS

- All pilot studies will be clearly acknowledged on the weekly list.

- If at any time the PI reports that the study is no longer considered a pilot, the PI will be **required** to submit a new AUP to replace the pilot study protocol. Once the new AUP is reviewed and approved, the pilot study will be closed.
- Any member of the IACUC may, at any time, request FCR of the protocol.