



Animal Program Policy

Title: **Pilot Studies**
Date Created: 1/1/2015
Date Reviewed: 3/20/2024

The Forsyth IACUC may, as needed, approve a limited number of animals for a Pilot Study. This policy describes the rationale and process for approving a pilot study and subsequent larger experiments.

Reason for Pilot study: to evaluate a new technique
to establish preliminary data for determination of appropriate sample size
to demonstrate feasibility of a new procedure

Initiator: PIs may submit a protocol as a pilot study or the IACUC may request that a regular protocol be revised to include only a limited number of animals for the pilot experiment.

Protocol Details: All the relevant information for the entire study (literature search, rationale, details of all procedures, breeding information if applicable etc), must be included in the protocol, even though a limited number of animals is requested. If the purpose of the pilot is to determine sample size, the animal numbers for the pilot do not need to be justified.

Animal Numbers: Only the number of animals needed for the pilot study should be included in the protocol. Typically pilot studies will include only 10-20 for mice or rats, but more animals can be included as determined by the IACUC.

Protocol Review: Pilot studies will be reviewed using the same criteria as for regular protocols, but approval if granted will be for only the limited number of animals. The committee should determine at the time of approval whether subsequent actions require full committee review or can be sent to DMR.

Follow-up: Upon completion of the pilot study, the results should be sent to the IACUC, together with an amendment requesting the full number of animals, together with justification for that number of animals if this was not provided in the original protocol. The committee can review the results and approve the amendment at a regular meeting or by DMR as determined when the pilot was approved. The total number of animals approved for the protocol that should be reported on the Annual Renewal Form will be the total of the originally approved number plus the animals added in the amendment.

Examples:

Dr. Heart wants to initiate a new area of research into cardiovascular disease, and proposes to surgically install stents in several groups of 15 rats. Because Dr. Heart's group has limited experience in this technique, the IACUC is unwilling to approve the protocol as written. They request that Dr. Heart submit a revised protocol for only 10 rats and that the veterinarian and/or director of animal care oversee the first two surgical procedures with these animals. The revised protocol is approved for 10 rats. After these two surgeries, the veterinarian reports that Dr. Heart is sufficiently skilled in this procedure. Dr. Heart submits the results of the pilot experiment together with an amendment requesting the original number of animals, which is then approved by the IACUC.

Dr. Li submits a protocol using three different models of bacterial infection in mice. Two of the models have been used in his lab previously, and he has sufficient data to do power analysis for the determination of sample size. However, one model is new to his lab, and although it is not technically difficult, it is hard to

predict what the variability will be when using his bacterial strains. Therefore he requests the total number of animals needed for the first two models, but only 10 mice for the new model. The protocol is approved, and he uses the 10 approved animals for the new model to generate preliminary data for power analysis, and determines that 8 mice per group will provide statistical significance for the effect size he desires. He then submits an amendment to the IACUC requesting additional animals for experiments using the new model, and including the pilot data as justification for these numbers.