Institutional Animal Care and Use Committee (IACUC)

Policy on Pilot Studies

Date of IACUC Approval: 6/28/19

I. Purpose: This policy establishes expectations for animal researchers when proposing to conduct a pilot study using animals and/or when the IACUC requires that a pilot study be conducted.

II. Background:

The Guide for the Care and Use of Laboratory Animals (the Guide) states that when novel studies are proposed or information for an alternative endpoint is lacking, the use of pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the Principal Investigator (PI), IACUC, and veterinarians. A pilot study may also be proposed when the PI is establishing his/her/their ability to perform a procedure or technique with which the PI/research team does not have significant experience, as self-determined by the PI or required by the IACUC. A system for communication with the IACUC should be in place both during and after [pilot] studies (the Guide, Page 28).

III. Procedures:

It is the responsibility of the PI to propose a pilot study, as necessary, and to promptly provide the results of the pilot study to the IACUC once completed. The IACUC may also require that a proposed research protocol include a pilot study. Procedures are as follows:

A. For some new techniques, or when new endpoints are proposed, an investigator may need to show that the technique can work on a small number of animals before requesting a larger number of animals and/or that new endpoints can be humanely achieved.

B. An IACUC protocol must be completed and submitted within InfoEd for review and approval by the IACUC. The initial IACUC protocol may include the pilot study and the larger scope research project.
C. If the pilot study is included within the larger scope protocol, the PI must submit the results of the pilot study to be reviewed by the IACUC prior to beginning the larger scope research project. This must be reported to the IACUC, in writing, via email to IACUC@brown.edu. The PI may not proceed with a larger proposed study, extending beyond the pilot, until the IACUC has granted such approval in writing.

D. A pilot study may be requested by the IACUC as necessary, at any time.

E. For new animal procedures, the IACUC may require and oversee a pilot study designed to assess both the effect of the procedure on the animals and the skills of the research team.

F. For alternative endpoints, the use of a pilot study is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC and veterinarians.

IV. REFERENCES: