Guiding Principle

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 PI, IACUC, and veterinarian. Communication between the PI, IACUC, and veterinarian must take place both during and after such studies.

Requirements

Guide for the Care of and Use of Laboratory Animals, ILAR, NAS, Eighth Edition 2011, pg 26, 28 Experimental and Humane Endpoints

Procedure

1. If feasible, the pilot study should be written and submitted as a separate protocol.
2. If the pilot study must be included within a protocol including the remainder of the project the following must occur:
   2.1. The protocol will be reviewed according to Review of Proposed or Continuing Animal Use Guiding Principle. If acceptable the protocol will be approved for the pilot study and the remainder of the project will be contingently approved pending the following:
      2.1.1. While conducting the pilot study, pertinent information (e.g. adverse events) must be communicated to the Attending Veterinarian.
      2.1.2. Upon completion of the pilot study, the Pilot Study Report Form must be completed and submitted to the IACUC.
      2.1.3. The Pilot Study Report Form will be reviewed via the Designated Review process and if found to be acceptable, the remainder of the protocol will be approved.