



Dartmouth College

Animal Care and Use Program

Institutional Animal Care and Use Committee

### IACUC Policies and Procedures

**Title:** Justification of Animal Numbers

**Policy:** Research and testing studies should be designed to provide a statistically significant result with a minimum number of animals, and the method by which the number of animals was determined must be clearly stated. Statistical techniques and/or power analysis are appropriate in most cases to maximize the analysis of the data generated from each animal. However, the IACUC acknowledges that the basis for an appropriate justification of animal numbers depends largely on the nature of the study itself. Prior experience and expertise with the model in question may be taken into account as well, but must be carefully documented in the protocol.

Consultation with a statistician or use of statistical software during the design phase of the experiment may be useful. Websites that may be helpful in performing a power analysis include:

- <http://members.aol.com/johnp71/javastat.html#Power>
- <http://calculators.stat.ucla.edu/powercalc>

Five basic types of studies are listed below, along with guidelines for justification of animal numbers appropriate for each type of study. These guidelines are intended to provide direction – any given study may not fall neatly into one of these five categories:

- **Teaching Protocols:** Animal numbers are determined by a specified student-to-animal ratio, which must be explained in the justification narrative. Animal numbers should be minimized to the fullest extent possible without sacrificing the quality of the hands-on teaching experience for students.
- **Tissue Harvest Required for In-vitro Work** (including antibody production): Animal numbers are determined by the amount of tissue required and the number of individual animals needed to provide the appropriate amount of tissue, antibodies, etc. A detailed explanation of how the required number of animals was determined must be included in the justification narrative.
- **Exploratory Study Requiring No Statistical Analysis** (use of live animals to demonstrate success or failure of a desired goal, such as the production of transgenic mice): Animal numbers are justified based on the probability of success of the experimental procedure; a detailed explanation of how that probability was determined must be included in the narrative.
- **Pilot Studies:** Animal numbers are determined by the investigator's experience and personal judgment, and are typically small. Data collected in pilot studies are generally used to determine statistically relevant sample size calculations for future experiments.
- **Studies Requiring Inferential Statistical Analysis:** If possible, animal numbers are determined by statistical power analysis; the justification statement must include the values of alpha, beta, sigma, and effect size used in the power analysis to determine sample size. Alternatively, minimum numbers of animals may be determined based on pertinent literature for comparable studies in which the desired effect sizes were shown to be statistically significant.

Animal numbers cannot be justified on the basis of how many experiments the lab personnel can perform in a week, month, etc. The cost of the animal should not be considered as the primary justification for the use of a particular species or model.

## References

1. Public Health Service. (1996) U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and training. PHS Policy on Humane Care and Use of Laboratory Animals. Washington, D.C.
2. National Research Council. (1996) *Guide for the Care and Use of Laboratory Animals*. National Academy Press, Washington, D.C.
3. CFR (Code of Federal Regulations) (1985) Title 9 (Animals and Animal Products), Subchapter A (Animal Welfare). Washington, D.C.: Office of the Federal Register.
4. Erb, H.N. (1996) A non-statistical approach for calculating the optimum number of animals needed in research. *Lab Animal*, 45-49.
5. Mann, M.D., Crouse, D.A., Prentice, E.D. (1991) Appropriate animal numbers in biomedical research in light of animal welfare considerations. *Laboratory Animal Science* 41:6-14.