Drexel University Animal Care and Use Committee Policy for Animal Number Requests

The purpose of this document is to provide a clear and consistent animal number approval policy that is relatively straightforward for investigators because using too many or too few animals for a particular study negatively impacts animal welfare. The Committee recognizes that it is often difficult to project the number of subjects you will need, given the inconstant? unpredictable? nature of biological experiments. However, it is possible to make an informed estimate, and we have mechanisms in place to handle totally unforeseen difficulties.

When deciding how many animals you need for the written justification in the protocol (item 11), or for amendments to existing protocols, please use one or more of the following approaches:

1) Base your request on a previous study (with reference), not necessarily by your group. Clearly state the similarity in experimental goals and that X number of animals was required in that study to accomplish the work- for example, gain statistical significance, or in a pilot study, determine if your approach is worthwhile. State how that led you to calculate the number of animals you need.

2) Perform a power analysis to determine the number of subjects needed. For example, you may be comparing groups on a numeric outcome measure. In that case,
you would estimate the differences you expect in the means between different groups and the variability of measurements (likely based on previous work) and do a power analysis. For example, in a previous study you (or someone else) found a 50% increase in healing rate with treatment compared to control, and now you want to look at a parameter related to healing, like blood flow or some other related measure, that is expected to show similar differences. Free interactive programs for determining sample size in this way are available on the web with clear explanations of the entries needed, (for example, http://www.quantitativeskills.com/sisa/calculations/samsize.htm

3) You may also base your request on a previous unpublished study using the same or a similar model, again citing how many animals were required to accomplish the objectives, and relate this back to the number of animals needed for your study. This latter approach is not optimal, but in some cases necessary. This method is not acceptable for USDA covered species.

Be sure to take into account attrition if this is a projected problem and adjust your requests accordingly. Also, if the research has several experimentally distinct aims, each with its own group of animals, numbers must be justified separately. If the aims are all related, and similar effects are expected, make that clear. Researchers using USDA covered species should follow the same procedures, but now must submit the references they cite along with the
proposal, in order to conform to new USDA regulations.

Note that a pilot study should normally involve only a small number of animals in total. The goal of such a study is often to show that a procedure can be made to work, or to determine variability preliminary to a power analysis. Once these steps have been taken, a more complete justification of numbers should be provided.

**Wildlife studies**: Power analysis and the statistical significance of previous studies are typically not relevant, so alternative methods are generally used to explain the animal numbers.

In studies for which it is important to maximize the diversity of species collected, it may be sufficient to emphasize that fact and argue that diminishing returns have a relatively small impact within the range of observations you will be making.

In single species studies, a statistical calculation around margin for error is an appropriate method to justify sample size. For example, determine a reasonable margin for error (95% confidence interval) for some key summary statistic, such as the mean number of eggs per nest. Starting with an estimated SD, an approximate sample size can be derived. If comparisons between years or regions are of interest, a power analysis could be considered even for wildlife studies. As stated above, we understand there are certain studies where this analysis may not be plausible and alternative methods of justification will be considered.

If you need help with your number determinations or
justifications please contact the IACUC directly at IACUC@drexel.edu .

Review date: April 11, 2012
Last Review Date: September 2018