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1. Overview

Purpose

The purpose of this document is to provide clear and consistent animal number approval procedures 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 evolving and somewhat 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.

These procedures apply to all investigators proposing to use live vertebrate animals under an IACUC-approved animal use protocol.

2. Animal Number Justification

2.1 General Approaches

All animals in the study must be justified, including those used for breeding, those unused, and mouse (*Mus musculus*) and rat (*Rattus rattus*) fetuses greater than embryonic day 16 (E16). Please contact the IACUC about justification requirements for the use of embryos from other species. When deciding how many animals you need for the written justification in the protocol, 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/s amsize.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.

2.2 Attrition

Be sure to account for **attrition** if this is a projected problem and adjust your requests accordingly.

2.3 Multiple Experimental Distinct Aims

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.

2.4 Complex Aims

Complex aims should be represented in either a table or an explicit formula. For example, in Aim 1 you need to use three different drugs to assay effects on four brain regions, focusing on 2 types of cells per region, and need 6 animals per assay, this should be explicitly represented in either a table or an explicit formula (e.g., 3 drugs X 4 regions x 2 cells x 6 animals per group = 144 mice for Aim 1).

2.5 USDA Covered Species

Researchers using **USDA covered species** (most often rabbits, cats, pigs, or dogs, but including any warm-blooded animal other than birds or lab rats or mice) should follow the same procedures, but now must submit the full paper of the references they cite (generally as a pdf) along with the proposal, in order to conform to new USDA regulations.

2.6 Pilot Study

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.

2.7 Wildlife Study

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.

2.8 Other Considerations

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.

3. Responsibilities

3.1 Drexel University IACUC Responsibilities

The Drexel University IACUC and the IACUC Office are responsible for maintaining these procedures, training, and monitoring. For inquiries regarding these procedures, please contact the Director of Animal Welfare, as part of the Office for Research & Innovation (ORI).

3.2 Principal Investigator Responsibilities

The Principal Investigator (PI) is responsible for ensuring all animals used are appropriately accounted for and justified for every IACUC Animal Use Protocol submitted to the IACUC. The PI is responsible for following the guidance set forth by these procedures.

4. Revision

Edition 001/Effective Date April 11, 2012 - Original Document
Edition 001/Review Date September 2018
Edition 001/Review Date February 2021
Edition 002/Effective Date May 22, 2023 – Revised Document.
Section 2.1-Addition of justification criteria for mouse and rat embryo use.
Version 003/Effective Date November 17, 2026 – Revised Document.
Updated title and overview to remove references to policies.