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SCIENTIFIC JUSTIFICATION FOR THE NUMBER OF ANIMALS TO BE USED IN RESEARCH, TEACHING OR TESTING

All animals described in an animal use form (AUF) must be accounted for and scientifically justified. This mandate is found in the *Guide for the Care and Use of Laboratory Animals (8th Edition, NRC 2011, p25)*, wherein protocol review includes “justification of the species and number of animals proposed” and further, “whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g., provision of a power analysis)”. In addition, for USDA-covered species, numbers of animals to be used must be rationalized (CFR9, Part 2, Subpart C, §2.31(d)8(e)(2)).

The motivation for mandatory animal number justification is to potentially **Reduce** the animal numbers requested, **Refine** the experimental endpoints to minimize pain and suffering, and **Replace** animal usage with alternative scientific models.

To assist Michigan State University with the scientific justification description required for the various animal use protocols, please see the following suggestions for approaching the calculation of appropriate animal numbers to be used:

- **Teaching:** animal numbers are typically 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 compromising the quality of the hands-on teaching experience for students or impacting animal welfare.
- **Tissue harvest required for *in vitro* work, including antibody production:** animal numbers are typically determined by the amount of tissue/cells required and the number of individual animals needed to provide the appropriate amount of tissue/cells or antibodies, etc.
- **Hypothesis driven research:** animal numbers should be determined by statistical power analysis or may be determined based on comparable studies for which the desired effect sizes were shown to be statistically significant.
- **Exploratory or pilot studies:** use of limited number of animals to demonstrate success or failure of a desired goal, such as the production of transgenic mice, proof of concept, or survey of a population (e.g., animal numbers are typically justified based on the probability of the experimental procedure, and the PI’s experience and professional judgment).
- **Field studies:** animal numbers are usually based on past experience, especially those with the intent of characterizing abundance.