Animal Study Proposal Guidance for Animal Number Justification

Part D of the NCI at Frederick Animal Study Proposal requires a justification for the number of animals to be used. In general, animal study proposals can be broken down into three categories when considering animal number justifications. Each category requires a different approach to the justification provision, as suggested below.

Proposals wherein an experimental design dictates the number of animals required:

Justification should include numbers and types of groups, numbers of animals per group, number of experiments per year to arrive at a total number of animals necessary to complete the study or for a maximum of three years. When appropriate, it should be demonstrated that the sample size is sufficient to assure reasonable power in significance testing or reasonable precision if the goal is estimation. If this information is included in Part E – Experimental Protocol, a reference to that section would suffice. Factors which may reasonably be expected to impact the numbers of animals in a significant way should also be included to preclude future amendments.

Proposals wherein the use of animals is merely for the harvesting of normal tissues, organs or fluids for in vitro use:

A short statement citing past usage levels per year (per experiment, etc.) necessary to meet the PIs tissue or fluid requirements for each year of the proposal would be sufficient. If no prior experience is available, a statement relating anticipated amounts of material needed and the number of animals expected to provide that amount would be sufficient.

Proposals wherein animals are used for the production of biologic reagents or cells:

A short statement citing the scientific requirement for this reagent or cells and the unsuitability of or inability to obtain the required materials from other sources or other methods. Information related to the anticipated amount of material needed and the number of animals required in order to provide that amount would be sufficient.

Power calculators

Software programs are commercially available (e.g. GraphPad Statmate2, GraphPad Software, La Jolla, CA). In addition, free power calculators are available at the following websites:

http://statpages.org/

http://www.cs.uiowa.edu/~rlenth/Power/

Should questions arise or if additional guidance is needed regarding the justification for animal numbers or any other aspect of the NCI at Frederick Animal Study Proposal Form, please call the ACUC Coordinator at 301-846-7544.