



动物用量的确定及科学性 Determination and Justification of Animal

Numbers

管理科研、测试、教学中动物的伦理使用的关键原则是禁止一切动物生命的浪费；每一个科研项目中使用动物的数量必须以最小化的必须使用量达到稳定有效的科研结果。A key principle governing the ethical use of animals in research, testing and teaching is that no animal life is wasted; the number of animals used in each project must be the minimum necessary to obtain valid and meaningful results.¹

实验方案设计大纲 Experimental Design Outline

动物数量的科学依据首先要有一个清晰的、假设的实验设计大纲。所有涉及活体动物或动物组织的实验都必须在方案中概述，为了实现项目的目标，所需动物的数量必须与实验设计直接相关。所有动物都必须被科学合理统计，包括实验动物、捐赠动物、生产动物，以及在繁殖不用于直接研究的动物。Justification of animal numbers begins with a clearly-stated, hypothesis-driven outline of the experimental design. All experiments involving live animals or animal tissue must be outlined in the protocol, and the number of animals required must be directly relevant to the experimental design in order to achieve the goals of the project. All animals must be counted and justified, including experimental animals, donor animals and live-born offspring of pregnant animals and animals that are produced in breeding colonies but cannot be used in research.



注意 NOTE: 繁殖保种的动物应该与实验用动物分开统计。繁殖用的动物不用再试验方案中描述。Animals used to establish and maintain a breeding colony (breeding pairs, offspring that cannot be utilized because of genotype, sex, etc.) should be justified separately. Breeding animals do not need to be included in the Experimental Design section.

研究负责人需要提供总的动物用量大纲, 包括 In order to assess the number of animals requested, the Lead Researcher must provide the IACUC with an overall outline of the proposed experiments in the protocol application. This outline must include (at minimum):

- 每个实验的目标是 The purpose of each experiment or set of related experiments,
- 每个实验的分组数 The number of experimental groups/subgroups;
- 每个品系动物的用量 The number of animals by species/strain per group/subgroup,
- 对照组的动物用量, 可使用表格说明 The total number of control and experimental animals should be drawn from the experimental design and summarized in the overall outline. For many studies, this information can be effectively presented using a table or grid design.
- 如果动物将用于安乐后取材, 请描述每只动物提供材料与后续实验研究的相关用量描述。
If the project involves euthanizing animals for tissue harvest, the relationship between the amount of tissue/cells needed for the experiments must be directly



correlated to the number of animals required to produce that tissue (e.g., each animal produces X amount of tissue, which is adequate to perform Y experiments.)

- 若动物使用过程中会出现审核科预计到的濒死或死亡, 请详细描述这部分动物的用量情况。Anticipated animal losses due to morbidity, mortality or other expected difficulties with the experimental procedures must be carefully described in order to justify the need for additional animals.

动物使用量的科学依据 Justification of Animal Numbers

研究和试验研究的目的是在动物数量最少的情况下提供具有统计意义的结果, 并且必须清楚说明动物数量的确定方法。一般可使用统计技术分析, 以最大限度地分析每一种动物产生的数据。动物数量合理的依据很大程度上取决于研究本身的性质。模型的预实验和专业知识也可以考虑进去, 但是必须将研究记录体现在方案中。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.



可在方案建立前进行数据分析。 Consultation with a statistician or use of statistical software during the design phase of the experiment may be useful.

推荐的分析网站 Websites that may be helpful in performing a power analysis

include:

- <http://www.nal.usda.gov/awic/newsletters/v7n1/7n1chamo.htm>
- <http://statpages.org>

下面列出了五种基本类型的研究，以及为每种类型的研究确定适当的动物数量的指南: 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:

- 教学方案 Teaching Protocols: 动物的数量是由特定的学生与动物的比例决定，应在不牺牲学生的动手教学体验的质量前提下，尽量减少动物的数量。 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.
- 组织采集 (包括抗体制备) Tissue Harvest Required for In-vitro Work (including antibody production): 动物数量取决于研究所需的组织用量以及动物所能提供的组织量。 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.

- 无需数据分析的开发性研究 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): 动物用量取决于试验成功的概率，方案中应描述如何确定试验成功与否。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.
- 预实验 Pilot Studies: 动物数量取决于研究负责人的经验几个人判断，数量较少。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.
- 需要统计分级数据的研究 Studies Requiring Inferential Statistical Analysis: 动物用量可由分析软件计算。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.



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注意 NOTES:

- 动物数量不能由科研人员每周或每月可操作的动物数量决定。Animal numbers cannot be justified on the basis of how many experiments the lab personnel can perform in a week, month, etc.
- 动物的成本不应被视为使用某种品系或模型的主要理由。The cost of the animal should not be considered as the primary justification for the use of a particular species or model.