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UNIVERSITY OF PRETORIA
Animal Ethics Committee
Onderstepoort

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Procedure title:

Importance of the sample size

Purpose:

1. To describe the sample size

Scope:

1. The SOP is applied to view the importance of the sample size

References:

1.

Terminology / Abbreviations:

1. N/A

Procedure:

One of the most important concepts in animal ethics is the principle or reduction. According to this principle, the fewest number of animals in the project should be used. To this regards the number of animals used in the study has to be justified by a proper sample size calculation.

1.To justify the sample size:

1.1 Provide the method of sample size calculation, and the parameters used in the said calculation. The full method for sample size calculations need not be provided unless requested by the committee OR Provide proof of similar sample sizes used in other similar types of studies e.g. in a study on wild rats Mathew et al was able to show that a sample size of 20 was needed to study the foraging behaviour of the ….. When using an article, attempts should be made to criticise the published sample size in an attempt to further reduce animal numbers in a research project OR provide other proof that the study makes use of a general acceptable sample size for the type of studies e.g. OECD approved toxicity protocols.

1.2 Please note, it is not acceptable to purely state that the sample size was determined by a statistician or Prof XYZ, without providing the method they used for the calculation. However the committee will consider sample size based on a person's past experience with similar studies as long as long as this is clearly articulated.

2. The study design also requires justification to ensure that the number of animals is the minimum sample size possible.

2.1 The committee would thus need to see the basic study design, in words and diagram

2.2 It is important to point out to the committee whether the study is negative controlled, positive controlled or self-controlled.

2.3 If a study relies on untreated infections or harmful procedures to the negative control, this needs to be properly justified as the process of refinement indicates that the pain and suffering should be at all times mitigated

3. Another important consideration in the study is the use of pilot studies when the intention is to evaluate the effect in a large sample size. While it is general accepted that pilot studies may not be useful in ecological/zoological studies, the principle is sound:

3.1 For all medical, veterinary, production or behavioural research pilot studies need to be undertaken before exposing larger sample sizes when basic information is not available.

3.2 Pilot must be used when painful experiments are undertaken on larger number of animals.

3.3 In-phase analysis can be undertaken for studies, to show that the study needs to continue

3.4 Pilot studies are necessary even for poultry studies. In these cases, the pilot study information is important for scale up to intermediate sample size e.g. sample size of 60, then 3000, then 20000.