

<b>Institutional Animal Care and Use Committee</b>		<b>UNT Health</b>
<b>Title:</b> Animal Numbers Approved in a Protocol		
<b>Document #:</b> 043	<b>Version #:</b> 04	
<b>Approved by IACUC Date:</b> October 22, 2024		

**A. BACKGROUND INFORMATION**

- a. *The Guide for the Care and Use of Laboratory Animals* states that “justification of the species and number of animals proposed; whenever possible, the number of animals and experimental group sizes should be statistically justified” should be included in an animal use protocol.
- b. The PHS Policy states that the “identification of the species and approximate number of animals to be used” should be included in an animal use protocol.

**B. RESPONSIBILITIES**

- a. It is the responsibility of the Principal Investigator to justify the number of animals requested in the protocol using citations of previous research, using a power analysis, or other means (why a specific number of tissues is needed, for example).
- b. It is the responsibility of the IACUC to review all justifications for animal numbers. They must ensure that a sufficient but not excessive number of animals are used.

**C. PROCEDURES**

- a. Principal Investigators should enter the number of animals required for studies in an animal use protocol.
- b. The three-year total is the number of animals that can be used during the three-year approval period.
- c. Justification for the number of animals should be adequately described in the protocol. There are a number of methods used to determine the number of animals selected as the lowest number available to achieve scientific validity within a study.
  - 1. Previously published work
  - 2. Pilot Study to estimate variabilities and effect size, to in turn justify the number of animals needed for the full-scale study.
  - 3. Power Analysis
- d. Once sample size is established, provide the number of groups and calculations to achieve the total number of animals requested, including considerations for failures and death.
- e. Animal numbers should also be added to the flow chart and should match the total number requested.
- f. Additional animals can be requested at a later time via an amendment and SOP 002 Amendments to Approved Protocols should be followed. When adding animal numbers to a protocol through an amendment, a justification for the numbers should be provided using similar methods aforementioned.

#### **D. REFERENCES**

- a. [Public Health Service Policy on Humane Care and Use of Laboratory Animals. NIH, Office of the Director. Revised 2015.](#)
- b. [Institute of Laboratory Animal Resources \(2011\). Guide for the Care and Use of Laboratory Animals. National Academy Press, Washington, D.C.](#)