BACKGROUND: Per the PHS Policy, research proposals must specify a rationale for the approximate number of animals to be used, and animal use must be limited to the appropriate number necessary to obtain valid results. According to the Guide, the IACUC must evaluate the justification of the species and number of animals proposed; and “whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g., provision of a power analysis).” Minimization of the number of animals necessary for results is a key principle in the ethical considerations of animal research.

4.8.1 RATIONALE FOR ANIMAL USE NUMBERS IN PROTOCOL:

Investigators must include a rationale for the approximate number of animals proposed to be used in their animal use projects (AWAR §2.31, e, 1; §2.31, e, 2; PHS Policy IV, D, 1, b; Guide p. 25). Beyond the animals actually used in study activity, this expectation includes any number of animals that are:

- kept for breeding purposes
- produced and culled prior to research use and not subjected to any experimental manipulations
- held in unassigned pools
- used in field research

When determining animal number requests, researchers should also account for expected mortality, animals used for training purposes, the number of offspring produced to obtain specific genotype models, and unexpected fertility and fecundity beyond the number of animals needed for statistical significance.

Approval for increases in animal numbers: Any increase in the number of animals produced, acquired, or used in a specific category or procedure must receive prior approval from the IACUC. Production colony managers should ensure protocols are amended promptly when indicators of unexpected robust breeding become evident.

4.8.2 REPORTING ANIMAL NUMBERS FOR CONTINUING (ANNUAL) REVIEW:

Animal use protocols are approved for a maximum of three years. UT Austin IACUC requires investigators to report annual animal use on the continuing review form. All animals used during the reporting period should be included. If the same animals are used for multiple years, this can be pointed out on the renewal form so it is clear what the overall total use has been. The date range used for reporting on the continuing review form is as follows:
Example: A behavioral experiment is carried out over two years using the same animal. Alternatively, a primate is used for the entire life of the protocol (three years). These animals are to be reported each year they are used. The fact that an animal was used over multiple years can be pointed out on the renewal form.

Year three animal use numbers (2nd anniversary – 3rd anniversary) may be reported on the protocol closure report form.

Expected Accuracy in Counting Animals

The IACUC requires exact head counts to be reported for all vertebrate species except for fish and tadpoles. “Compared with mammals or other terrestrial vertebrates, when it is relatively easy to count a few animals in a cage or pasture by visual inspection, it is difficult to count fish without handling them and causing them undue stress.” (ILAR 2003) For this reason, fish and tadpole users may report their best approximation of animals used that year.

Age to Count Animals in Production

Any non-embryonic vertebrate animal must be counted at the time of experimental manipulation as part of an approved research project regardless of age. Animals produced in a research colony and held for future use in a research project should be accounted for as indicated in the following table:

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>WHEN TO COUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mice, rats, voles, guinea pigs, and other rodents</td>
<td>At time of birth (*see below)</td>
</tr>
<tr>
<td>Birds</td>
<td>Day of hatching</td>
</tr>
<tr>
<td>Frogs and other amphibians (including tadpoles)</td>
<td>Day of hatching or equivalent (**see below)</td>
</tr>
<tr>
<td>Fish</td>
<td>Day of hatching or equivalent (**see below)</td>
</tr>
<tr>
<td>Reptiles</td>
<td>Day of hatching</td>
</tr>
<tr>
<td>All other vertebrate animals</td>
<td>At time of birth</td>
</tr>
</tbody>
</table>

*Counting rodents can be done at first manipulation to avoid stress/cannibalism. These manipulations may include but are not limited to experimental procedures, genotyping, or cage changing/handling.

**For many oviparous aquatic vertebrates, "hatching" is not easy to observe. In these cases, the equivalent developmental stage is considered to be the point where the yolk sac has been absorbed and the larvae begins to feed, e. g. the "buttoned up" stage for fish or the equivalent of the NF stage 45 for Xenopus or Gosner stage 20 for other anurans.

4.8.3 REPORTING ANIMAL NUMBERS FOR FEDERAL AND ACCREDITING AGENCIES:

In the fall, the Office of Research Support and Compliance gathers information from investigators about animal usage from the past fiscal year (October 1 – September 30) to be reported to federal and accrediting agencies.

- This report covers animals used at the University of Texas at Austin (and UT satellite locations in the US) only. Animals used in collaborations at other institutions or locations should not be included.
• This is the total numbers report covering all protocols for which each investigator is the primary Principal Investigator.
• Animals are reported by pain/distress categories and each animal should only be recorded under one column.
• Animals should be recorded in the highest category of pain/distress under which they were used (B through E).
• Animals are reported each year they are used (even if the animals were included in the previous year’s report). They should be reported in the column consistent with the greatest amount of accompanying pain or distress they experienced during each reporting period.
• If an animal is used by more than one primary Principal Investigator on each of their animal use protocols during the reporting period, then each Principal Investigator should report the animal’s use. The primary Principal Investigators must immediately contact ORSC to notify the office of the dual reporting to avoid incorrect reporting to federal and accrediting agencies.

Example: An animal is used on Dr. X’s protocol and then transferred onto Dr. Y’s protocol during the reporting period. Both Dr. X and Dr. Y must report the use of this animal. They then must contact IACUC@austin.utexas.edu to notify IACUC staff of the double reporting so an accurate number of animals are reported to federal and accrediting agencies.

Example 2: An animal undergoes surgery during year one of the protocol and is reported under category D. During year 2, the same animal only undergoes behavioral testing and is reported under category C. During year 3, the same animal undergoes a second surgery and is reported under category D.

The following reference contains additional examples that may be helpful to investigators submitting annual reports: https://oacu.oir.nih.gov/system/files/media/file/2021-02/a1-usda.pdf

If there are questions about how to properly report animals studied by more than one PI, please contact the IACUC for clarification so that the annual reports for the institution as a whole are accurate.

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REFERENCES


<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/04/2022</td>
<td>Section 4.8.3 revised to include additional description and example for animals used for multiple years of the protocol.</td>
</tr>
<tr>
<td>07/10/2023</td>
<td>Changed counting rodents to “At time of birth” with clarification *</td>
</tr>
</tbody>
</table>