

## **Division of Animal Resources**

### **Notifications of 75% and 90% of Approved Animal Use**

#### **Overview**

On July 1, 2005, the IACUC announced beginning September 1 the DAR would implement procedures to notify investigators at various stages of animal acquisition relative to the number approved for research, [http://www.emory.edu/IACUC/policy\\_animal\\_usage.php](http://www.emory.edu/IACUC/policy_animal_usage.php).

The DAR will contact specific investigators when 75% and again when 90% of the animals authorized on any approved protocol have been acquired, whether through purchase or breeding. We hope this information will serve to help investigators monitor and manage their animal usage. Depending upon the pace and schedule of research, persons may elect to disregard the courtesy notice or act to modify the existing protocol to add animals.

#### **Frequently Asked Questions**

**Q:** I have been advised to modify my protocol to add additional animals. How is this done? Where can I find the form?

**A:** The modification form can be found at: [http://www.emory.edu/IACUC/general\\_forms.php](http://www.emory.edu/IACUC/general_forms.php) and can be submitted electronically to the IACUC office ([iacuc@emory.edu](mailto:iacuc@emory.edu)) for immediate designated review.

**Q:** In filling-out the modification form, will it be sufficient merely to list the number of additional animals needed?

**A:** We recommend giving a logical numeric rationale in Section 11 and distributing them by pain/distress category in Section 12. If this is not done, you are likely to end up in the predicament of a lengthy and drawn-out review. Where possible, statistical analysis should be used (*Guide for the Care and Use of Laboratory Animals*, p. 10). Examples of rationales to add additional animals include new experimental initiatives, compensation for unforeseen technical failures or failed experiments, failure to account accurately for weaned and culled animals of the wrong gender or genotype, and not carrying existing animals from an old to a new protocol. In most cases, providing appropriate detail takes the guesswork out of IACUC review and enables hassle-free approval.

**Q:** You speak of “providing appropriate detail” regarding the request for more animals via the modification process and in order to ease and hasten review and approval. Can you give some examples?

**A:** In some instances, such as in the case of technical or experimental failures, it may be sufficient to list the number of failures, explain why they failed, and request an equal number of replacements. Similarly, if there was a failure to carryover existing animals, this could be explained in a straightforward manner. Where breeding and progeny have not been accurately forecast, it may get more complicated. The IACUC appreciates that activities involving the production of genetically-manipulated animals are of low yield, but require the production of unpredictably large numbers of animals, the vast majority of which are unsuitable for research. The expectation, however, is that the number of breeders and the

expected number of offspring both useful experimentally and culled will be accounted. For mice on an inbred background, a safe rule of thumb is to assume the birth of 0.3-0.5 live pups of either gender per breeding female per week. Some proportion of these pups will be useful for experiments or continued breeding (e.g., backcrossing) and it is recommended that this be described. Where animals are used as sources of tissue (or cells), providing a detailed breakdown of how many additional experiments must be done, the amount of material needed for each, the amount available from the typical animals, and a calculation of animal numbers takes the guessing (and more questions) out of reviewer hands.

**Q:** Why is it even necessary to track animal use? I've read the NRC "Guide for the Care and Use of Laboratory Animals" and the regulatory requirement is only to consider the approximate numbers of animals used. Precise tracking does not seem to have much scientific relevance and, given tight funding, PIs are not likely to acquire or maintain animals exorbitantly beyond their need. It seems as though DAR and IACUC resources could best be used doing other things.

**A:** Although neither the PHS Policy nor the Animal Welfare Act Regulations (AWAR) explicitly require an institutional mechanism to track animal usage by investigators under IACUC-approved activities, both require that proposals to the IACUC specify and include a rationale for the approximate number of animals proposed to be used (AWAR §2.31(e)(1-2); PHS Policy IV.D.b, p. 9; *Guide for the Care and Use of Laboratory Animals*, p. 10). These provisions implicitly require that institutions establish mechanisms to monitor and document the number of animals acquired/produced and used in approved activities (Potkay S, Garnett N, Miller JG, Pond CL and DJ Doyle. Frequently asked questions about the Public Health Service Policy on Humane Care and Use of Laboratory Animals. Cont Topics Lab Animal Sci 36 (2):47-50, 1997). The PHS, through the Office of Laboratory Animal Welfare, has more recently clarified: "...it is incumbent upon an institution to establish mechanisms to monitor and document the number of animals acquired and used in approved activities...Many institutions have automated tracking systems that will alert an appropriate individual when an investigator has reached a preset percentage (e.g., 80-90%) of the animals approved for a specific project, and can prevent ordering animals in excess of the number approved."

Source: Institutional Animal Care and Use Committee Handbook, 2<sup>nd</sup> edition, Office of Laboratory Animal Welfare, NIH, 2002, p. 153. DAR has also found that our notifications have been helpful to alert investigators unaware of animal breeding or purchases in excess of their plans and budgets.

**Q:** I have been notified that my protocol is reaching its limit of mouse use. The reason seems to be related to breeding excessive animals, but I keep careful records and it simply is not possible that I produced so many. How can this be prevented in the future?

**A:** The DAR uses a cage population benchmark of 3.5 mice per cage. Any time a new cage is added to the census, 3.5 mice are debited from the number original

number approved by the IACUC. In lieu of this methodology, it is possible for investigators to report the actual number of weaned mice to DAR. To enable smooth and hassle-free debiting, this must be done consistently on a monthly basis and before the 10th of the month.

**Q:** I wean many more animals than I use and would prefer that these not be accounted and debited. Is this possible?

**A:** Unfortunately, no. Once animals are weaned and put into a new cage, a new cage card is generated. Each new cage card is linked to an account number and an approved IACUC protocol. Our software assumes there are 3.5 mice in the new cage and the protocol is debited accordingly. *Per diems* also begin to accrue at the time the new cage is established.

**Q:** Since my work is supported by a rodent breeding colony, can you give me any tips on how to reduce the likelihood that I will run into situations of excessive use? For example, how can I reduce the likelihood of weaned animals that are culled and not used scientifically from being tabulated with those used experimentally?

**A:** One approach would be to biopsy neonates for genotyping before weaning and cull them prior to weaning. The IACUC, for example, permits tail biopsy and accompanying toe snipping without anesthesia on mice up to 12 days of age. This also saves costs preventing the generation of cages of unneeded animals. For more information see “Biopsy Policy” at <http://www.emory.edu/IACUC/>. If this approach is not possible, the IACUC does appreciate that some protocols may generate many more animals than are used particularly if supported by a breeding colony where there may be extensive back-crossing or other genetic manipulations ongoing. The recommendation is that cull animals weaned but not to be used experimentally should be listed in Class B on the IACUC application (Section E). It is recommended that these be delineated parenthetically as “(culls)”. If procedures are done requiring anesthesia, such as tail biopsy of weaned animals, these mice should be categorized in Class D (painful or distressful with relief) and also identified as “(culls)”.

**Q:** I buy rodents and keep them up to 5 per cage by gender until divided to set-up breeding pairs or for experiments. It seems to me that setting up these new cages will put me at risk for 3.5 mice to be debited from my approved totals each time. Have you addressed this?

**A:** This can be prevented by using cards or labels with the “EU Separation” designation instead of “EU Weaned” counterparts. Please see the facility supervisor to obtain these.

**Q:** I desire to move some animals from one protocol to another and transfer some others to a colleague here at Emory. Is it possible to keep the animals from being counted and debited twice?

**A:** This can be accommodated by using cards or labels with the “EU Transfer” designation for the newly transferred animals and scanning-out their former cage card. Facility staff can provide these cards or labels.

**Q:** I renewed an expired protocol a year ago and have already used my full allotment of animals per DAR records in the first year of my three-year period of approval. The only reasonable explanation for this seems to be animals that existed at the time of expiration/renewal of my protocol were deducted from the new number.

**A:** This is most likely the case. When the old cage card was scanned-out and the new one was scanned-in, the animals were treated as newly acquired on the new protocol. This should be taken into consideration when renewing an existing protocol at a 3-year time point. Any residual animals carried over from the old to the new protocol should be identified parenthetically as “(carryover)” in the appropriate pain/distress category (Section E) of the new protocol.

**Q:** How can I receive notification of usage at levels other than 75% or 90%?

**A:** DAR can do individual queries on an as-needed basis. Please call (7-8395) or email ([mkulasi@dar.emory.edu](mailto:mkulasi@dar.emory.edu)) if you are in need of this service.

**Q:** What happens if I acquire or breed animals in excess of the threshold listed in my protocol and approved by the IACUC?

**A:** The DAR has been instructed by the IACUC to inform the IACUC office of these situations. The IACUC will then work with the investigator to take necessary action.