Animal usage on approved protocols

Exceeding approved numbers in any pain category could constitute non-compliance

Principal Investigators are responsible for ensuring that all work being done on their protocols is within the parameters authorized by the IACUC. This includes making sure that the numbers of animals used in all pain categories do not exceed the numbers approved by the IACUC. Any incident of exceeding animal numbers is reportable to the IACUC.

For those PIs whose animals are in facilities that are bar-coded in eSirius, an alert appears on your eSirius home page once 80% of the animals in any pain category are used up. Please pay attention to this alert. Do not assume that the alert is an eSirius error.

PIs whose animals are not in bar-coded facilities should work with their facility manager at least monthly to make sure that animal usage on all protocols is within approved numbers. This is especially important when acquiring new animals, transferring them from another pain category or protocol or adding animals that have been produced by breeders on the protocol.

If you are not sure of the reason why animal usage is recorded at a particular level, or if you suspect an error in reporting, please work with your facility manager and the IACUC staff to get answers and take action, especially if you believe that you are likely to need more animals than are remaining. To increase animal numbers, please submit an amendment and allow for a minimum of 4 weeks for the amendment to be approved.
Common mistakes in requesting animal numbers

#1: An amendment to increase animal numbers results in a reduction of the total approved number
Consider the scenario:
- Approved number on the protocol: 500 in Category C.
- The PI would like to request 200 more mice in Category C.
- In the amendment, section 13.1 is changed from 500 to 200. In section 13.12, numbers in Category C are changed from 500 to 200. Number justification in 13.13- describes the use of the 200 extra mice.
- Problem: Once the amendment is approved, the PI is now approved for ONLY 200 mice for the entire 3 year duration of the protocol. So, s/he now has fewer animals than the originally approved number. In some cases, if the PI has already used more than 200 mice, the usage registry number will immediately be in the negative, creating a situation of non-compliance.
- Correct amendment: Section 13.1- ask for 700 mice (500 + 200). In section 13.12- change the Category C number from 500 to 700. In Section 13.13, justification for numbers, add the justification for the 200 extra animals to the existing justification for the 500 animals. This will ensure that you now have 200 more animals in pain category C.

#2: Requesting animals for use in the current year only
Consider the following scenario:
A PI plans to use 5 horses each year of the three years of the protocol. How many horses should s/he request? 5? or 15?
- If the same 5 horses will be used every year, the PI only needs to request 5 horses for the three years of the protocol.
- However, if 5 different animals will be used each year because the procedure can be done only once in each animal, or the research requires use of different animals for any other reason, the PI must request 15.
- Do not ask for only the number of animals that you plan to use in one year. In doing so, you will most likely exceed the approved number by the second year.

The IACUC performs a thorough review of protocols before approval, so that such problems can be detected before approval. However, it relies on the PI to provide an accurate assessment of their animal numbers. Please consider your animal number needs carefully before submitting an amendment or new protocol. This careful consideration could save a lot of trouble afterwards.

#3: Requesting reduced animal numbers when animal usage is lower than expected.
Consider the following scenario:
A PI had planned to use 100 rats on a protocol every year. Total number requested- 300. This past year, s/he only used 50 rats. Should s/he submit an amendment to reduce the number of rats from 300 to 50? Or from 300 to 250?
- Reducing the number to 50 is not recommended. Since the amendment applies to all three years of approved activity, s/he now has changed the total approved for the entire three-year period from 300 to 50! If s/he uses any animal in the coming year, there is danger of non compliance. In this case, it is OK to submit an amendment to request 250 animals instead of 300, as long as s/he is confident that the number will not be exceeded.
- PIs have sometimes thought that they had to amend the protocol to reflect actual number usage for the year. This attention to detail is laudable and appreciated. However, it is not a requirement. If you used fewer than planned animals in the current year, you do not need to submit an amendment to update animal numbers. Using fewer than approved animals is not a problem.
Breeding Rodents: Category B or C? Almost all should be Category C

Rodents that are being bred for use later in the course of the protocol are often requested by PIs in the pain category B. A tail snip or single blood collection for genotyping, or even the act of eliminating excess breeders or offspring through euthanasia, constitute a manipulation that requires a designation of Pain Category C. As irrational as this seems, the only breeders that can be reported as Category B are those that live out their life in captivity without ever being handled for tissue collection or euthanasia. These sorts of breeders are clearly quite rare, and this is why the IACUC so often asks PIs to change animals requested under Category B to be changed to Category C. Please ensure that when requesting animal numbers, all breeders, except in the rare circumstances outlined above, are requested in Category C. When recording animal usage against your protocol, make sure that the numbers are debited against the correct pain category: almost always C. Please refer to the IACUC policy on assignment of pain categories for more guidance.

Revised Annual Review form to be implemented on April 19, 2010

The Annual review form in eSirius has been modified and will be implemented on April 19, 2010. The new form consists of a series of check boxes and additional questions to allow the IACUC to perform required review of the Annual reports. The process for receiving notifications and submitting the annual review will remain unchanged. Changes are required for the reports that are submitted before April 16. For all other Annual reviews, the PI will only see the new version of the form in eSirius.

Why the change?

The PHS Policy at IV.C.5. states "the IACUC shall conduct continuing review of activities covered by this policy at appropriate intervals as determined by the IACUC but not less than once every three years (3)". The USDA regulations 9 CFR 2.31(a)(5) (4) use similar language, except that continuing review must be performed not less than annually.

Cornell Policy 14 on the Care and Use of Animals in Research and Teaching states: “The IACUC conducts an annual review of the protocol. The Investigator is required to report annually on the status of the protocol and that ongoing activities are conducted in accordance with the approved protocol”

Thus, the purpose of continuing Annual review is threefold: to inform the IACUC of the current status of the project; to ensure continued compliance with PHS, USDA and institutional requirements; and to provide for re-evaluation of the animal activities at appropriate intervals. Federal requirements, research ethics, and moral obligations of the scientific community to society demand that IACUCs conduct appropriate and meaningful reviews of ongoing animal protocols in the same responsible manner that initial reviews are affected. At the same time review procedures should be reasonable, meaningful and efficient, and should not burden the PIs or the IACUC with unnecessary requirements that do not contribute directly to the welfare of the animals or compliance.

What is the change?

The new form requires answers to the following questions. (Click here to view a sample form)

1. Current status of the project
2. Whether the PI plans to continue or terminate the study. If termination is planned, a disposition plan for any remaining animals on the protocol must be in place.
3. Whether animal numbers were exceeded on the protocol during the previous year.
4. Whether any significant adverse events related to the animals on the protocol occurred in the previous year.
5. Whether any new information related to the three Rs (refinement, replacement or reduction) has appeared in the previous year.
6. A brief summary of the work accomplished during the previous year and a summary of the planned work in the coming year (if applicable)

**New IACUC policy on use of biohazardous agents with animals**

The intent of this policy is to define the requirements and process for the review and approval of protocols that propose the use of biohazardous materials with animals.

A copy of the complete policy and IACUC procedures document is available on the IACUC website. The key principles of the policy are as follows:

- All animal protocols involving the use of biohazardous materials (regulated animal and plant pathogens, biological toxins, and recombinant DNA molecules), are subject to additional review by the Institutional Biosafety Committee (IBC).
- The IBC must approve the Memorandum of Understanding and Agreement (MUA) describing the use of a Biohazardous agent in a lab setting, before it can be approved for use with animals on an IACUC protocol. Therefore IACUC approval of an animal protocol involving the use of Biohazardous agents is contingent upon IBC approval of the MUA describing the use of the agent.
- The AUHSP (Animal User Health and Safety Program) Working Group is responsible for performing occupational health and safety reviews of IACUC protocols submitted in eSirius together with MUAs submitted to the IBC and making recommendations to both the IACUC and IBC.

If you have any questions or comments regarding these or any other topics relevant to the IACUC, please contact the IACUC office at iacuc@cornell.edu. Also visit the IACUC website for updates and other information pertinent to conducting research or teaching activities with animals at Cornell University. The IACUC review timeline is available at [http://www.iacuc.cornell.edu/requirements/IACUC%20timeline.pdf](http://www.iacuc.cornell.edu/requirements/IACUC%20timeline.pdf)