



# ANIMAL TRACKS



A newsletter for the Duke research community

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<http://www.duhs.duke.edu>

## The New Duke Protocol Template

Few words cause more distress in the minds of scientists and IACUC members alike, than p-r-o-t-o-c-o-l! But why? By definition, a protocol is simply a method or process of gathering sufficient information to allow a panel of animal welfare advocates and scientists to make an informed decision on the proposed use of animals for testing, teaching, data collection, or experimentation. If the definition is so clear, then why must a protocol be so confusing and so difficult? Great question!

One answer could be the manner of information gathering and information processing is confusing and difficult. Researchers sometimes think submitting a protocol to the IACUC is a 'guessing game,' so they 'guess' what the IACUC wants to hear (and often guess wrong). IACUC members sometimes think that a protocol is really just a few simple questions, so Committee members become frustrated with the information provided by the researcher. It could be that our present process of 'information gathering and information processing' is not working sufficiently.

There are a number of possible solutions. For example, the IACUC could use more tables, 'select' options, or drop down lists on the protocol template; the protocol template could have a ready and accessible 'instruction sheet' which clearly describes the specific information required; researchers could be assured of access to the current version of the protocol template from a central server; researchers could submit only those sections of the master protocol template that apply to their research rather than pages and pages that do not apply; the IACUC could provide education on protocol submission practices.

About two years ago, the IACUC determined that the present system was not working as it should. The IACUC began a series of initiative to improve the process. One initiative involved appointing a Sub-Committee to work on development of a new protocol template and an improved submission process. The IACUC instructed the Sub-Committee to build a template that would be usable in a 'hard-copy' version but would also transition smoothly to a 'web' format for the eventual development of a web based protocol submission and review process. The IACUC instructed the Sub-Committee to build a template that captured the required regulatory issues, minimized the number of questions that must be answered by individual researchers, and resulted in a final protocol package that was complete (so it can be reviewed by the IACUC smoothly and efficiently).

This month, the IACUC Sub-Committee presented to the IACUC a draft protocol template which the Sub-Committee believes will capture the required information, capture information in a logical and reasonable manner, and facilitate the writing, the review and the approval processes. The Committee wishes to include the insight of the institution's faculty and staff in its final review

steps. This is why the February Brown Bag Seminars (there will be two sessions) have been reserved for the first viewing of the draft protocol template by the Duke research community. During the last weeks of February, IACUC will receive comment and constructive criticism on further improvements of the new protocol template. March and April will allow final IACUC review, modification, and decision on the new template. May and June will be the beta test of the new template. July 1 is the planned initiation of the new protocol template.

It is important to note that the new protocol template will only be required on new protocols (original) or de novo protocols (3 year re-writes). Currently approved protocols may be maintained in their present format until the de novo review is required. In practice, this means that a protocol approved in January of 2007 will not require the new protocol template until January 2010. Researchers may (at their own choosing) re-submit their current protocols on the new template at any time prior to the 3 year termination period of the current protocol.

We are certain that at some time in the not to distant future, the animal program will be authorized a move to a web based protocol submission and review system. When this occurs, we will already have a protocol template that is web friendly and knowledgeable to our research community. But until the web based process is active, the new protocol template will more clearly gather necessary information, will support a more efficient review process, and will prepare our community for the transition ahead.

Your IACUC has begun that process and invites you to partner with the Committee for the completion of this important task. The Committee realizes that change is never easy, and new processes are never without trial. The IACUC recognizes that there will be minor speed bumps along our way, and accommodations will be made when necessary. The IACUC and OAWA will, as has been our program's custom, provide education on completing the new protocol template. We will provide 'free' pre-reviews for any researcher, to assist in development of the new protocol. We will facilitate the transition to a protocol development, review, and approval process that meets the challenges of the 21st Century and is worthy of the ideals of Duke medicine and research.

Best wishes as we partner together for a productive research future,

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## Cage Space Requirements for Mice

(Duke Animal Care Policy)

Mice will be maintained in a density consistent with this policy as supported by *The Guide for the Care and Use of Laboratory Animals*.

This policy is based on a standard cage of 75 square inches. If larger or smaller cages are used, please consult DLAR for housing requirements.

### Mice from the age of weaning to adulthood:

Mice of weaning age and above should be housed with no more than five mice per cage at a density of 15 square inches per mouse.

### Breeding mice:

1. No more than three adults in a cage when a litter is born.
2. No more than two adults and ten pups in the cage when any of the pups are older than seven days of age. More than ten pups older than seven days can reside in a cage with one adult female if the pups are the progeny of the adult female.
3. No litters in the same cage that are more than two weeks apart in age.
4. Pups must be weaned at 21 days of age unless an exemption has been approved by the IACUC or the DLAR veterinary staff for health concerns. Breeding cages containing pups past the age of weaning that do not meet the criteria for exceptions are considered overcrowded.
5. Write the date of birth of all litters and the IACUC or DLAR Veterinarian-approved weaning date, if different than 21 days of age, on a designated cage card.
6. When litters need to be separated, the mothers and litters must be observed sufficiently to determine the appropriate mother for each litter before mice are moved from one cage to another.

The full Duke IACUC policy can be found at this link: [http://vetmed.duhs.duke.edu/documents/iacuc/pdf/policy\\_on\\_cage\\_space\\_requirements.pdf](http://vetmed.duhs.duke.edu/documents/iacuc/pdf/policy_on_cage_space_requirements.pdf)



## Principal Investigators

(Duke Animal Care Policy)

Authority and responsibility for performing animal care as approved by the Duke IACUC or consistent with Duke DLAR Care SOPs is assigned to the Principal Investigator (PI).

Policy:

1. The definition of a Principal Investigator at Duke is one of the following:
  - A. Faculty of Duke University of Duke University Medical Center.
  - B. Veterinarians on staff at the DLAR, DUPC, or VAMC.
  - C. Duke or DUMC staff, students (graduate or undergraduate), or third party individuals are considered as a PI with a faculty member (see 1A above) or a veterinarian (see 1B above) serving as a sponsor for the proposed activity.
2. In all cases (sponsored research or internal research) the Principal Investigator is responsible for all animal care and use activities performed under the approved protocol.
3. In all cases, the Principal Investigator is responsible for all activities performed by research personnel on the animals approved under the protocol.
4. The sponsor is also responsible to Duke and the IACUC for all activities and obligations involving the animals.
5. All correspondence will be sent to the sponsor as well as the Principal Investigator.

For a copy of the full Duke IACUC policy, follow this link: [http://vetmed.duhs.duke.edu/documents/iacuc/pdf/policy\\_on\\_definition\\_of\\_a\\_principal\\_investigator.pdf](http://vetmed.duhs.duke.edu/documents/iacuc/pdf/policy_on_definition_of_a_principal_investigator.pdf)

## Upcoming Events

February 1	SC meeting
February 5	New protocol deadline
February 5	SC deadline
February 15	SC meeting
February 15	Brown Bag Seminar
February 19	Brown Bag Seminar
February 22	SC deadline
March 1	SC meeting
March 5	New protocol deadline
March 5	SC deadline

SC= Significant change

## Q & A

**Question:** Our laboratory uses Ketamine and Xylazine frequently for our animal anesthesia. How does ketamine work? Why is it used with xylazine?



**Answer:** Ketamine (also called Ketaset®, Vetalar®) differs from most other anesthetics by providing 'dissociative anesthesia,' kind of a separation of what the body feels and what the brain acknowledges. Dissociative anesthesia is characterized by excessive muscular tone, mild respiratory depression, and sometimes profuse salivation. The drug is commonly administered by the IP, IM or SC route. After IP and IM injection, full effects occur in five minutes, and anesthesia lasts 30 to 60 minutes in most species. Post-anesthetic behavioral changes, such as depressed activity, may last as long as 24 hours.

Ketamine used alone can cause convulsions and does not cause surgical anesthesia (DO NOT USE KETAMINE ALONE FOR ANY SURGERY!). To provide muscle relaxation and prevent seizures, ketamine should be used in combination with a tranquilizer. Xylazine is often used for this purpose. The anesthetic and analgesic actions of xylazine and ketamine are additive, which allows the use of a reduced dosage of each and increases the margin of safety of these drugs. In combination, the disadvantages of xylazine (lowering of blood pressure) and ketamine (muscular rigidity) tend to cancel each other out.

The combination of ketamine and xylazine has become one of the most widely used anesthetic agents in laboratory animal medicine. It is critical to remember that Ketamine is a controlled substance and must be stored and used in accordance with DEA requirements.

**Question:** Rather than providing details of an experimental procedure on the protocol form, I chose to provide the literature references that clearly describe the details of what you wish to do. The IACUC rejected the proposal and required that I provide the details of the procedure. Why?

**Answer:** The IACUC approves a proposal for specific animal work. The IACUC does not approve previously published activities. The actual proposed procedure must be part of the IACUC protocol so that the specific experimental steps are clear to the Committee and so that the specific IACUC approved procedures can be reviewed during a compliance review. The literature references could be used as background information, but cannot be used as a substitute protocol section.

**Question:** If an investigator wishes to conduct research using animals at a foreign institution, must the Duke IACUC also approve the protocol? What if samples are obtained by citizens of the foreign country and then sent to our institution?

According to the federal regulations, all animal activities supported by the PHS must be reviewed by the IACUC of the domestic-assured awardee institution. As an accredited institution, we must maintain consistent review of all animal activities, regardless of funding source.

If foreign institutions are using US Government funds while serving as a performance site for Duke awarded research, then the foreign institution must also have Assurances on file with the NIH Office of Laboratory Animal Welfare (OLAW). The OLAW considers institutions whose scientists are engaged in such collaborative work, regardless of location, accountable for the animal-related activities from which they receive animals or animal parts, and the initial recipient institution (Duke) as holding ultimate obligation for the proper expenditure of those funds and the well being of the animals used.

In the specific case of sample collection, the IACUC's review should take into account the species involved, nature of the specimen, and the degree of invasiveness of the procedure, giving appropriate consideration to the use of anesthetics and analgesics. In cases in which samples are obtained directly by citizens of a foreign country for subsequent shipment, Duke (as the recipient PHS-supported institution) must should determine the proposed methods of collection and animal use and assure that the methods are humane and appropriate. Duplicate IACUC review is not required, however, Duke University has historically reviewed (and approved) all funded work (regardless of location or collaboration) for which Duke was the primary contract recipient. This review is for the protection of the animals, but even more so for the protection of our Duke scientists as well as the institution's good name.

**Question:** What does the IACUC look for when it considers personnel qualifications?



**Answer:** All funding and regulatory agencies require that personnel caring for animals be appropriately trained to accomplish the tasks required of them. The IACUC serves as the institution's representative assuring the funding agency that the investigator can provide the necessary formal or on-the-job training to ensure adequate care of the animals.



## OAWA's Brown Bag Seminar

Thursday, February 15<sup>th</sup>, 2007  
And Monday February 19<sup>th</sup>, 2007

Noon – 1 p.m.

Bryan Research Building: Room 103

Dr. Ron Banks

Director of the Office of Animal Welfare  
Assurance will be presenting:

## The New Duke IACUC Protocol Template: We Want Your Input

The Duke IACUC has been working for over a year to develop a new animal use protocol template. The new template has several goals:

1. To develop a 'back-bone' document for the soon-to-be-coming web-submission for animal use applications;
2. To have a protocol template form that asks the questions necessary for the IACUC to make an informed decision;
3. To have a protocol template form that is easier for researchers to follow;
4. To decrease the number of clarification questions required; and
5. To allow reviewers to be able to review protocol submissions in an effective and complete manner.

**The planned release (and use) of the new template is 1 July 2007.**

At this seminar, the Office of Animal Welfare Assurance will give a preview of the animal use protocol template currently under development, and requests input for changes or enhancements to the template under design. The presentation will follow this outline:

1. General overview of the purpose of a protocol template;
2. General overview of the Duke IACUC's actions in developing the new template; and
3. General overview of the structure of the new template and the concept of how it will work, by Part and Section.

Hard copies of the template core will be available at the seminar with a web-link for the various appendices for specific sections of the protocol. Dr. Banks will briefly touch on each of the appendices of the template. P.I.s, laboratory managers, and research associates are invited to attend. A process for comment and suggested enhancements will be advertised at the seminar.

The presentation on **Thursday, February 15<sup>th</sup>, 2007** will be **repeated on Monday, February 19<sup>th</sup>, 2007** to allow for as many people as possible to voice their opinions and suggestions.

The session will be held in room **103 of the Bryan Research Building**, located at 421 Research Drive, on Duke University's West Campus.

Attendees are encouraged to bring a lunch. OAWA will provide drinks and desserts. The session will begin promptly at noon. Please arrive early to sign-in and find a seat.