



ANIMAL TRACKS

letter for the Duke research community



A news-
March 2007

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

Deadline? What Deadline?

Whether the deadline is Valentines Day (Feb 14), Tax Day (April 15), or Grant Submission, missing a deadline by just day or two can have a life altering effect. Miss the Grant Submission date and the dollars may be slim in the days ahead; miss the tax deadline and the IRS may be calling; miss Valentines Day and well, enough said.

The IACUC has deadlines too, although not as life changing as other deadlines, still important. If you miss an IACUC deadline, then you're running to catch up with the process, and that isn't easy. The IACUC has determined that a few moments refresher would seem in order. Why the refresher? There are two reasons:

A) Occasionally PIs request 'special consideration' on a document submitted after the deadline, but the animal program deadlines are based upon federal requirements. Frequently granting 'special consideration' reflects poorly on the institution (potentially affecting our NIH Assurance, USDA Registration, and AAALAC Accreditation). Since all of these associations are important to the institution and the individual researcher, we must limit the numbers of 'special considerations' accepted by the IACUC;

B) The animal program is experiencing an increasing number of 'missed' deadlines, creating extra work for the PIs, OAWA staff, and the IACUC. Missed deadlines may require suspension, reporting to funding agencies, a new submission, and new pre-reviews and reviews. In these cases, OAWA, DLAR, and the IACUC must struggle to speed up processes and obtain clearances more rapidly – all because a deadline was missed.

In the case of new protocols or amendments, the deadlines are posted on the animal program web site. These are not target dates, they are deadlines. Documents received after close of business on the date listed as the deadline must be forwarded to the subsequent IACUC meeting.

For renewal protocol and annual reviews, the IACUC sends a memo advising the PI of the up-coming deadline a minimum of sixty days before the deadline.

This being said, I end this message with a plea. Please adhere to the deadlines for applications and reports, assuring on-time submission and approvals. Partnering together, this is one deadline that will not interfere with our lives.

Best wishes for a productive research month,

Non Compliance Resulting From 'Protocol Drift'

According to USDA regulations and the PHS Policy, everyone working on the protocol is obligated to perform only those procedures that are approved on the protocol. Of additional significance, those procedures being performed must be performed as approved by the IACUC.

The IACUC has observed an increasing number of non-compliance incidents involving 'protocol drift.' There are generally two reasons for 'protocol drift:'

Reason 1: The laboratory is working actively and developing new research ideas and procedures.

Solution: While it is a good thing to develop new procedures, new procedures must be approved by the IACUC BEFORE the new procedure is conducted. The Duke animal program has an amendment process that reviews (and can approve) changes to the approved protocol (amendments) in a few days.

Reason 2: The members of the laboratory are not performing procedures as described in the approved protocol. Or to say it another way, the lab member have not sufficiently reviewed the approved protocol to know what the IACUC has approved.

Solution: Assure all members of the laboratory have reviewed the IACUC approved protocol BEFORE beginning any work on the protocol. It is also a good idea to have the laboratory staff revisit the approved protocol with some frequency (e.g. quarterly, semi-annually, or annually) to assure they clearly understand what the IACUC has approved and assure they are remaining consistent to the protocol.

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Protocols and Lab Staff: Simple Steps to Maintaining Protocol Compliance

The IACUC has had a number of instances of recent where the laboratory member performing the animal procedure was not as familiar with the IACUC approved animal use protocol as was desirable. As a matter of lab communication, the IACUC strongly recommends the following (so similar) steps be employed by all Principal Investigators.

The IACUC approved protocol must be discussed with the individuals in the laboratory who will be performing the animal experiment. This is to assure the Principal Investigator that what they requested approval for, and what the IACUC approved, will be performed in the laboratory.

The laboratory may request (and receive) a copy of the IACUC approved protocol file from the Office of Animal Welfare Assurance. This file will come as a pdf file and will include all of the communication regarding the protocol. The request for this file must come from the Principal Investigator or their designee (if the PI has designated a laboratory manager to serve on their behalf). The pdf file will be sent to the Principal Investigator (or their designee) only.

As a suggestion, the laboratory may wish to develop a 'shared drive' storage site on the server. This location can be limited to only the member of the laboratory and can serve as a repository for all of the laboratories approved protocols. In this manner, any of the laboratory staff who are confused or unsure of the approved procedures, can check the lab 'shared drive' section of the server and look at the IACUC approved protocol.



Zebrafish and Xenopus Food

As zebrafish and xenopus models gain prominence in embryology, developmental biology and toxicology, genetic analysis and other research studies, Harlan Teklad implements new product lines to fulfill these new research diet needs. Harlan Teklad now offers Harlan Teklad Irradiated Adult Zebrafish Diet (product number 1912) and Harlan Teklad Irradiated Adult Xenopus Diet (product number 1910). These diets enhance the Harlan Teklad line.

Harlan Teklad Irradiated Adult Zebrafish Diet is a nutritionally complete, soy-free diet used for zebrafish reared in the laboratory. It is specially formulated to promote healthy fin and tissue development, and has demonstrated increased fecundity in laboratory conditions. The diet utilizes highly digestible ingredients which minimize excreted waste, thereby helping to maintain good water quality. In addition, the diet is free of soybean meal, making it uniquely beneficial to developmental research as it eliminates any potential estrogenic effects. It also includes carotenoid pigments to sexual dichromatism.

Harlan Teklad Irradiated Adult Xenopus Diet is a nutritionally complete diet used for xenopus frogs reared in the laboratory. It is a highly palatable, floating diet formulated to minimize excreted waste and help maintain good water quality. The diet utilizes highly digestible ingredients, along with stabilized vitamin C and brewers yeast, to promote proper bone and tissue development.

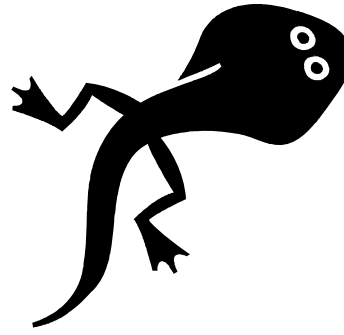
To place an order, please contact Harlan Teklad Customer Service at (800) 483-5523. www.teklad.com

**Are you looking for a Duke
IACUC Policy?
Look no further.**

Check out the index of policies at:

[http://vetmed.duhs.duke.edu/
index_of_program_policies.htm](http://vetmed.duhs.duke.edu/index_of_program_policies.htm)

Q & A



Question: Does the NIH/PHS Policy apply to larval forms of amphibians and fish?

Answer: Yes, larval forms of fish and amphibians have vertebrae and are covered by the PHS Policy and must have an IACUC protocol.

Question: Is an IACUC approved protocol required for the production of ‘custom’ antibodies, or to the purchase of surgically modified animals?

Answer: The generation of custom antibodies is considered an activity involving vertebrate animals (and is covered by PHS Policy, the source of most of our funding). Antibodies are considered ‘customized’ if produced using antigen(s) provided by or at the request of the investigator (i.e., not purchased off-the-shelf). According to the federal regulations, an organization producing custom antibodies for a PHS funded institution (e.g. Duke) must have a PHS Assurance, and must maintain on file the Duke protocol approval date.

The same guidance applies if surgery is conducted in response to a specific, custom request (as opposed to animals previously modified and available prior to the request). An organization conducting ‘custom’ surgery for a Duke researcher must have a PHS Assurance. In addition, the organization providing the ‘custom’ surgery must maintain the date of project-specific IACUC approval for conducting the surgery.

Question: Is a protocol required for animal tissue or materials obtained from dead animals?

Answer: The use of dead animals or parts of animals is not covered by the federal requirements unless the activity involves (1) killing animals for the purpose of obtaining or using their tissues or other materials, or (2) project-specific antemortem manipulation of animals prior to killing them. If either circumstance is applicable to the acquisition of dead animals, body parts or tissues, prior IACUC protocol review and approval are required.

Question: Does the PHS Policy apply to live embryonated eggs?

Answer: Although avian and other egg-laying vertebrate species develop backbones prior to hatching, NIH’s Office of Laboratory Animal Welfare interprets the PHS Policy as applicable to their offspring only after hatching. (The female egg-laying animal would be covered by the federal rules.) A protocol is required for egg laying species for the female that produces the eggs and for eggs that are within a few days of hatching (in case animals hatch prematurely, then procedures must be in place to protect the well being of those hatched animals).



Question: Do the federal requirement for a protocol apply to animal research that is conducted in the field?

Answer: If the institution is PHS-supported (Duke is) and the work involves vertebrate animals, then the IACUC is responsible for oversight in accord with PHS Policy. IACUCs must know where field studies will be located, what procedures will be involved, and be sufficiently familiar with the nature of the habitat to assess the potential impact on the animal subjects. Studies with the potential to impact the health or safety of personnel or the animal’s environment may need IACUC oversight, even if described as purely observational or behavioral. When capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures are involved, the IACUC must ensure that proposed studies are in accord with [The Guide](#). The IACUC must also ensure compliance with the requirements of pertinent state, national and international wildlife regulations. A study on free-living wild covered species that involves invasive procedures, harms or materially alters the behavior of an animal under study is covered by USDA animal welfare regulations and requires IACUC review and approval.

Upcoming Events

March 1	SC meeting
March 5	New protocol deadline
March 5	SC deadline
March 15	SC meeting
March 22	IACUC meeting
March 26	SC deadline
April 5	SC meeting
April 9	New protocol deadline
April 9	SC deadline

SC= Significant change