DUKE IACUC IMPLEMENTS FORM CHANGES

The Duke IACUC continues to consider methods to improve processing of investigator requested changes to approved protocols (Amendments). The IACUC has previously announced simplification of Amendment processing and now announces a simplification of the Amendment Form.

Instead of having to guess which form is necessary, the new approach removes the mystery. There are only two options—one for personnel changes and the other for everything else (both Minor and Significant).

**AMENDMENT FORM:** The IACUC now uses three different review processes (depending upon regulatory significance of the proposed activities) to speed the approval of Amendments. Effective immediately, Duke researchers only have one amendment form to use—for all amendments regardless of the invasiveness or procedure (except personnel changes).

**PERSONNEL ADDITIONS / DELETIONS:** Researchers no longer have to wade through a long set of questions that have nothing to do with personnel, but can use a unique form for requesting personnel changes.

The direct web link for these forms is: [http://vetmed.duhs.duke.edu/index_of_forms.htm](http://vetmed.duhs.duke.edu/index_of_forms.htm) The new forms are available on the Animal Program Web Site under the link titled “FORMS AND REPORTS.” See PROTOCOL AMENDMENT FORM (ALL PROCEDURES) and PROTOCOL AMENDMENT FORM (PERSONNEL CHANGES) SIGNIFICANT CHANGES and PERSONNEL CHANGES.

Animal Use @ Duke = Partnership

Animal use is a partnership, with both sides working to do the ‘right thing’ and result in the ‘right outcome.’

The institution is **required** to:

- Assure the welfare and well being of animals used at Duke.
- Assure that money granted for animal work is used for the purpose given by the funding agency.
- Assure all work is performed in a safe and healthy manner for the humans.

The institution **wants** to:

- Provide a strong and supportive infrastructure for cutting edge research.
- Facilitate the process of protocol review and reporting.
- Create an environment that fosters successful researcher.

The researcher **needs** to:

- Communicate experimental needs clearly and completely.
- Respond to IACUC questions quickly.
- Report adverse events promptly.

<table>
<thead>
<tr>
<th>Upcoming Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 4</td>
</tr>
<tr>
<td>May 4</td>
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<tr>
<td>May 8</td>
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<td>May 8</td>
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<td>May 18</td>
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<tr>
<td>May 22</td>
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<tr>
<td>May 25</td>
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<tr>
<td>June 1</td>
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</tbody>
</table>

*SC= Significant change*
Myth vs. Fact

⇒ Myth: The Duke IACUC is made up of people who don’t understand research.
⇒ Fact: The Committee consists of scientists, veterinarians, non-scientists, and community representatives.

⇒ Myth: The IACUC is fostering an animal rights agenda and trying to put researchers out of business.
⇒ Fact: The IACUC works diligently to assure the continued use of animals in biomedical research, testing, and teaching remains a reality at Duke.

⇒ Myth: The IACUC doesn’t have any stable reference that they use for assessing protocols.
⇒ Fact: The IACUC evaluates animal use proposals based on federal law, the Guide for the Care and Use of Laboratory Animals (Guide), and other appropriate references.

⇒ Myth: The IACUC review is only required for mice, rats, dogs, and primates.
⇒ Fact: All animal use activities (research, testing, or teaching) involving vertebrate animals must be IACUC approved.

⇒ Myth: I do not need to justify animals numbers of weanlings or embryos being used for research.
⇒ Fact: Yes …. And no. If the weanlings are simply part of a breeding expansion and will not be used for an experiment, and will be euthanized prior to weaning – then no. BUT! If the weanlings are the object of the experiment – then yes. Embryos are not counted – but dams are counted. Chick embryos are special.

Mouse Physiological Data

<table>
<thead>
<tr>
<th>Body temperature:</th>
<th>35.8-37.6°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate (per minute)</td>
<td>328-780</td>
</tr>
<tr>
<td>Weight, adult male:</td>
<td>25-40 g</td>
</tr>
<tr>
<td>Weight, adult female</td>
<td>25-40 g</td>
</tr>
<tr>
<td>Weight, newborn:</td>
<td>1 g</td>
</tr>
<tr>
<td>Water consumption:</td>
<td>4-7 ml</td>
</tr>
<tr>
<td>Food consumption</td>
<td>3-6 g</td>
</tr>
<tr>
<td>Life span:</td>
<td>1-3 years</td>
</tr>
<tr>
<td>Sexual maturity:</td>
<td>40-60 days</td>
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<tr>
<td>Estrous cycle freq:</td>
<td>4-5 days</td>
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<tr>
<td>Duration of estrus:</td>
<td>10 hours</td>
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<tr>
<td>Gestation period:</td>
<td>19-21 days</td>
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<tr>
<td>Average litter size:</td>
<td>6-12</td>
</tr>
<tr>
<td>Begins eating dry food:</td>
<td>12-14 days</td>
</tr>
<tr>
<td>Age at weaning:</td>
<td>21 days</td>
</tr>
<tr>
<td>Breeding life:</td>
<td>8 months</td>
</tr>
</tbody>
</table>


Brown Bag Seminar
Thursday, May 4, 2006
Bryan Research Bldg Room 103

“Dietary Phytoestrogens: Effects on Research Results”

Soy and alfalfa, common ingredients of laboratory animal diets, contain phytoestrogens that may alter your data or your ability to interpret results of various assays, particularly if you are working with active estrogen compounds. This includes, but is not limited to, studies that involve osteoporosis, behavior, specific forms of cancer (breast, prostate, colon, lung, stomach, etc.), cardiovascular and stroke research, and reproductive problems. **Mr. Terry Burns-Heffner**, of Harlan Inc. will discuss how research may be affected by “natural” constituents found in laboratory animal feeds. Other potential research variables lurking in common diet ingredients, including mercury and nitrosamines, will also be discussed. His seminar will include options available that could limit these variable effects of animal diets on your data.

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. Harlan will provide drinks and desserts. Please plan on arriving prior to noon in order to get refreshments, sign in, and be seated. For those who will be coming from off campus, driving directions and parking information can be found at the following link: [http://neuro.duke.edu/Links/map.htm](http://neuro.duke.edu/Links/map.htm) **Please see page four of this newsletter for the seminar flyer—please print and post in your area.**
Veterinary Authority

To: All Duke Research Investigators
Re: Veterinary Authority over Animals Being Used for Research and/or Testing at Duke University

Dear Colleagues: This memo is being sent to clarify the role of the DLAR veterinary staff in caring for animals used in research and teaching activities at Duke University.

USDA regulations state the following:

“Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.” (Animal Welfare Regulations 9 CFR, Section 2.33)

In order to ensure the provision of adequate veterinary care, it is institutional policy that the DLAR veterinarians have the ultimate authority in determining the need for medical treatment or euthanasia of animals used in all research and teaching activities. The DLAR veterinarians will make every attempt to seek your input should an emergency arise with one of your animals, but whether or not contact is possible, the course of action will be guided by veterinary professional judgment. Please understand that they have full institutional support in exercising that responsibility.

Should you have any questions regarding this policy, please contact the Duke University Institutional Animal Care and Use Committee (DUIACUC) at 668-6720.

Sincerely yours,

R. Sanders Williams, M.D.
Dean, School of Medicine
Vice Chancellor for Academic Affairs
Institutional Official

Ed. Note: This letter was originally sent in 2005. This is a reprint of an existing institutional position on the authority of the role of Duke Veterinarians.

IACUC SEMI-ANNUAL SITE VISITS

The Duke Institutional Animal Care & Use Committee (IACUC) will schedule a semi-annual inspection visit of your procedural and/or animal holding spaces as part of our on-going program for animal care and use, as prescribed by the Public Health Service, the United States Department of Agriculture, and AAALAC, International.

According to the 9th Code of Federal Regulations, the IACUC must inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas ...” The Duke University IACUC uses a sub-committee of 2 or 3 Committee Members to perform this federal mandate.

While having visitors in the research laboratory can be an anxious experience, if the research team is prepared for the IACUC's review, then the outcome will be successful, and relatively painless. The goal of this document is to provide a general overview of the process of IACUC Semi-Annual Review and to offer the laboratory staff a suggested plan for preparation of these visits.

The first step in managing the IACUC site visit, is realizing that the goal of the IACUC’s review is to confirm that the expected standards of animal care and use are being maintained. A sound and compliant laboratory benefits the entire university community, and supports successful research outcomes.

One significant benefit of the IACUC Semi-Annual Review process for the research laboratory staff, is the opportunity to receive important program information, in a clear and non-threatening manner. When the IACUC visits, it is all ‘in-the-family.’ When outside regulatory agencies visit, it may be all-over-the-family. Problems can usually be resolved more easily, when they can be handled collegially, rather than having potentially serious consequences that could occur with an adverse reportable event.

Sometimes concerns develop because the research group was not familiar with an expectation, or previous practices have been simply forgotten. Regardless of the reason for the issue, the Semi-Annual review process can be useful, if the laboratory staff are prepared and facilitate the review.

Please follow this link to the full article: http://vetmed.duhs.duke.edu/documents/iacuc/pdf/preparing_for_an_IACUC_semi-annual_review.pdf
Soy and alfalfa, common ingredients of laboratory animal diets, contain phytoestrogens that may alter your data or your ability to interpret results of various assays, particularly if you are working with active estrogen compounds. This includes, but is not limited to, studies that involve osteoporosis, behavior, specific forms of cancer (breast, prostate, colon, lung, stomach, etc.), cardiovascular and stroke research, and reproductive problems. Mr. Terry Burns-Heffner, of Harlan Inc. will discuss how research may be affected by “natural” constituents found in laboratory animal feeds. Other potential research variables lurking in common diet ingredients, including mercury and nitrosamines, will also be discussed. His seminar will include options available that could limit these variable effects of animal diets on your data.

The presentation will be on Thursday, May 4th, 2006 from noon to 1 p.m.

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.

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