ANIMAL TRACKS
A newsletter for the Duke research community
http://vetmed.duhs.duke.edu

September 2015

REPORTING HEALTH CONCERNS
If you work in an area that has been approved by the Duke IACUC as a PI-Managed facility, you are responsible for reporting animal health issues to the DLAR Veterinary Staff. When animals appear ill or injured, or when there are abnormal changes in the animal's behavior, PI-Managed operations are obligated to report the animal to the DLAR Veterinary Staff. The steps for reporting abnormal behavior or suboptimal health are:

1. Complete a RED Veterinary Examination card and place it on the animal’s cage. Note: Red cards are available from DLAR.
2. Page the ‘Veterinarian On-Call’ at 970-9410 and wait for a response. If there is no response after 5-10 minutes, page the Veterinarian again.
3. Report the animal’s condition and wait for instructions. Stay with the animal until the Veterinarian relieves you of that responsibility.

The DLAR veterinary staff will examine the animal and consult with the PI regarding treatment options, up to and including euthanasia. The DLAR veterinary staff will write treatment instructions on red card and discuss any care issues with you. The veterinary staff will remove the red card when treatments are complete (you should NOT remove the red card). The most critical issue is to be aware of animals in need, and communicate those needs to DALR veterinary staff, providing the support you are capable of doing until the veterinary staff arrive.

TIPS FOR SURVIVING AN AAALAC SITE VISIT
October 12-15, 2015

Our next AAALAC site visit is fast approaching. During the site visit AAALAC representatives will visit the animal facilities and several of the research labs where animal procedures occur. While we try to give advance notice to labs they wish to visit, often they will make impromptu requests at random times during the day. So below are some common topics and issues that have arisen during previous site visits.

Know your protocols: The most important thing you can do to prepare for an AAALAC site visit or any other kind of review is to know what has been approved in the animal protocols, and to do those things as approved. If, after reviewing your approved protocols, you discover that changes need to be made, then submit an amendment right away! Site visitors will talk to you about the procedures you perform and they will review your protocols to ensure you are doing those as you describe or demonstrate.

Ensure personnel are listed on the protocol and have access to the most recent versions: Since research personnel and students rotate in and out of labs frequently it can be difficult to keep the paperwork updated. Assure all personnel working with animals are listed on the protocols under which they are working, and that they have the ability to look at those protocols whenever they wish to read them.

Personnel Protection Equipment (PPE): Shoe covers are required in all facilities. Follow the signage posted on animal rooms for the required PPE for that space or activity.

Proper aseptic technique: Assure appropriate aseptic technique for the procedure. The IACUC policy Aseptic Technique is posted on the web. Review and confirm your lab is meeting these expectations.

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Special diet storage: If you are storing a non-standard animal diet or food treat in your lab:
⇒ You must have the proper signage, and
⇒ The diet should be stored in conditions based on the manufacturer recommendations.
⇒ Food (or treats) must be stored in air tight containers and labeled with the name, manufacture date and/or open date, and the expiration date (generally 6 months from opening). If the food item is a common human foodstuff, it must be labeled “not for human consumption”.

Clutter: Please remove all materials stored on the floor. Do not store cardboard on the floor or under the sink.

Needles: Please do not recap needles. Needles and sharps should be placed directly into the sharps container.

Safety: Look around the lab. If you see unrestrained gas cylinders, missing eyewash station covers, uncertified chemical fume hoods or biosafety cabinets: Report it to your lab manager or PI or DLAR staff or OESO.

Microdrop technique for gaseous anesthesia: If you are using isoflurane without a vaporizer there are a few things to keep in mind:
 a) the animals cannot come into contact with the anesthetic,
b) you need to know how to calculate the correct dose of isoflurane for your container, and
c) the container must be allowed to vent the waste gas at the end of the procedure.

Labeled materials: All materials (such as disinfectants in spray bottles, etc.) must be properly labeled.

Maintaining surgical records: While detailed animal health records may not be required for the species you work with, it is very important that some record of surgical procedures (and for any sedation or anesthesia) is maintained. These records should reflect what procedures the animals have undergone, the frequency of monitoring, and verification that the animals received the appropriate pre- and post-procedural care provisions! Sorry to say, but if you didn’t write it down … it didn’t happen. Got to have documentation!

Gas vaporizer certification: Anesthesia vaporizers must be validated annually unless manufacturer recommendations indicate otherwise. DLAR can provide contacts for validation. F-Air canisters must be:
* Weighed and recorded before the first use;
* Weighed and recorded after each use; and
* Discarded when the F-Air weight increases more than 50 grams.
F-Air canisters should be resting on the side or suspended from a pole. Do not cover up the exhaust holes!!!

Expired materials: Survival Procedures: Any substance, material or device that goes in or on an animal MUST BE within its expiration date. Non-survival Procedures: While fluids and other things may be used in non-survival animal after the expiration date, anesthetics, analgesics, and euthanasia agents MUST BE within the expiration date! No exceptions!

If you are unsure about how to dispose of expired drugs or substances please contact OAWA (Bill Wade @ 668.6720).

Controlled substances: Controlled drugs must have corresponding log sheets that are accurate and up to date! All substances must be secured behind two (2) locks. If drugs have been diluted or mixed, the container must be labeled with this information and the date on which the new mixture was made. If you have questions, contact Bill Wilkison @ 668-6720.

Signage: Know and understand what cage markers indicate and how to respond (e.g., Attention Sick Animal, Clinical, Separated, and Overcrowded). Room signs should be printed and posted. If you have questions, contact Bill Wade @ 668-6720.

Just relax: Most importantly, just relax! Be proud of the work you do in your lab. YOU are the expert in your lab area, just show the Site Team and we’ll do great. Be open and excited to discuss your work and animal use with the AAALAC Site Team. And most of all, be yourself. Our program is a strong program—we’re not perfect, but each of us works to assure we do the absolute best we can for our animals. We are successful because of you. You are an important part of the process and the great name recognition our program enjoys. Thank you for your dedication to animal welfare and research quality!

Wishing you a wonderful research month,
REPORTING
ADVERSE ANIMAL CONDITIONS

Question: Who is responsible for the condition of Duke owned animals?

Answer: All of us!!

So, if I am responsible for animals I observe in distress, pain, or experiencing poor welfare, then:

I am obligated to report the distress immediately!

⇒ For reports requiring immediate veterinary care: Call the veterinarian on-call: 919.970.9410

⇒ All reports of adverse animal conditions or animal welfare concerns: Report your observations to (only one is required):

⇒ Laura Hale, MD, Ph.D.
Chair, Institutional Animal Care & Use Committee
919.668.6720
IACUC@duke.edu

⇒ Ron Banks, D.V.M.
Director, Office of Animal Welfare Assurance
919.684.4744
ron.banks@duke.edu

⇒ John Norton, D.V.M., Ph.D.
Director, Division of Laboratory Animal Resources
919.684.4204
john.norton@duke.edu

⇒ the Duke Animal Welfare Hotline
(919.684.3535)

⇒ Email the IACUC at IACUC@duke.edu

⇒ Submit an Adverse Event Report

Duke University will not tolerate any misuse or neglect of animals. Your report will be confidentially handled—no one will be told who you are. There are federal and university protections against reprisal for reporting animal abuse or neglect.

ANNUAL ANIMAL NUMBERS REPORT

In a few weeks all researchers using animals in research, testing, or teaching will receive an email requesting they report the numbers of animals used this past year. This is a TIME SENSITIVE report to the federal agencies; it is critical that the institution respond by the deadlines, which requires timely reporting from each of our researchers who use animals in their work.

The reporting period is from October 1, 2014 thru September 30, 2015. The report includes all animals purchased, bred, or used for all manners of research. The categories of reporting are:

⇒ Category B: The number of animals being acclimated or held for use (not yet used); but not reported in Category C, D, or E. (Animals not euthanized as of September 30, 2015).

⇒ Category C: The number of animals used in procedures not causing pain, distress and not requiring the use of pain relieving drugs (Examples: AVMA approved methods of euthanasia, non-surgical procedures requiring brief restraint, behavioral observations, and field observations).

⇒ Category D: The number of animals used in procedures which could be painful, but for which appropriate anesthetic, analgesic, or tranquilizing drugs were used (Examples: Any use of anesthesia or analgesia such as surgery or invasive studies).

⇒ Category E: The number of animals used in procedures producing pain or distress for which the use of an anesthetic, analgesic or tranquilizing drug would adversely affect the procedures, results, or interpretation of the scientific purpose of the experiment.

Please begin considering what data you will need to draw together to make the necessary reporting deadline. Watch your email for reporting processes!

Upcoming Dates & Deadlines

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<tr>
<th>Date</th>
<th>Event</th>
<th>Contact Information</th>
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<td>September 21</td>
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<td>September 24</td>
<td>New Protocol Meeting</td>
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<td>October 1</td>
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<td>October 5</td>
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Deadlines are 5 PM on the date listed!
VISITATION, HANDLING, OR PHOTOGRAPHY OF DUKE-OWNED ANIMALS

The Animal Welfare Act, PHS Policy, and the Guide for the Care and Use of Laboratory Animals (Guide) require a stable, safe, and supportive environment for animals engaged in research testing, or teaching. Unscheduled lights, novel sounds, smells, or non-routine activity (e.g. camera flashing, loud camera clicks, video lights) can have a significant effect upon animals, may cause animal distress, may alter their physiology, and may adversely affect research outcomes. For these reasons, access to Duke-owned animals is strictly controlled and visitors approved on a case-by-case basis.

Visitation of animal facilities: Only persons having a recognized need and the approval of the appropriate authority shall be allowed to visit Duke animal care or use facilities or research laboratories. The approving authority shall assure the visitor has met and will comply with procedures for prevention of personal risk, facility contamination, and zoonosis transfer. There are several types of visitors to Duke-owned animal facilities. These include:

- **Researchers:** Duke researchers may visit any facility for which they have need or purpose such as an approved protocol, collaboration, or serving an oversight role.
- **Compliance / Regulatory Inspectors:** Persons who have a recognized need to audit or inspect animal care activities, such as USDA, NIH, AAALAC, IACUC, OAWA, DLAR, or granting agency.
- **Visiting Faculty, Scientists, or Prospective Employees:** Visitors not having a Duke ID Badge shall be escorted at all times while in the animal facility. No contact with animals is permitted, unless the individual is listed in Section A-3 of a Duke approved protocol.
- **General Public:** Duke encourages visitors to the Duke Lemur Center.
- **Media:** On occasion, members of the media may be allowed entry into animal facilities, but a) Shall remain fully escorted by a Duke employee having the approved access to the specific animal space; b) Will not have any direct contact with animals (no handling/holding); c) will obtain prior clearance from the Director, DLAR for photography; and d) will have alerted the university’s Office of Communication prior to obtaining escorted access to animal care or animal use areas.

Handling of animals: Only persons approved on the protocol, Duke veterinary care personnel, IACUC, OAWA, or other oversight personnel performing an oversight duty shall handle contact Duke-owned animals. No visitor shall handle, pet, collect samples from, or physically manipulate any Duke-owned animal.

Photography (Still and video):

- **Researchers (except Lemur Center):** Researchers may require photographs of animals as a component of their research activities. Researchers may photograph their study animals by: a) Including the description and purpose of photographs in the protocol (or adding as an amendment); or b) Obtaining permission from the Director or Deputy Director of DLAR. The approval for photography must be in advance of the planned photography. The application is available on the web site at: [DLAR form for photography](#).
- **Compliance / Regulatory Inspectors:** Persons who have a recognized need to audit or inspect animal care activities, such as USDA, NIH, AAALAC, IACUC, OAWA, DLAR may take photographs - no special approval is required.
- **Visiting Faculty, Scientists, or Prospective Employees:** These visitors may photograph animals when it has been approved by the Director or Deputy Director of DLAR.
- **Media:** On occasion, members of the media may be allowed photographs of Duke-owned animals, but shall: a) First obtain the approval of the Director or Deputy Director, DLAR, and, b) Have alerted the university’s Office of Communication.
- **Client-owned Animals:** Photographing client-owned animals that are participating in a Duke IACUC-activity approved protocol is solely at the discretion of the client who owns the animal(s).

The 64,000 dollar question!

**Question:** When is it ok to leave an animal unattended during anesthesia or recovery?

**Answer:** **NEVER!** All animals must be observed continuously while anesthetized or while recovering. If you must leave the room for any reason, assure there is someone else there to observe the animal while you are gone. Failure to provide CONTINUOUS monitoring for anesthetized or recovering animals is a violation of several federal expectations. Yep, reportable to your funding agency.

So … DON’T ever leave animals alone while less than full awake!
ADVERSE EVENTS OR (ANIMAL WELFARE) CONCERNS

Experimental manipulation of animals in research, testing or teaching may occasionally result in serious, unanticipated, or adverse clinical consequences (e.g., poor animal welfare). The Duke IACUC believes that effective communication between researchers, veterinarians, and animal care staff is crucial for clear and timely management of animal disease, injury, or adverse outcomes. In addition to the obligation to report adverse events to the clinical veterinary staff, the IACUC must also be aware of adverse events that involve animals owned or housed by Duke University or listed on Duke IACUC approved protocols. The Duke IACUC must be informed of conditions outlined in this policy as partial fulfillment of the institution’s obligations of effective regulatory oversight. The Duke IACUC shall determine which events / outcomes must be reported to oversight agencies, whether protocol modifications are required (e.g., changes in procedures, monitoring, humane endpoints, etc.), whether SOP changes are necessary, or whether specific corrective actions, beyond those which may be PI-generated, are required to ensure animal well-being.

Personnel having concerns regarding animal care and should report those concerns by one of several avenues, to animal program or institutional authorities to allow addressing of animal well-being issues. Investigation of adverse events, allegations, or complaints against the animal care & use program, including researchers, care providers, or program managers are conducted in a legal, impartial, and professional manner; focusing on protecting animal welfare / well-being, institutional integrity, and personnel corrective action trainings.

An adverse event is any instance of unfavorable or unanticipated (not in the approved protocol) signs or outcomes involving a Duke-owned animal. Adverse events include suboptimal well-being (i.e. poor welfare), animal death, disease, distress, or trauma that was not the anticipated result of approved protocol or SOP activity.

When identifying a concern with animals at Duke, you should provide the IACUC an ADVISEMENT, and a NOTIFICATION. If animals are injured or in need of veterinary care, you should immediately call the veterinary pager (919.970.9410) or speak to a veterinary technician or care staff member.

Advisement: This is the initial alert to the IACUC, via phone, email or other means, of an adverse event / poor welfare condition involving Duke-owned animals, work on a Duke approved protocol, Duke SOP, or Duke personnel working with animals. An advisement does not equal a notification or a report. An advisement alert the IACUC to the concern and allow for immediate action to protect the interest of the animals.

Notification: This is the written documentation of an adverse event provided via email submission of the Potential Adverse Event / Unanticipated Event Notification form (available on the animal program web site). A notification may be submitted initially, or in lieu of an advisement if it meets the deadline for advisement submission. Submission of the notification form to iacuc@duke.edu concludes your responsibility for timely descriptions of adverse events or unanticipated.

Can I be held responsible for reporting? What is someone tries reprisal against me for reporting a concern? Duke University does not tolerate any misuse or neglect of animals nor will the institution accept reprisal against an individual who has come forward with concerns or allegations of wrong-doing involving the care and use of animals. Such reprisal is prohibited by federal law (USDA Regulations & the 9th Code of Federal Regulations). Individuals who feel that action has been taken against them because they reported an apparent violation of animal care and use requirements, should present their case to the Chair of the IACUC, the Director of the Division of Laboratory Animal Resources, the Director of the Office of Animal Welfare Assurance, or the Duke Office of Institutional Integrity. Anonymous allegations are accepted (but may be difficult to clearly address). Confidential reports are often easier to document and clarify. The confidentiality of the reports and reporting individuals will be respected; names of reporting individuals will not be released.

While most laboratories have the plasticized placards advertising the routes of reporting, attached as the next page are the two placards showing how to report and to whom to report animal care issues, animal welfare issues, or adverse events involving animals.
Safeguarding animal welfare is the responsibility of every individual associated with the Duke Animal Program.

REPORT ANIMAL HEALTH EMERGENCIES
to DLAR using the Veterinary Pager (24 hrs/day): 919-970-9410

REPORT OTHER ANIMAL WELFARE CONCERNS
to the Office of Animal Welfare Assurance (24 hrs/day)
via the Animal Welfare Hotline: 919-684-3535

or to the IACUC at iacuc@duke.edu

Cut out and post in your laboratory (if you don’t already have this posted)

Reprint from NATURE regarding the seriousness of IACUC-approval before performing any animal activities!

Protection priority
All involved in animal research must ensure that rules for ethical experiments are observed.

More than a million people in Europe signed a petition earlier this year to halt research with animals. One reason why Nature and many scientists are able to defend these experiments is that all involved do everything they can to minimize pain and suffering. Animal experiments are approved only after thorough discussion and are carried out according to strict regulatory controls. Society sees the benefits of animal research, but it does not seek them at any cost.

When breaches of the strict rules that govern animal research occur, it is vital — to both supporters and opponents — that they are investigated thoroughly, and that lessons are learnt and shared. This week, Nature publishes a correction on its website that details such a breach of experimental protocol in a previously published paper (L. Raj et al. Nature http://dx.doi.org/10.1038/nature15370; 2013). The relevant experiments grew tumours in mice as a way to test possible treatments. This type of study is common, as is the way they are approved and regulated. Researchers typically plan the experiments and then submit details to an institutional review board for approval. In making its decision, the board follows guidelines set out by a separate body charged with oversight of animal procedures — an institutional animal care and use committee. These guidelines are country-specific, and in the case of tumour experiments should include limits on the maximum tumour size allowed, and instructions to the researchers to monitor both tumour size and signs of distress.

In this case, prompted by a complaint from a reader and following consultation with the authors and the relevant bodies, Nature has established that the scientists did not carry out the required monitoring properly. As a result, some of the tumours grew larger than permitted. These mice could therefore have experienced more pain and suffering than originally allowed for.

As well as writing to correct their paper to mark the breach of animal-welfare guidelines, the authors apologize for the breach. They are right to do so. Cases such as this could provoke a justifiable backlash against animal research. All involved — scientists, institutions, funders and journals — must do more to ensure that regulations are strictly observed.

Nature’s policy is that the corresponding author on a paper that reports experiments with animals must confirm that the research was carried out in accordance with the relevant rules (see go.nature.com/a9pyjm). As a result of this case, we are increasing the amount of information we request from authors. In experiments in which tumours are grown, we now require authors to include the maximal tumour size permitted by the institutional animal-use committee, and to state that this was not exceeded. Authors must also provide the source data for any figures that analyse tumour growth.

Nature does not want to publish the results of experiments that have not been performed under ethical guidelines. As such, the authors in this case are correcting their paper to withdraw the portion of the data collected in experiments that the institutional committee concluded were in breach. The scientific conclusions of the paper remain valid and useful, and still stand.

Institutions should do more to make sure that the guidelines they set are respected. At the very least, on completion of each project — and before data are submitted — institutions should verify that approved protocols were followed. Funders and institutions must consider better training for young researchers doing work with animals. And the broader community should continue to scrutinize and improve how it carries out these types of experiment. Discussions are already under way, for example, on whether the control arms of similar cancer studies truly need to let (untreated) tumours grow as large as they currently do. Nature is happy to join these discussions and to help to improve practice.
AAALAC is Coming
Is Your Lab Prepared?

Do you know?
⇒ Who is AAALAC?
⇒ Why is AAALAC coming to Duke?
⇒ When will AAALAC be at Duke?
⇒ What will AAALAC do while at Duke?

What should your lab know?
Location of your approved protocol.
Location of animal records.
What the protocol says.
⇒ Proper arrangements for animal use.
⇒ Correct sanitation for animal use.
⇒ Training for staff is current.
⇒ Certification dates of hoods/anesthesia machines.
⇒ How to report concerns with animal use.
⇒ How to get to the Duke Animal Program Web Site.
⇒ That iACUC@DUKE.EDU is for IACUC business.
⇒ The animal hotline number is 684-3535.
⇒ The role of the IACUC.
⇒ The role of the DLAR.
⇒ The role of the OAWA.
⇒ The roles and responsibilities of the PI.
⇒ The roles responsibilities of the lab members.
⇒ Requirements for controlled substance management.
⇒ The requirements for anesthesia machine certification.
⇒ The requirements for hood certification.
⇒ The requirements for waste anesthetic gas.
⇒ The lab member in charge of PI-managed housing (if you have it)

What should your lab do?
⇒ Review your protocol.
⇒ Have a copy of the protocol (amendments) in the lab.
⇒ Know where to review a copy of ‘The Guide’ (http://www.nap.edu/readingroom/books/labrats/index.html)
⇒ Confirm your procedures match the protocol.
⇒ Assure all procedures are in the protocol.
⇒ Be sure all animal handlers are IACUC approved.
⇒ Check sterilized equipment for current dates.
⇒ Double check drug dates, proper storage & accuracy of logs.
⇒ Discard / replace out-of-date items.
⇒ Alert DLAR about all diseased animals.
⇒ Know your HUMANE ENDPOINTS.
⇒ Confirm personnel skills with animal procedures.
⇒ Ensure that all animal records (e.g. analgesics used, surgical procedures and post-op care) are current and available for inspection.
⇒ Know your approved methods of euthanasia.
⇒ Confirm accuracy of PI managed housing records.

QUESTIONS? PLEASE CONTACT ANY OF THE FOLLOWING
⇒ Your departmental representative to the IACUC.
⇒ The IACUC Chairman (668-6720).
⇒ A Duke Compliance Liaison (668-6720).
⇒ DLAR veterinarians (684-6792).
⇒ The Office of Animal Welfare Assurance (668-6720).

Or visit the Animal Program Web Site @ http://vetmed.duhs.duke.edu