PI MANAGED FACILITIES: 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:

- Complete a RED Veterinary Examination card and place it on the animal’s cage. Red cards are available from DLAR.
- 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.
- Report the animals condition and wait for instructions. Stay with the animal until the Veterinarian relieves you of that responsibility.
- Complete Section A of the Investigator Managed Colonies Request for Health Check. (forms available on line).

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). Probably the most critical issue is to be aware of animals in need. If treatment information is not written on the red card within 24 hours after you have placed the card on the cage / tank, then call:

Dr. Yohannes Asfaw 919.812.2349
Dr. Angela Garner 336.317.1689
Dr. Clay Rouse 919.724.6479
Dr. Francis Sun 919.358.9114
Dr. Jai Tubbs 919.943.5904
Dr. Kyha Williams 919.323.6438
Dr. Randall Reynolds 919.812.1240
Dr. John Norton 919.812.1807

TIPS FOR SURVIVING AN AAALAC SITE VISIT

Our next AAALAC site visit is fast approaching so we have compiled a list of key areas you can prepare your lab for beforehand. The 2012 site visit will occur in early October 2012. 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 during the inspections. So below are some common topics and issues that have arisen during previous site visits.

Know your protocols: The most important thing you and your staff can do to prepare for a site visit or any other kind of inspection is to review and understand what has been approved in the animal protocols. If you discover that changes need to be made you will need to submit a modification. Site visitors will talk to you and your staff about the procedures you perform and they will review your protocols to ensure congruency.

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 often be difficult to keep the paperwork updated. It is very important that 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 needed.

Personnel Protection Equipment (PPE): Shoe covers are required into all facilities. Follow signage for PPE on doors of animal rooms.

Maintaining surgical records: While detailed animal health records may not be required for the species you work with, it is very important that you are keeping some record of surgical procedures on specific animals or groups of animals. These records should reflect what procedures the animals have undergone and verification that they received the appropriate Pre- and Post-operative treatment, including analgesia.

Proper aseptic technique: When performing surgeries it is crucial to apply the appropriate aseptic technique for the procedure. The IACUC policies for Aseptic Technique provide the basic requirements for applying aseptic technique.

Continued on Page 2
TIPS FOR SURVIVING AN AAALAC SITE VISIT (cont. from page 1)

Special diet storage: If you are storing a nonstandard 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 must be stored in air tight containers and labeled with the name, manufacture date and/or open date, and the expiration date. 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: Common safety issues found in labs include unrestrained gas cylinders, failing to replace covers on eyewash stations and conducting work in uncertified chemical fume hoods or biosafety cabinets. If you see any of these issues in the ARP housing facilities, please report it to the ARP building supervisor or care staff.

Just relax: And be proud of the work you do in your lab. If you are doing the things listed above and aware of the activities in your lab, there is no reason you can’t be open and excited to discuss your work and animal use with the site visitors.

(continued on Page 3)

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 bred, conditioned, or held for use (not yet used); but not reported in Category C, D, or E. (Breeding, conditioned animals not yet euthanized as of September 30, 2009)

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.
**TIPS FOR SURVIVING AN AAALAC SITE VISIT**

(cont. form page 2)

**Microdrop technique for Isoflurane 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.

**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; weight after each anesthetic session and record weight; discard the F-Air after a weight change of 50 grams. F-Air canisters should be resting on its side.

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

**Expired materials:** Any substance, material or device that goes in or on an animal as part of a survival procedure must be within its expiration date. Any substance used for anesthesia, analgesia, or treatment as part of a non-survival procedure must be within its expiration date. 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 have been completed with all required information and the drugs must be secured behind 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 OAWA (Bill Ware @ 668-6720).

**Signage:** Know and understand what cage markers indicate and how to respond (such as: Attention Sick Animal, Clinical, Separated, and Overcrowded). Room signs should be printed out and laminated for posting. If you have questions, contact OAWA (Bill Ware @ 668-6720).

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**Upcoming Dates & Deadlines**

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*Deadlines are 5 PM on the date listed!*

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**REMAINING FALL 2015 IACUC SEMIANNUAL SITE VISITS**

**OCTOBER 15TH: GHRB—VRH Durham**

**OCTOBER 29th: VIVARIUM—MSRB1**

**NOVEMBER 5th: LEMUR CENTER—MSRB2—MESOCOSM**

Please mark your calendars for your facility. Please e-mail Bill Wade at w.wade@duke.edu with the name and contact number for the individual form your lab who will be present on the day of the site visit. Thank you for your time and commitment to the highest standards of animal care and use.

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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.
- **General Public:** Duke encourages photography in public areas at the Duke Lemur Center. Individuals wishing to take ‘behind-the-scenes’ photographs at the DLC must first obtain approval by DLC leadership.
- **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).
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.

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

The identity of any person making a report is always kept confidential. Individuals making reports are protected against reprisals.

Go to [http://vetmed.duhs.duke.edu/AnimalWelfareHotline.html](http://vetmed.duhs.duke.edu/AnimalWelfareHotline.html) for more information, including anonymous reporting options.

**NOTE: Reports Can Be Made Anonymously**

**DISPOSING OF EMPTY CONTROLLED SUBSTANCE BOTTLES:**

Just a note to remind research staff that there is no need to save empty controlled substance bottles. These may be disposed of in an appropriate Sharps container. Please make sure that all dispensing logs for that bottle have been completed, initialed and are accurate.

DLAR no longer provides reverse distributor services and does not collect empty controlled substance bottles.

If you have any questions please contact the OAWA at 668.6720.
**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](mailto: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

**What should your lab do?**
Review your protocol.
Have a copy of the protocol (amendments) in the lab.
Have a copy of ‘The Guide’ in the lab. ([http://www.nap.edu/readingroom/books/labrats/index.html](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](http://vetmed.duhs.duke.edu)
POLICIES UPDATE:

Over the last 6 months all of Duke’s Animal Care and Use Policies have been reviewed, and when necessary revised. Changes were made to most of the policies, but this largely consisted of grammatical corrections. You are encouraged to review any policies that may affect you, your animals, or your research by visiting [http://vetmed.duhs.duke.edu/ProgramPolicies.html](http://vetmed.duhs.duke.edu/ProgramPolicies.html). Here are some select policies that had important changes:

Reuse of Animals – This is a brand-new policy and worth a read.

Principal Investigators (Definitions, Obligations, Signatures) – Research animal coordinators will now automatically become a PI’s Contact Person upon RAC graduation.

Top shelf housing of rodents - If your animals are housed in static cages they should not be placed on the top shelf of a rack

Counting animals – Fish should be counted as an adult at the time of hatching. For example Zebrafish hatch approximately 3 days post-fertilization.

Visitation, animal observations, or photography of animals - Photographs and videos need to be approved. Remember to be respectful when taking photos.

Genotyping and Identification (Including Tail and Toe Clipping) - Toe clipping must be scientifically justified and should be used for dual purpose (identification and genotyping)

Use of non-pharmaceutical grade substances in laboratory animals – This entire policy has been revised. Please ensure that ALL drugs given to animals are within its use date. Any drug not in its original container that has an expiration date MUST have an expiration date.

Acclimation / stabilization of animals - Recently added acute use (i.e., euthanized before 12hrs) as a program wide exemption. These do not required an IACUC exemption (Section U).

P.I. managed (housing/holding) facilities – This policy has been revised and if you are part of a PI-managed facility you are encouraged to re-read it.

Notification of hazardous work in animal care areas - Remember to contact DLAR 5 days before using a hazardous agent, label the door and cage when in use and REMOVE YOUR SIGNS when not in use.

Animal transport (pedestrian and vehicular transport in non-patient care areas) – Transportation of animals outside of the facility (outdoors) requires a SECTION I. If you use USDA-Covered species DLAR must perform the transportation unless approved via a SECTION U.