Lessons Learned from LSRC

The recent loss of a Duke colleague, Mr. Ray Cotter, was deeply troubling for all of us. Ray’s support of the animal research program, while behind the scenes and completely unseen to most, was crucial for the safe and effective performance of Duke animal research. His efforts of assuring a humane and consistent living environment for our research animals provided the necessary foundation for the high quality research regularly reported out of our institution. While we are confident that the fine utilities support we have grown to expect will continue, the loss of our co-worker is a loss that will be remembered for a very long time.

In addition to the loss of our friend, there was a potential for additional damage to the research animals in LSRC. Thanks to the strong efforts by DLAR staff in disaster recovery, the on-going research impact was minimized.

What are the 'lessons learned’ from LSRC?

1. **VALUE HUMAN LIFE:** Leave the area immediately. If you were working with hazardous agents, stabilize the agent (e.g. cap the vial, place it in a BSC), then leave the area. If you are wearing PPE when an emergency occurs, grab a trash bag and wear the PPE out of the building; removing it once you are out of doors and away from other people. Stay away from people — OESO representatives will come to you and assist you further (if needed).

2. **PROTECT ANIMALS:** If you are working with animals when a disaster occurs, return the animals to their cages, secure the caging and leave the area immediately. If you are working on an anesthetized animal, consider euthanizing the animal. DO NOT leave an anesthetized animal behind, and do not take the animal with you.

3. **CONTACT DLAR:** Use the emergency vet pager (970-9410) to alert DLAR veterinarians to the location and condition of animals left inside.

New OAWA Staff Member

Julie Sharp, DVM has been promoted to the position of Assistant Director, Office of Animal Welfare Assurance (OAWA). Dr. Sharp has served in the capacity of Compliance Liaison for the OAWA for the last 3.5 years. In this role she has observed hundreds of animal procedures all around the Duke research program. Her interactions with staff and faculty have always been reflective of her desires for humane and progressive animal use in a research environment.

In her new role as Assistant Director, Dr. Sharp will be assuming a more strategic role in planning and developing the campus animal research program while providing direct support to the IACUC and assuring general support to the Office of Animal Welfare Assurance.

Dr. Sharp noted that the new position will stretch her professional skills and allow her increased opportunity to facilitate the needs of researchers while assuring animal well-being at Duke. She is excited to have a new set of opportunities serving the Duke community, and looks forward to working with the IACUC and the research community at Duke.

What Opponents Say About Research

Chris DeRose (Former actor, Director of Last Chance for Animals): "If the death of one rat cured all diseases, it wouldn't make any difference to me."

Ingrid Newkirk (President and co-founder of PETA):

"Animal liberationists do not separate out the human animal, so there is no rational basis for saying that a human being has special rights. A rat is a pig is a dog is a boy. They are all mammals."

"Even if animal research were to produce a cure for AIDS, we'd be against it."

"Even painless research is fascism, supremacist, because the act of confinement is traumatizing in itself."
OLAW Updates FAQ Website

OLAW (The Office of Laboratory Animal Welfare) updated its frequently asked questions (FAQs) on its website on the care and use of laboratory animals. The website is located at http://grants.nih.gov/grants/olaw/faqs.htm.

**Question:** Is it acceptable to have different individuals names as PI on the grant application and the IACUC protocol?

**Answer:** Yes.

**Question:** Can IACUCs authorize the adoption of research animals as pets after the animals are no longer needed for study?

**Answer:** The PHS Policy, the Guide and the Animal Welfare Act are silent on the issue of private adoption of research animals for pets after a study has been completed and the animals are no longer required. The 9 CFR recordkeeping regulations and official policies offer institutions the option of developing and implementing an adoption policy. OLAW is supportive of the concept of adoption but reminds institutions that NIH grant funds may not be used to support the cost of the program. The PHS will not assume legal or financial responsibility for any adoption program or any results of adoption. The institution should ensure that its policy meets pertinent state and local regulations for transfer of animal ownership and is encouraged to coordinate with local animal shelters. *Note:* The Duke IACUC has an approved adoption policy in place. To view this policy, visit the animal care program website at: http://vetmed.duhs.duke.edu/documents/iacuc/pdf/policy_on_disposition_of_research_&_teaching_animals.pdf

**Question:** What are the institution’s responsibilities in ensuring that animals are shipped safely and in reporting adverse events that occur in shipment of animals to or from the institution?

**Answer:** OLAW expects all parties involved to apply due diligence in assuring that animals are shipped under appropriate conditions to prevent morbidity or mortality due to temperature extremes or other adverse events. When animals are shipped from an institution, that institution should consider and address all relevant factors to ensure safe transport of the animals. OLAW expects shipping institutions to report adverse events that occur to animals in transit. Receiving institutions should notify the shipping institution when animals are received in extremis or dead.

**Question:** How can institutions and their IACUCs best prepare for a pandemic?

**Answer:** Institutions must adhere to provisions of the PHS Policy, the Guide, and the commitments detailed in their Animal Welfare Assurance with OLAW. This includes advance planning for conditions that could arise as a result of a human pandemic (e.g., influenza) that could jeopardize the health and wellbeing of animals because of a lack of personnel to care for the animals and/or to conduct IACUC official business.

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**Upcoming Dates & Deadlines**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 3</td>
<td>SC meeting</td>
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<tr>
<td>July 7</td>
<td>New protocol deadline</td>
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<tr>
<td>July 17</td>
<td>SC meeting</td>
</tr>
<tr>
<td>July 28</td>
<td>SC amendment deadline</td>
</tr>
<tr>
<td>August 4</td>
<td>New protocol deadline</td>
</tr>
<tr>
<td>August 7</td>
<td>SC meeting</td>
</tr>
<tr>
<td>August 11</td>
<td>SC amendment deadline</td>
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</tbody>
</table>

*Deadlines are 5 PM on the date listed! No exceptions!*
Calculating Anesthesia Dosages

To calculate how many milliliters to inject you will need to perform two calculations:
1. Multiply the drug dose by the weight of your animal. This will give you the needed milligrams of your drug, then ….
2. Multiply the milligrams you just calculated by the concentration of the drug. This will give the final dose in milliliters.

For example:

STEP I: Assume you have a 250-gram rat. Since dosages are calculated using weight in kilograms, first convert grams to kilograms. This means you have a 0.25kg rat.

STEP II: Assume you will be using ketamine. The protocol says the dose is 80mg per kg of body weight. There are 100 mg per milliliter of ketamine in this solution.

STEP III: Calculate how many milliliters will you give your rat?

Calculation Number 1: Calculation Number 2:

\[
\begin{align*}
\text{Dose} & \times \text{Weight} = \text{mg} \\
80\text{mg} & \times 0.25\text{kg} = 20\text{mg}
\end{align*}
\]

\[
\begin{align*}
\text{mg} & \times \text{concentration} = \text{ml} \\
20\text{mg} & \times \frac{1\text{ml}}{100\text{mg}} = 0.2\text{ml}
\end{align*}
\]

**ANSWER:** You will inject your rat with 0.2ml of ketamine.

If you do not already have a copy of the emergency contact list, cut this one out and post it on your laboratory bulletin board. Remember, we are ALL responsible for quality animal care!

**EMERGENCY CONTACT INFORMATION**

FOR ANIMAL EMERGENCIES:

24 hour DLAR Veterinary Pager: 919-970-9410

John Norton, DVM, PhD
University Veterinarian
Director of the Division of Laboratory Animal Resources
919-681-6792

FOR ANIMAL WELFARE CONCERNS:

24 Hour Animal Welfare Hotline: 919-684-3535

Ron Banks, DVM
Director of the Office of Animal Welfare Assurance
919-668-6720

James D. Reynolds, PhD
IACUC (Institutional Animal Care & Use Committee) Chair
In 2004, the Duke animal care & use program, under the auspices of the IACUC, began a process of compliance assessment. The goal of this program was to capture and correct problems before they became significant events. In general, the process has been both successful and well received by the research community and the federal regulatory officials. Animal use auditing was assigned to the Duke Office of Animal Welfare Assurance (OAWA).

OAWA developed a long term strategic goal to assess all IACUC approved protocols each year, and audit protocols identified as 'higher risk impact' (e.g. primates, multiple survival surgeries, etc.) more frequently. Presently, OAWA is auditing approximately 85% of the institution’s approved protocols annually (1482 site visits within the last year).

Each audit includes a review of the approved protocol (or SOP) and confirmation that the activities observed are being performed consistent with the IACUC approved protocol (or SOP), as well as accepted veterinary practice and care. OAWA audits included research activities and animal care procedures. For research activities, the IACUC approved protocol is used as the reference document. For animal care procedures, the approved SOP is used as the reference document.

Presently, our animal care and use community is achieving over 80% compliance. To be considered compliant, there must be NO deviations from the approved practices. While an 80% compliance report is respectable for a complex campus-wide program such as ours, the IACUC has established a definition of a fully compliant program of animal care and use as ≥ 90% compliance, and no ‘significant deficiencies.’ In this regard, continued effort is necessary to improve our research community’s compliance with federal regulations and Duke expectations for animal care and use.

CONTINUING PROBLEM AREAS: The most non-compliant area of the animal program at present involves cage card management. Generally, this is a failure to keep a current cage card on each cage of animals. As required by federal regulation, all animals being held or under study at the institution must be properly identified. The root cause of this non-compliance centers two points:

- Failure to replace expired protocol cage cards (end of a 3 year study to the follow-on study); and
- Mis-use of temporary cage cards (failure to replace with a permanent cage card having the required regulatory information, failure to remove within 5-7 days from placement, failure to record necessary management information on the cage cards).

This non-compliance issue is a shared non-compliance between PIs and the institution’s husbandry care staff.

Overcrowding is the second most common non-compliant issue. Overcrowding, a deviation of federal guidance for animal cage density, is principally a concern of mouse breeding operations. Researchers tend to maximize the use of a single cage, and in doing so may exceed the federal guidance and Duke policy on cage density. Whereas a given cage may appropriately house up to 5 adult mice, when breeding, cages should be limited to a maximum of 2 breeding females with litters separated by no more than 10 days of age. While mice are social animals, keeping 6-8 offspring from either one or two litters whose date of birth may differ as much as 10 days or more, presented density and environmental care concerns and results in a non-compliance. The majority of overcrowded cages reported were those that had been labeled as requiring separation within 24 hours, but had not been separated - this means this non-compliance was a shared failure of research staff and husbandry staff.
Did you know that a child born today in the United States is expected to live into his or her late 70s, whereas the same child born at the turn of the 20th century would have been expected to live only into his or her 40s?

Eating better and learning how to keep ourselves and our environment clean played a role, but medical research using laboratory animals was a vital factor driving this incredible progress.

**What is medical research that uses animals?**

Animals and people get many of the same illnesses. Certain types of animals can stand in for humans with particular diseases. The information we gain from these studies—about how we’re the same and how we’re different—benefits people and animals.

<table>
<thead>
<tr>
<th>Animal Model</th>
<th>Medical Benefit for People</th>
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<tbody>
<tr>
<td>Dog</td>
<td>Discovery of insulin</td>
</tr>
<tr>
<td>Monkey</td>
<td>Polio vaccine</td>
</tr>
<tr>
<td>Mouse</td>
<td>Rabies vaccine</td>
</tr>
<tr>
<td>Pig</td>
<td>Skin grafts for burn victims</td>
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<tr>
<td>Pig</td>
<td>Computer-assisted tomography (CAT) scans</td>
</tr>
<tr>
<td>Rabbit</td>
<td>Corneal transplants</td>
</tr>
<tr>
<td>Rat</td>
<td>Carcinogen screening</td>
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Medical research with animals is one type of medical research, but other types include experiments with cells and chemicals and simulations on computers. Animal research usually describes research involving vertebrates, such as cats, mice, frogs, pigs, and primates. Most animals used in research are specifically bred for use in medical research.

Another important type of research is clinical research, in which scientists conduct studies with humans. These studies almost always require the results of preliminary tests in animal research studies.

**How do scientists decide to use animals in medical research?**

All medical research is carefully planned, and this includes medical research with animals. Experts who review a scientist’s proposed experiment involving animals weigh several considerations before approving each study.

The most important thing is that the research must be relevant to human or animal health. Studies need to protect the animals’ welfare. That means that only the fewest number of the most appropriate species may be used. Under federal law, all animals must be treated humanely and undergo the least distress possible.
Who does medical research with animals?

Medical researchers who have Ph.D., D.V.M., or M.D. degrees oversee animal research studies. These scientists study animals because they are a lot like people when it comes to basic body functions like breathing, eating, hearing, and seeing. That's because nature is extremely economical. Throughout vast evolutionary time—from bacteria to plants to people—the same biological processes are recycled over and over.

Veterinarians with specialized training in laboratory animal medicine are an integral part of a medical research team. As part of this research group, veterinarians assure the humane treatment of animals and provide medical and surgical support throughout research studies. Emergency veterinary care for research animals is available on a 24-hour basis.

How are animals protected?

Congress and the Public Health Service have set up laws, regulations, and policies to ensure humane treatment of all animals in research. The Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act give details about day-to-day animal care. (Links to these publications are provided at the end of the fact sheet.)

Scientists use this and other information to answer important questions about setting up the proper environment for research animals. How big should the cages be, and how warm or cool do the animals need to be to stay healthy? What kind of food is best, and how much noise do the animals like to have (some like it very quiet)? Do the animals like bright or dim light, and do they need other animals or toys to play with?
Why do medical research with animals?

Results from animal studies are crucial for closing knowledge gaps about health and disease in both humans and animals. Understanding cell and organ function—which is similar in all vertebrates—helps researchers design experiments to test new treatments in people.

Cell culture studies or computers are important but cannot at present take the place of research models that use animals. No single set of results from a particular model—whether animal, cell, or computer—can predict exactly what will happen, so researchers often ask the same questions in different kinds of studies. When different models yield similar results, the results are much more believable.

Where is medical research with animals conducted?

The National Institutes of Health funds most of the basic medical research in the United States and beyond. This research takes place at universities and medical schools in all 50 states. In turn, biotechnology and pharmaceutical companies, often in partnership with the NIH, expand on this foundation of knowledge to develop medical treatments.

Every academic institution funded by the NIH that conducts medical research with animals is required to have a committee called the Institutional Animal Care and Use Committee that oversees care of animals in research. These committees are responsible for making sure that all the researchers at the institution obey the animal welfare laws. Additionally, the government even has rules about who should serve on these committees.
When do research results in animal studies get applied to humans?

Sometimes quickly, sometimes slowly. Scientists don’t understand human biology enough to risk using new medical treatments or surgical procedures directly on people. Because research is a quest to understand the unknown, the rate of progress varies a lot. In research, one discovery builds upon another.

Nearly everyone considers finding lifesaving cures through biomedical research to be one of humanity’s highest purposes. Although research helps humans protect and provide for themselves, humans are also the only species capable of considering the needs of other species on the planet we share.

Table 2. Medical Research that Helps Animals

<table>
<thead>
<tr>
<th>Discovery</th>
<th>How it Helps Animals</th>
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<tbody>
<tr>
<td>Research on viruses</td>
<td>Dog parvovirus vaccine</td>
</tr>
<tr>
<td>Research on reproduction</td>
<td>Breeding programs for endangered species (like pandas, white tigers)</td>
</tr>
<tr>
<td>HIV/AIDS research</td>
<td>Cat leukemia vaccine</td>
</tr>
<tr>
<td>Surgical research</td>
<td>Dog heart valves, hip replacements</td>
</tr>
<tr>
<td>Chronic disease treatments</td>
<td>Diabetes, heart disease treatments for pets</td>
</tr>
</tbody>
</table>

Learn more at these Web sites:

National Institutes of Health
http://www.nih.gov

Animals in Research
http://science.education.nih.gov/animals

Living Laboratories

NIH Office of Laboratory Animal Welfare
http://grants.nih.gov/grants/olaw/olaw.htm

Public Health Service Policy on Humane Care and Use of Laboratory Animals
http://grants.nih.gov/grants/olaw/references/phspol.htm

Guide for the Care and Use of Laboratory Animals
http://books.nap.edu/readingroom/books/labrats

Animal Welfare Act
http://www.access.gpo.gov/uscode/title7/chapter54._.html

Office of Animal Care and Use Regulations and Standards
http://oacu.od.nih.gov/regs/index.htm

NIH Clinical Research
http://grants.nih.gov/grants/funding/PHS398/instructions2/p2_human_subjects_definitions.htm

ClinicalTrials.gov
http://clinicaltrials.gov
OAWA’s Brown Bag Seminar
Friday, July 11th, 2008
Noon – 1 p.m.
Bryan Research Building: Room 103

Dr. Ron Banks
Director of the Office of Animal Welfare Assurance will be presenting:

“Oh-No! The IACUC is Coming!”

The Duke Office of Animal Welfare Assurance will provide a practical discussion of how to effectively (and painlessly) prepare for an IACUC Semi-Annual Review of your laboratory or procedure area. Several common scenarios will be used as discussion points to clearly identify what the IACUC Site Visitors are looking for. Presenters will share preferred responses to the most common questions asked during a Semi-Annual Site Visit.

The Semi-Annual IACUC visits are an on-going part of the institution's program for animal care oversight. Often, these visits appear to bring angst and anxiety to the laboratory members, but understanding the process and how to prepare for a Semi-Annual Visit will ease the distress. This session is designed specifically for laboratory managers, but is useful for all laboratory members.

The presentation will be on Friday, July 11th, 2008 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. OAWA 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

This session will count for 1 CEU of AALAS In-house Training Credit