WHO IS RESPONSIBLE?

According to the NIH, grantee adherence to the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) is a term and condition of all PHS grant or contract awards that include use of live, vertebrate animals. Additionally, institutions with species regulated by the USDA must also comply with the Animal Welfare Act and Regulations. But at the end of the day, who is responsible for the care and use of animals?

The short answer is the Principal Investigator (PI) with whom the Duke Institutional Animal Care & Use Committee has established a contract – known as an approved protocol. Failure to assure proper care or compliant experimentation is the fault of the PI. While many others may be involved in animal care or animal use, at the end of the day, it is the PI who has been entrusted by the granting agency with the funds, and by the IACUC with the authority to use animals, and therefore, it is the PI who is obligated.

At Duke there are several infrastructural activities to assist and support PI obligations. For example, the Division of Laboratory Animal Resources (DLAR) operates full service vivaria; the Occupational and Environmental Safety Office (OESO educates, evaluates, and assures safe working conditions; or the Institutional Animal Care & Use Committee (IACUC) assuring adherence to the stipulations of animal use approval and compliance with federal or

(See Who Is Responsible … Page 5)

UPCOMING DATES & DEADLINES

December 2  Amendment Deadline
December 16  New Protocol Meeting
December 23  Amendment Deadline
January 3, 2011  New Protocol Deadline
January 6, 2011 Amendment Meeting
January 10, 2011 Amendment Deadline
January 20, 2011 Amendment Meeting
January 24, 2011 Amendment Deadline
January 27, 2011 New Protocol Meeting

For more information on this survey and what you can do to foster a climate supportive of animal use in research, visit the FBR website at www.fbresearch.org

SUPPORT BY REGION

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>East</td>
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<tr>
<td>South</td>
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<tr>
<td>Midwest</td>
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<td>West</td>
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SUPPORT BY POLITICAL PARTY

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<tr>
<th>Party</th>
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<tbody>
<tr>
<td>Dems</td>
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<td>Repubs</td>
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<td>Independents</td>
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SUPPORT BY IDEOLOGY

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<td>Moderates</td>
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<td>Conservatives</td>
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SUPPORT BY RACE

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<td>Hispanic</td>
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<td>Afr-American</td>
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<td>Asian</td>
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SUPPORT BY RELIGION

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<tr>
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<td>Jewish</td>
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<tr>
<td>Other</td>
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SUPPORT BY GENDER

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<tr>
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MONTHLY TRACKING POLL RESULTS

Public support for the use of animals in biomedical research now stands at 55.8% through the end of October, compared with 52.7% in September and 43.5% in August. Here’s how ALL demographics from the latest poll break down:

PUBLIC OPINION REPORT—Nov 2010

(Paul McKellips)

Monthly tracking poll results are in from Zogby International. Exactly 2,100 adults were surveyed and the poll has a margin of error of +/- 2.2%. A total of 1,067 women and 1,033 men participated in the poll.

For more information on this survey and what you can do to foster a climate supportive of animal use in research, visit the FBR website at www.fbresearch.org
WHAT INVESTIGATORS NEED TO KNOW ABOUT THE USE OF ANIMALS
(From the NIH Web)

Principal investigators are responsible for the scientific and technical aspects of a grant award and must ensure compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals when using live, vertebrate animals. PHS Policy incorporates U.S. Government Principles, the Guide for the Care and Use of Laboratory Animals, and the Report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia. Vertebrate animals include traditional laboratory animals, farm animals, wildlife, and aquatic animals. Animal use encompasses research, teaching, or testing. Generation of custom antibodies is considered an activity involving vertebrate animals.

Who Must Comply With the PHS Policy? The PHS Policy on Humane Care and Use of Laboratory Animals applies to extramural and intramural activities supported by any PHS agency, including the National Institutes of Health (NIH), the Food and Drug Administration, and the Centers for Disease Control and Prevention. All funding mechanisms, including research and training grants, cooperative agreements, and contracts, conducted at domestic and foreign institutions, are covered by the Policy.

What is the IACUC's Task? Institutional Animal Care and Use Committees (IACUCs) are local institutional committees with federally mandated oversight responsibilities, including:
• Reviewing animal-use protocols;
• Reviewing significant changes to protocols;
• Evaluating institutional compliance with PHS Policy, U.S. Department of Agriculture (USDA) Animal Welfare Regulations, and institutional policies;
• Monitoring institutional animal care and use programs, including inspecting animal facilities;
• Reviewing concerns about animal care or use;
• Reporting noncompliance and suspensions to the Office of Laboratory Animal Welfare (OLAW).

Institutional and Investigator Responsibilities: The NIH has certain specific and detailed expectations of Duke and each Investigator holding a federally funded grant. These expectations include:
• Describing proposed use of animals in grant applications.
• Obtaining IACUC approval prior to using animals and prior to implementing significant changes.
• Ensuring research is conducted in accord with the protocol.
• Complying with institutional policies and procedures.
• Addressing significant changes to the use of animals in progress reports.
• Addressing changes in the use of animals that may be a potential change in scope of the grant.

How to Write an Application Involving Research Animals: New investigators, or post docs wishing to learn, can complete the on-line tutorial at the NIH website listed as: [http://www.niaid.nih.gov/ncn/clinical/researchanimals/tutorialUnindex.htm](http://www.niaid.nih.gov/ncn/clinical/researchanimals/tutorialUnindex.htm) While the tutorial differs form the Duke protocol template, the concepts and procedures are applicable to the Duke template.

Applying for Funding: The proposed involvement of vertebrate animals is evaluated as part of the agency peer review process. In addition to providing IACUC approval status, applicants must address five points in the Research Plan of the grant application:
1. A detailed description of the proposed use of the animals, including species, strains, ages, sex, and numbers.
2. Justification of the use of animals, choice of species, and numbers to be used.
3. Information on the veterinary care of the animals.
4. A description of the procedures for ensuring humane treatment (i.e., minimization of discomfort, distress, pain, and injury).
5. The method of euthanasia, the reasons for its selection, and consistency with the AVMA Euthanasia Report.

Failure to address these elements will result in the application being designated incomplete and is grounds for PHS to defer the application or may negatively affect the priority score.
Obtaining IACUC Review: IACUC approval is required prior to award except in rare circumstances. The use of animals as described in the protocol approved by the IACUC must be congruent with the description in a competing grant application. Any modification required by the IACUC that affects the content of the application must be submitted to the agency along with the IACUC approval date.

Receiving all Award: To receive an award the grantee organization and every performance site where animal work will be performed must have an Animal Welfare Assurance approved by OLAW. OLAW will contact an organization with specific instructions when an Assurance is required. An inter-institutional Assurance is negotiated when the grantee does not have its own animal facilities and the animal work will be performed at an institution with an Assurance.

Working with a foreign (non-US) institution? Foreign institutions provide a Statement of Compliance with Standards for Humane Care and Use of Animals.

Past Award
IACUC approval is required at least every 3 years (annually if covered by USDA regulations). Significant changes in animal care and use are to be approved by the IACUC prior to implementation. Check with your IACUC to determine what constitutes a significant change. Conducting research in the absence of a valid IACUC approval or implementing a significant change without IACUC approval constitutes noncompliance.

Investigators also must be aware of and comply with additional institutional policies that may be more restrictive.

For additional information:
- http://www.nap.edu/readingroom/books/labrats

Note: You can view the entire text of this publication online at http://grants.nih.gov/grants/olaw/GuideBook.pdf
NEW RODENT RESOURCES AVAILABLE FROM AALAS

TECHNIQUES TRAINING: MOUSE is a visual guide to research techniques developed by the AALAS Educational Resources Committee to provide a new resource for hands-on training. The book is a step-by-step guide that pictorially shows how to perform basic techniques. For each technique shown, variations are provided for adapting a procedure to a specific situation. The book includes sections on neonatal mouse development, sex identification, restraint, identification, blood collection and compound administration.

COMPARATIVE ANATOMY OF THE MOUSE AND RAT: A COLOR ATLAS AND TEXT provides detailed comparative anatomical information for those who work with mice and rats in research. If you need to find information about anatomical features and landmarks for conducting physical examinations, collecting samples, administering compounds or performing surgeries, this atlas will be a valuable resource. In each set of illustrations, the same view is depicted in the mouse and the rat. Text is provided to draw attention to important anatomical features and distinctive differences relevant to the care and use of these species in research.

For more information about these new publications plus other rodent resources, visit the AALAS bookstore: http://www.aalas.org/bookstore/products/

Test Your Knowledge

Toe clipping in mice must be performed prior to _____ days of age?
   A. 12  
   B. 21  
   C. 15  
   D. 18

2. Anesthesia must be used performing tail clipping in mice over _____ days of age.
   A. 12  
   B. 20  
   C. 21  
   D. 18

3. Institutional Animal Care and Use (IACUC) meetings are held
   A. As needed  
   B. Monthly  
   C. Weekly  
   D. Every six months

4. Mice can be identified by using
   A. Ear tags  
   B. Tattoos  
   C. Micro chips  
   D. All of the above

5. All individuals who have contact with or will be participating in the use of animals are required to complete Animal Handlers Parts I and II training prior to receiving approval on a protocol.
   True  
   False

6. Euthanasia via CO2 must be ensured by a secondary method.
   True  
   False

7. CO2 is an acceptable form of euthanasia for mice aged 0-14 days.
   True  
   False

8. A protocol annual review will not be approved until all individuals listed on the protocol have completed CO2 training.
   True  
   False

Reporting Adverse Animal Conditions

If you observe an animal in distress, as a member of the Duke animal care program you are obligated to report the distress immediately! You are encouraged to take actions to prevent any further distress to the animal if you can. To report adverse animal conditions, contact the Duke Animal Welfare Hotline (919.684.3535) or Email the Duke IACUC at IACUC@duke.edu Duke University will not tolerate any misuse or neglect of animals.

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

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

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

Concordance reviews, is a comparison between the grant submitted to the funding agency and the protocol reviewed by the IACUC, are required prior to receipt of grants funds for animal approved procedures.

Concordance reviews are performed by the OAWA or IACUC and generally require 5-7 business days to complete. Why so long? To be concordant, everything you told your granting agency you would do with animals, even if it will not be done until the 4th or 5th year, must be IACUC approved before the concordance letter can be generated.

The OAWA / IACUC requires the whole grant EXCEPT the bio-sketches and the budget pages. It is preferred that an electronic copy be provided when the protocol is submitted (if you have the grant at that time). If not, a concordance review can be done at any time, but it will take the 5-7 business days to complete.

The secret? PLAN AHEAD! If you think you MAY need a concordance review, request it up front, because these reviews cannot be rushed, and do re-

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**CO2 EUTHANASIA**

Performing CO2 euthanasia is a critically important activity for those laboratories using rodents. Performing CO2 euthanasia humanely is a critically important activity for the university and the animal care program. Performing CO2 for certain ages of rodents – will not work. Failure to perform CO2 properly requires a federal report to the NIH. These few facts are some of the most troublesome requirements of any animal care and use program. The guidelines below apply to mice, rats, hamsters, gerbils, guinea pigs, and rabbits:

**Gestational age 0 to gestational age 14:**
- Euthanasia of the mother; or
- Removal of the uterus/fetus

**Gestational age 15 to birth:**
- Skillful injection of chemical anesthetics; or
- Decapitation with surgical scissors; or
- Cervical dislocation

**Birth to 14 days of age:**
- Overdose of chemical anesthetics; or
- Decapitation; or
- Cervical dislocation.

**15 days of age through weaning:**
- CO2 euthanasia (with extreme caution); or
- Overdose of chemical anesthetics; or
- Decapitation; or
- Cervical Dislocation.

**Post weaning through adulthood:**
- CO2 euthanasia (with extreme caution); or
- Overdose of chemical anesthetics; or
- Decapitation; or
- Cervical Dislocation.

**Caution:** Animals younger than weaning may not respond to CO2 as full grown adult do, some are resistant to CO2 euthanasia for up to 30 days of age.

**ALWAYS USE A SECONDARY METHOD OF EUTHANASIA!**

For more information on methods of euthanasia, consult: [http://vetmed.duhs.duke.edu/policy_phs_euthanaisa.htm](http://vetmed.duhs.duke.edu/policy_phs_euthanaisa.htm)

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**Answers for the quiz on page 4**
1-A; 2-B; 3-B ; 4-D; 5-True; 6-True ; 7-False; 8-True

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(from Page 1, Column 2... Who is Responsible?)

state regulations and standards. In addition to these three, there is an alphabet soup of PI supportive agencies at Duke (e.g. EOHW, ORA, ORS, etc.).

One goal of all animal oriented research infrastructure at Duke is simple: To provide the strong foundation from which cutting edge research can be performed in a manner which has the highest regard for scientific integrity and humane animal engagement. It is along this line that the animal program has recently embarked on a Research Animal Coordinator Certification program.

Over the next several months, individual leaders of various campus laboratories will be engaging in focused and specialized training to uncover the hidden gems of research infrastructural support at Duke. They will be provided with tools and resources which can assist their laboratory in most effectively performing research using animals at Duke. If you’ve a lab that wants to learn the secrets for successful and efficient animal care and use at Duke, contact Bill Wade, RLATG (w.wade@duke.edu) for details on the program and procedure for entering into the RACC process.
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.

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.

<table>
<thead>
<tr>
<th>Animal Model</th>
<th>Medical Benefit for People</th>
</tr>
</thead>
<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>
</tr>
<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>
</tr>
</tbody>
</table>

Medical Research with Animals Saves Lives
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.

Computer Models in Research
Even though computer models are very valuable, they are limited by what is already known about a process or disease. Data for computer models often comes from animal studies. In turn, computer models reveal gaps for further study in living organisms. Thus, medical research with animals and computer modeling studies work together to increase our understanding of health and disease.

In Vitro Studies in Research
In vitro experiments are performed in test tubes and plastic dishes. These studies usually use tissues or cells obtained from animals or people. When scientists study living cells in laboratory containers, they cannot reproduce the whole, complex, interactive system that is present in an animal or a human. But researchers can learn a lot from in vitro studies. The results of these experiments help scientists design further experiments to conduct in an animal.

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>
</tr>
</thead>
<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  

Animals in Research  
[http://science.education.nih.gov/animals](http://science.education.nih.gov/animals)

Living Laboratories  

NIH Office of Laboratory Animal Welfare  

Public Health Service Policy on Humane Care and Use of Laboratory Animals  

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

Animal Welfare Act  

Office of Animal Care and Use Regulations and Standards  

NIH Clinical Research  

ClinicalTrials.gov  
[http://clinicaltrials.gov](http://clinicaltrials.gov)