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

NEW WEB FORMS TO REQUEST DLAR SERVICES

The Division of Laboratory Animal Resources (DLAR) is introducing a new method of requesting DLAR Services: on-line interactive web forms that simplify the process and update users as to request status. On-line requests will be available for the following:

- Animal Location and Protocol Transfers
- Imports from Other Research Institutions
- Exports to Other Research Institutions
- Animal Housing Space
- Transport Pick-ups and Deliveries

These interactive forms have drop-down lists and other aids to ease completion. Users will receive email updates as the request moves through the process.

DLAR will provide training sessions for Location and Protocol Transfer Users beginning the week of July 8th, and has on-line presentations of the various forms and how they work. The following link provides additional information and links to training materials:

http://labanimal.duke.edu/modules/testing/index.php?id=16

CONTROLLIED SUBSTANCE AUDITS: What are they and How do they affect you?

There are very few ways in which a research career can be ended prematurely. Mismanagement of controlled substances is one of those ways. A corrective measure by the state or federal agency (e.g., citation, fine, refusal to grant a registration) could prevent an individual or a group of individuals from having access to the medications necessary for preventing pain or distress in research animals. Since pain prevention and management is critical to the use of animals, well, no access to controlled substances could mean no access to animals.

Recently, Duke University, through the Office of Animal Welfare Assurance, began audits of Controlled Substance registrants. It is important to note that the OAWA audits are not compliance audits. Actually, OAWA Audits are a service of the institution for the controlled substance registrant.

Continued on Page 4 ... See Controlled Audits

DR. JULIE SHARP DEPARTING DUKE TO JOIN UNIV. OF PENN

It is with joy and sadness that we report Dr. Julie Sharp has accepted a position at the University of Pennsylvania and will be leaving Duke University at the end of July.

The joy comes in the professional growth and new opportunities Julie will find at another of the nation’s elite animal care and use programs. It is great move for the UPenn program, and a wonderful opportunity for Julie. We find joy in her successes and her advancement.

The sadness is that such opportunities require loss of experience, wise counsel, and friendship to our program. Julie has been instrumental in several successful accreditation reviews and regulatory inspections - a true partner and respected colleague through many challenging days.

What began for Julie as a role of Non-Affiliated IACUC member almost 10 years ago, matriculated into her initial duty as OAWA Compliance Liaison, subsequently Assistant Director, and more recently Associate Director of the Office of Animal Welfare Assurance. While at Duke she successfully passed board certification with the American College of Laboratory Animal Medicine and became a Certified Professional IACUC Administrator. Her accomplishments as a member of our campus program are many and remarkable, and reflect great credit upon her.

Please join us and thank Julie for her many contributions to Duke animal program. Also wish Julie well in her new challenges and opportunities at the Univ. of Pennsylvania.

Wishing you a successful research month,

Upcoming Dates & Deadlines

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<th>Event</th>
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<tr>
<td>July 1</td>
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Deadlines are 5 PM on the date listed!
Research Animal Coordinator Training Program
Applications Now Being Accepted!

The Duke Animal Care & Use Program offers a training and certification program for individuals wishing to serve as their laboratory ‘go-to’ person for animal care and use activities. Referred to as the Research Animal Coordinator (RAC), individual’s who participate in this program will receive specific and detailed information concerning animal care & use at Duke. Those who achieve certification may be designated by the Principal Investigator to serve as the laboratory coordinator for all animal activities and provide in-lab guidance regarding animal care & use at Duke. In addition to assisting with protocol development and processing, the RAC will be trained to provide internal compliance assistance to laboratory members. This program has direct applicability to the researcher while also benefiting the RAC candidate. RAC training is consistent with required training for certification with AALAS.

The RAC program is voluntary, and offered at no-cost by the Duke animal care & use program. Managed by the Office of Animal Welfare Assurance (OAWA) with significant contributions from the Division of Laboratory Animal Resources (DLAR) and the institutional Animal Care & Use Committee (IACUC), the RAC program uses a multi-modal educational approach (e.g., lectures, web-modules, meetings, one-on-one discussion, and hands-on learning). The Research Animal Coordinator will develop new knowledge and research skills in all aspects of animal program oversight and management to include protocol development, compliance oversight, common animal procedures involving anesthesia and analgesia, aseptic surgical technique, DLAR husbandry procedures, facility security, alternatives and literature searches, and much more. The RAC candidate will be evaluated throughout the RAC program and those meeting or exceeding the minimum knowledge and skill requirements will be certified as a Duke ACUP RAC. As a certified RAC, individuals shall have a greater overall knowledge of animal research, and a clear understanding of how to efficiently conduct fully compliant research at Duke.

RAC training includes:

- Protocol application and amendment development: Tips and suggestions for writing an animal use application which is complete and will easily pass muster of IACUC review.
- Protocol application and amendment processing: Training in specific processing measures and tips to make the application process most efficient. The RAC will be able to facilitate the principal investigator through the application processes.
- Protocol and grant congruence: Training in performing grant & protocol congruence reviews. Having this skill set will encourage an earlier assessment and, if necessary, proper amendment submission to make the protocol and grant congruent, and therefore a more rapid receipt of congruence letters for the researcher.
- Policies and guidelines: Training in Duke animal program polices, the process of policy development, interpretation and application of the Duke policies, and the differences between polices and guidelines. The RAC will know how to determine applicable policies, how to request modification of existing policies, and what other guidance is available to researchers.
- Laboratory Personnel Training: Advice and direction on effective monitoring of laboratory personnel training status and recommendation to ensure that all members are up-to-date and compliant.
- Basic Animal Procedures: Receive wet-lab training and be able to instruct laboratory personnel on appropriate animal handling and basic animal procedures.
- Laboratory Liaison: Training with how to conduct internal compliance audits, and how to most effectively communicate with the Compliance Liaison and the IACUC. The RAC will obtain knowledge useful for guiding laboratory personnel with reporting animal concerns, protocol noncompliance, and devising self-corrective measures which have a high likelihood of being IACUC approved.
- Ombudsman: The RAC can serve as a central laboratory member who will disseminate updates in protocol information, new or modified policy updates.
The RAC program consists of small classes of participants, generally 6-8 candidates in a specific class. The successful candidate will complete both ‘PHASES’ of the RAC program.

PHASE I will consist of an introductory session which describes the expectations and sets a time frame for accomplishment of the required modules. PHASE I is Core material required of all candidates. Core material training is approximately 80% web module training which can be accomplished at the convenience of the candidate, but within the range of dates for the specific CLASS. The remaining sessions are small group seminars with animal program leadership.

PHASE II will consist of species specific training. The discussions and activities of PHASE II will focus on the specie(s) in use in the RAC candidate’s laboratory.

For more information on the Duke Research Animal Coordinator Training and Certification Program or to submit an application, please contact Bill Wade at 668.6722 or email Bill (w.wade@duke.edu).

A more detailed review is also available on the animal program website Research Animal Coordinator Webpage

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**IACUC Tip Sheet**

**Reporting Adverse Animal Conditions**

**Question:** Who is responsible for the condition of Duke owned animals?  **Answer:** All of us!!!

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.

Duke University will not tolerate any misuse or neglect of animals.

**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 IACUC@DUKE.EDU

The identity of any person making a report is always kept confidential. Individual making reports are protected against reprisals. Go to http://vetmed.duke.edu/animalwelfarehotline.html for more information, including anonymous reporting options.
Why provide this service? Because the state and federal controlled substance agencies have ramped up their interest of research use of controlled substances and of those using controlled substances in animals. A finding by the state or federal agency could be significant.

- The state issues fines to the tune of $10,000.00 per non-compliance/per day. So a single non-compliance that continues for many weeks ... well, it could be very expensive!
- The state removes the authorization of keeping controlled substances, and that makes animal work very difficult!

The goal of the OAWA audits is to confirm all aspects of the registrant obligations have been met in a manner that would meet stipulations of either the state or the federal agencies. Where concerns are identified, OAWA staff will partner with the registrant to complete required actions / activities. Audits identifying shortcomings are not report-ed to the IACUC and do not generally affect protocols.

How does the process work? Dr. William Wilkison is leading the controlled substance audit effort and he will contact the registrant to discuss the process and arrange a time for a visit. The first step is to have the registrant or an authorized user complete the Duke Controlled Substance Self-Audit. This works best if the self-audit is completed several days prior to the visit by an OAWA staff member. Performing a good self-audit will likely identify any shortcomings, and you can correct any of those prior to the OAWA visit. During the OAWA visit, any discrepancies noted will be discussed collegially. The OAWA staff member will provide suggestions focused toward correcting any concerns. The OAWA staff member will coordinate any training or destruction of expired or un-needed controlled substances.

Self-audits should be performed quarterly. The OAWA shall perform semiannual audits for the near future. At some point down the road, registrants that have a history of fully compliant audits may be shifted to annual OAWA audits. But since this is a new process for us, all registrants are on a semiannual audit schedule for 2013.

The OAWA audit is a physical audit of your controlled substance storage site. The OAWA staff member will confirm the geographical (room number) location, amounts of CS stored and your recordkeeping (receipt logs, authorized user list, etc.). Currently the most common corrective items are: 1) The address on the registrant does not match the storage location of the controlled substance; 2) The registrant does not have a current Authorized Users List; 3) Expired or no longer needed substances are being maintained in the controlled substance cabinet.

Let’s keep this thought in mind. The OAWA wishes to keep Duke University and all of our researchers free from fines and sanctions! Please ask questions and work with Dr. Wilkison when he calls to schedule an audit.

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**Definiton of Pain & Distress**

American College of Laboratory Animal Medicine

Position Statement (approved October 2001)

The International Association for the Study of Pain has defined pain in human beings as "an unpleasant sensory and emotional experience associated with potential or actual tissue damage, or described in such terms" (Institute for Laboratory Animal Research (ILAR), Volume 41, Number 2, 2000). While the ability of animals to feel pain is not completely understood, scientists and ethicists believe that animals perceive pain in very similar ways to humans.

As a result, the Interagency Research Animal Committee (IRAC) in 1985 advised that "unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." Distress is a much more difficult term to define, particularly in animals. Carstens and Moberg, in "Recognizing Pain and Distress in Laboratory Animals" (ILAR 2000), provide the definition of stress "as the biological responses an animal exhibits in an attempt to cope with a threat to its homeostasis."

When stressors are mild and/or of short duration, the animal may regain homeostasis without any lasting effects. However, stress results in distress to the animal when the stressor results in disruption of biological functions which are critical to the animal's well being. When normal function is disrupted, pathology may occur, threatening the animal's welfare, and the animal experiences distress.

Note: Activities which involve pain or distress requires an alternate search in the animal use protocol. A clear understanding of pain or distress is the first step toward an effective alternatives search.

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**A Commitment to Animal Well-being**

All members of the Duke University animal care & use program are obliged to prevent unnecessary pain or suffering in animals owned or used in Duke University animals. All Duke employees, staff, and visitors are charged to provide immediate first aid as would be necessary in such situations, and to report situations of animal distress or unnecessary pain or suffering. Use the Duke University Adverse Event Form to submit the report.

Remember: Anyone having knowledge of animal distress or abuse and not reporting it, is also culpable for the adverse conditions. Animal care & use is a privilege, not a right. Collectively we can protect that privilege!
Animal Use Ethics

The Principal Investigator at Duke has an ethical obligation to:

- Assure the benefits of the research clearly outweigh pain, discomfort, and distress that might be experienced by the animals. Alternatives to animal use must be considered: alternatives must be used if appropriate alternatives exist.
- Select the optimal species for a particular project, while assuring the number of animals utilized are the minimum consistent with sound scientific design and statistical standards.
- Ensure that all animals are lawfully acquired.
- Seek the least painful techniques feasible that will allow accomplishment of the protocol objective(s).
- Estimate the probably occurrence, magnitude, and duration of the pain, discomfort, or distress in order to adequately plan for the preventions and treatment of pain.
- Take all necessary steps to assess and monitor pain as well as discomfort and distress.
- Minimize pain and distress in intensity and durations through the administration of appropriate anesthetics, analgesics, and tranquilizers.
- Never conduct potentially painful experiments on an awake animal while under the influence of paralytic or curarizing drug without the concomitant use of an appropriate anesthetic.
- Choose the earliest possible end-point in order to minimize pain and discomfort. An animal in pain that cannot be alleviated must be euthanized.
- Subject no animal to multiple survival surgeries, except when they are approved by the IACUC.
- Use physical restraint procedures on awake animals only after alternative procedures have been considered and found to be inadequate.
- Ensure adequate post-surgical/procedural care is provided to all animals.
- Use only methods of euthanasia that are consistent with the guidelines of the American Veterinary Medical Association.
- Assure all procedures are performed by individuals with the appropriate qualifications and experience relative to the procedures to be carried out on live animals.
- Adhere to the 4 R’s of Research:
  - Reduction
  - Replacement
  - Refinement
  - Responsibility

Program Points of Contact

Protocol Submission:
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Dr. April Kolstad, DVM  
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Protocol Veterinary Review:
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919.668.0220 debbie.vanderford@duke.edu

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919.668.5985 stephen.pomeroy@duke.edu

Office of Animal Welfare Assurance

2424 Erwin Road  
Suite 606  
Durham, NC 27705

Phone: 919.668.6720  
FAX: 919.668.6725  
Email: iacuc@duke.edu
**Five Day Notification When Dosing Animals With Hazardous Agents**

If you dose animals with toxic chemicals or biohazardous agents, follow the safety precautions outlined in the [SOP for Handling Animals Dosed with Toxic Chemicals](#) and animal use section of the [BSL 2 SOP](#), respectively. Both of these SOPs require notification on the animal facility Operations Manager at least 5 days prior to dosing animals with hazardous agents. You can refer to your protocol’s approval form from OESO for clarification on which agents are included. Please send a completed copy of the animal handling SOP to the facility manager, along with an MSDS (for chemicals). You can only initiate work once you have received confirmation that your notification has been received. These SOPs also require that cage cards and door signs be used to notify researchers and animal handlers of the hazardous agent the animals were dosed with, along with listing any additional precautions they should take when entering the room, changing the cages and/or manipulating the animals.

For additional information please contact OESO.

**APPROVED SECONDARY METHODS OF EUTHANASIA**

The Duke University Policy on Euthanasia outlines the approved secondary methods of euthanasia following CO2 asphyxiation. They are as follows:

- Bilateral Thoracotomy
- Collection of tissues sufficient to assure that the animal will not recover
- Exsanguination
- Decapitation

**CERVICAL DISLOCATION IS NOT AN APPROVED METHOD OF SECONDARY EUTHANASIA**

Direct questions regarding about the use of CO2 or secondary methods following CO2 exposure to the [Office of Animal Welfare Assurance](#) (919.668.6720).

**USDA Reports Institutional Citations**

As a USDA registered research institution, Duke University is subject to unannounced inspections by the USDA. The most recent visit to Duke occurred during June of 2013. The results of that unannounced USDA inspection were ‘No Non-Compliance.’ Yes, it would have been nicer if they USDA would have said ‘Yall done well,’ but that isn’t how the USDA reports inspections. So, we’ll take the ‘No Non-Compliance’ and recognize that it doesn’t get any better in the USDA world. But what about all institutions across the country? How does Duke fit with other institution? The chart below is provided by the USDA and notes the total picture of unannounced inspections.

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<tr>
<td>No Non–Compliances</td>
<td>1198 (71%)</td>
<td>1172 (68%)</td>
<td>1086 (70%)</td>
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Can You Answer These Questions?

What is AAALAC?
AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. AAALAC stands for the ‘Association for Assessment and Accreditation of Laboratory Animal Care,’ and is international in scope.

More than 880 companies, universities, hospitals, government agencies and other research institutions in 37 countries have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use. These institutions volunteer to participate in AAALAC’s program, in addition to complying with the local, state and federal laws that regulate animal research.

Duke University has been accredited by AAALAC, international since 1976. Our most recent accreditation was in 2012, and we were once again confirmed for Continued Full Accreditation, the highest category of accreditation offered by AAALAC.

Why is AAALAC accreditation important to Duke?
For some, animal research is a controversial topic. But like others in the animal welfare arena, AAALAC endorses the use of animals to advance medicine and science when there are no non-animal alternatives, and when it is done in an ethical and humane way.

When animals are used, AAALAC works with institutions and researchers to serve as a bridge between progress and animal well-being. This is done through AAALAC’s voluntary accreditation process in which research programs demonstrate that they meet the minimum standards required by law, and are also going the extra step to achieve excellence in animal care and use. In this way, AAALAC International is where science and responsible animal care connect.

AAALAC is really the only common method to compare programs across structures and styles. Not all facilities with which we collaborate are USDA registered, most but not all are NIH/PHS Assured. But if we focus on AAALAC accreditation as a basis for collaboration, then we can be assured that whether academia, government, in the USA or outside of the USA; their program focuses on animal welfare as a critical component of the research equation, just as we do at Duke.

There are certain attributes that describe why we are accredited:

⇒ **Accreditation represents quality:** Accreditation shows that Duke is serious about setting, achieving and maintaining high standards for animal care and use and committed to animal welfare in science.

⇒ **Accreditation promotes scientific validity:** When research involves animals, reliable scientific results depend on superior animal care - an assessment that ultimately results in improved animal welfare and better research practices and outcomes.

⇒ **Accreditation provides assurance in a global marketplace:** Our researchers partner with other research entities around the world. Because laws and regulations related to animal research vary widely from country to country, AAALAC International accreditation can be used worldwide as a way to gauge the quality of a particular program, harmonize animal care and use practices, and provide assurance to diverse stakeholders.

⇒ **Accreditation is a recruiting tool:** Duke can use our accreditation as a recruiting tool to attract the best and brightest researchers and professors. Talented professionals look for high quality programs to support their research, and that is what they find when the look at Duke.

⇒ **Accreditation demonstrates accountability:** Accreditation through AAALAC International is voluntary and demonstrates a willingness to go above and beyond the minimums required by law. It tells the public and our stakeholders that Duke is committed to the responsible care and use of animals in science.

DUKE HAS BEEN ACCREDITED CONTINUOUSLY SINCE 1976.
What Investigators Need to Know About the Use of Animals

"Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative." 
U.S. Government Principle IV, 1985

Institutional and Investigator Responsibilities

- 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.

How to Write an Application Involving Research Animals:
https://www naln ih gov /ncia /clinical /researchanimals /tutorial /index.htm

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.

Receiving an 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 OLA W. OLA W 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.

Foreign institutions provide a Statement of Compliance with Standards for Humane Care and Use of Animals.

SBIR/STTR investigators should be aware of the requirements in order to address them in a timely fashion so that the necessary Assurances are in place and grants can be awarded.

The date of IACUC approval is essential in order to receive an award and will be requested if not previously provided.

Post 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.

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 an IACUC?

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,1 and institutional policies;
- Monitoring institutional animal care and use programs, including inspecting animal facilities;
- Reviewing concerns about animal care or use; and
- Reporting noncompliance and suspensions to the Office of Laboratory Animal Welfare (OLAW).

1The USDA implements the Animal Welfare Act through requirements found in the Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1-4. These regulations are congruent with PHS Policy but exclude, e.g., the use of farm animals and some of the animals used in research.

"Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals..."

Obtaining IACUC Review

IACUC approval is required prior to award except in rare circumstances. Your IACUC will require you to submit information about the care and use of animals on a protocol form. Most animal-use protocols require a description of the following elements:

- Research project;
- Rationale for animal use and consideration of alternatives;
- Justification for the choice of species and number of animals;
- Research procedures involving animals;
- Procedures to minimize pain and distress;
- Animal living conditions and veterinary care;
- Names and qualifications of personnel who will perform work with animals;
- Method of euthanasia; and
- Endpoint criteria.

The use of animals as described in the protocol approved by the IACUC must be conformed to 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 with the IACUC approval date.

Visit the following Web sites for additional information:
NIH Office of Laboratory Animal Welfare
http://grants.nih.gov/grants/olaw/olaw.htm

1996 Guide for the Care and Use of Laboratory Animals
http://www.nap.edu/catalog/books/labrats/


PHS 398 Grant Application
http://grants.nih.gov/grants/funding/phs398/phs398.html

SF424 (R&R) Application and Electronic Submission Information

Good animal care and good science go hand in hand.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Office of Extramural Research
Office of Laboratory Animal Welfare
7605 Rockledge Drive, Suite 360
Bethesda, MD 20892

The National Institutes of Health (NIH), part of the Department of Health and Human Services, is the principal health research agency of the U.S. Federal Government. The Office of Extramural Research (OER) provides policies and guidelines for extramural research grants administration. OER has primary responsibility for developing and implementing NIH Grants Policy, including policies related to data and safety monitoring; protection of human subjects; humane care and use of laboratory animals; program guidelines; invention reporting requirements; and the information systems for grants administration. Within OER, the Office of Laboratory Animal Welfare has primary responsibility for animal welfare policy matters.

NIH Publication No. 06-6009

From the NIH / OLAW Webpage on Grants & Funding (http://grants.nih.gov/)