**PAUL MCKELLIPS SPEAKS AT DUKE BROWN BAG SEMINAR**

On February 15th, the Duke animal program hosted Mr. Paul McKellips, Executive Vice President at the Foundation for Biomedical Research (FBR) and FBR Global Media. Mr. McKellips gave a powerful, motivational, and inspirational presentation. He noted that for many who work in research, we are often forced to be less than transparent about their jobs due to public scrutiny and widespread misinformation.

In a 60 minute multimedia presentation, Paul traced the 30-year decline in public support for the use of animals in research and outlined the rise and exploits of the Animal Rights (AR) movement in both mainstream media and underground terrorism. Mr. McKellips played several videos from the Animal Liberation Front and other extremist groups. Contrasted to the AR movement, McKellips revealed how positive, assertive media messaging that features biomedical research increases public support for the use of animals in research.

Mr. McKellips surprised the audience with statistics showing that in many cases less than 1% of the dollars received by so-called ‘animal rights’ or ‘animal welfare’ organizations actually go for caring or improving the care of animals. His review of commercials and YouTube video clips gave a clear message that many organizations which espouse animal welfare are in fact quite good at marketing a message; using misleading emotional messages to open the purses and wallets of middle America.

Mr. McKellips concluded his presentation with an encouragement to everyone working in animal facilitated research, testing, or teaching. He reminded attendees that failure to speak up would result in ultimate abolition of any use of animals for any purpose. He nurtured attendees to speak out concerning the needs for animals in research, on the quality

**NEW FROM THE NIH**

**New Vertebrate Animal Section (VAS) Factsheet**

(Posted by the NIH on February 2, 2012): The Office of Laboratory Animal Welfare (OLAW) has prepared a new factsheet to assist with completing the VAS of grant applications, contract proposals and cooperative agreements. The factsheet, which outlines the requirements for each of the 5 points of the VAS, is available at [http://grants.nih.gov/grants/olaw/VASfactsheet_v12.pdf](http://grants.nih.gov/grants/olaw/VASfactsheet_v12.pdf)

Additional information can be found in the VAS worksheets for Grant Applications (PDF) and Contract Proposals (PDF).

**Notice Regarding NIH plan to Transition from use of USDA Class B Cats to Other Legal Sources**

(Release date February 8, 2012): The NIH is implementing a plan to limit the expenditure of funds for the acquisition of cats for NIH-supported research to legal sources other than USDA Class B dealers. There are two important statements in the NIH Notice:

- All ongoing NIH-funded research involving cats previously obtained from any legal source may continue.
- Noncompeting and competing awards issued on or after October 1, 2012 (with FY 2013 funding) are prohibited from using NIH funds to procure cats from USDA Class B dealers. The procurement of cats may only be from USDA Class A dealers or other approved legal sources.

So the short term appears to be ‘no significant impact,’ but going forward, PIs who require cats for studies will need to include the additional cost of Class A animals.

**Upcoming Dates & Deadlines**

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of animal care where they work, and to use our own unique experiences to share with others the benefits of animal investigations. Paul noted that a 2011 Emmy nominated public service clip “Jen’s Story” was filmed at Duke. He stated that our campus has been a leader in clearly identifying and living a commitment to compassionate animal care and humane animal use, but even this was not sufficient if we were to ensure the continuing privilege of using animals for research, testing, and teaching.

At the conclusion of the Seminar, attendees were reminded that each of us working at Duke have “skin in the game.” As members of the Duke community, we are part of the institutional commitment to compassionate caring for animals and humane use of them; and if we observe or become aware of animals be inappropriately used or misused, we are obligated to report our concerns to the Duke animal care & use program. As a special treat, Brown Bag Seminar attendees were gifted with a signed copy of Mr. McKellips top of the charts biomedical thriller, UNCAGED.

WHO IS PAUL MCKELLIPS?
A native of Neenah, Wisconsin, McKellips served in Iraq as a civilian public affairs specialist and was embedded with four Iraqi journalists during the height of “the surge” in 2006-2007. Subsequently, he spent several months serving on the front lines of Afghanistan where he was the media trainer of the Afghan National Army and produced a television documentary on Afghan culture at the request of General David H. Petraeus. Mr. McKellips has written, directed, and produced three motion pictures and numerous television shows. He has received 20 Telly Awards and earned a 2011 Emmy nomination for his FBR documentary on breast cancer research (which was filmed at Duke). He is currently producing a 22-program series on biomedical research and publishes the quarterly magazine, Research Saves. His daily radio show, The Animal Research Minute, is heard on 3,500 stations across the United States.

For more information about the Foundation for Biomedical Research or Mr. McKellips, go to the web link: http://www.fbresearch.org/

ANIMAL SHARING

“Animal Sharing” is an opportunity to facilitate the use of animals that would otherwise be euthanized, and therefore is an effort to conserve animal life as well as decrease costs for the research efforts within Duke. Researchers who have or will have animals available for use by other Duke PIs and PIs needing animals can communicate this information through the animal sharing link on the DLAR website (http://labanimal.duke.edu/).

The animal sharing link can be accessed by clicking on the “Animal Purchasing and Animal Sharing” link on the webpage. Transfers from one PI to another will be accommodated through the standard DLAR transfer process, using the DLAR Transfer Request Form. Communication regarding transfer should be made directly between the involved PIs or their designees. This is for internal use only and cannot be used to acquire animals from outside of Duke.

SCIENTIFIC MERIT REVIEW OF ANIMAL USE PROTOCOLS

The National Research Council’s Guide for the Care and Use of Laboratory Animals (8th) Edition and the Animal Welfare Act require the IACUC review all activities involving animals. While the responsibility for scientific merit review normally lies outside the IACUC, the federal oversight agencies expect the institution should evaluate scientific elements of the protocol as they relate to the welfare and use of the animals. For example, hypothesis testing, sample size, group numbers, and adequacy of controls can relate directly to the prevention of unnecessary animal use or duplication of experiments. For most grant proposals, a scientific merit review is conducted by the granting agency. In the absence of evidence of a formal scientific merit review, the IACUC conduct such a review which will consist of three components:

⇒ Review for Scientific Merit: For those proposals where the funding / granting agency has not performed a scientific merit review (e.g., departmental funding), the IACUC may require a scientific merit review be performed by the Department Chair or their designee (which is not conflicted with the PI or portions of the protocol).
⇒ Ethical Use Review shall be performed by the IACUC during its routine review processes.
⇒ Humane Care & Use Review shall be performed by the IACUC during its routine review processes.
Ohio Animal Rights Activist Charged with Murder for Hire Plot

Police say a self-proclaimed animal rights activist in Ohio has been charged with soliciting a hit man to fatally shoot or slit the throat of a random person wearing fur.

In a case that is rapidly becoming a media sensation and likely to prove to be a black eye for animal rights militants, Meredith Lowell, 27, appeared yesterday in U.S. District Court in Cleveland where she was ordered held by U.S. Marshals until a hearing next week.

Authorities say the FBI was notified in November of a Facebook page that Lowell had made under the alias Anne Lowery in which she offered between $730 - $850 for the murder of a person wearing fur.

According to an affidavit, an FBI investigator posing as a possible hit man began emailing Lowell. In increasingly bizarre communications over a period of several months, she offered to pay for the killing of a victim of at least 12 years old "but preferably 14 or older" outside a library in her hometown of Cleveland Heights. She said she wanted to be present when the killing occurred so that she might distribute papers afterward. It is reported that Lowell will be charged with one count of solicitation to commit murder.

REMAINING IACUC SEMINANNUAL SITE VISIT SCHEDULE. PLEASE MARK YOUR CALENDARS!

MARCH 1, 2012: JONES; ENGINEERING; RP 2-4; GSRB2 ANNEX; GSRB1

MARCH 8, 2012: MARINE LAB; MUSEUM OF LIFE & SCIENCE

MARCH 15, 2012: CARL, EYE CENTER; DLAR FARM; INDEPENDENCE PARK

MARCH 29, 2012: CCIF

APRIL 5, 2012: FOSTER ST.; BIOLOGY; FRENCH

APRIL 12, 2012: DUKE SOUTH (CR2); GHRB; CIE-MAS

APRIL 19, 2012: VIVARIUM; MSRB 1

MAY 3, 2012: LEMUR CENTER; ECOTOX FACILITY; MSRB2

RESEARCH SAVES!

FBR’s quarterly biomedical magazine ResearchSaves showcases medical and scientific breakthroughs with foundations in animal research and strong human interest elements. All articles are submitted by universities, nonprofits and companies across the country. Each magazine also includes a full-length DVD, poster or educational program. Annual subscriptions are available for $39, which includes shipping and handling. Complimentary issues are available to K-12 teachers, thanks in large measure to the generous sponsorships granted from individual biomedical researchers. To sign up for a one-year subscription click the "Subscribe today" button below. Please contact FBR at info@fbresearch.org for more information.

MYTH VS. FACT

MYTH: There are no laws or government regulations to protect research animals.

FACT: The USDA has set forth federal regulations governing the care and use of animals in biomedical research that are considered more extensive than those covering human research subjects. The Animal Welfare Act sets high standards of care for research animals with regard to their housing, feeding, cleanliness, ventilation, and medical needs. It also requires the use of anesthesia or analgesic drugs for potentially painful procedures and during post-operative care. Most importantly, research institutions are required – by law – to establish an Institutional Animal Care and Use Committee (IACUC) to oversee their work with animals. IACUCs require researchers to justify their need for animals; select the most appropriate species and study the fewest number of animals possible to answer a specific question.

The U.S. Public Health Service (PHS) Act requires that all institutions receiving research funds from the National Institutes of Health, the Food and Drug Administration, or the Centers for Disease Control adhere to the standards set out in the Guide for the Care and Use of Laboratory Animals. Under the PHS policy, institutions must follow detailed animal care Recommendations and establish an IACUC to ensure that all animals are treated responsibly and humanely.
Three UCLA Researchers Honored for Bravery in Face Of Threats by Animal Rights Militants

The American Association for the Advancement of Science has conferred its Scientific Freedom and Responsibility Award on David Jentsch, Edythe London and Dario Ringach for their "strong defense of the importance of the use of animals in research and their refusal to remain silent in the face of intimidation" by animal rights extremists.

AMP’s Board of Directors and staff join in saluting the resolve and commitment of Dario, Edythe and David.

Here is the award citation as detailed in the AAAS program book:

"Drs. Jentsch, London, and Ringach—scientists who use non-human primates in their research on schizophrenia, addiction, and visual processing—are recognized for the rare courage they have demonstrated in speaking out forcefully for the value of the use of animals in biomedical research.

"In March 2009, Dr. Jentsch was awakened by a loud noise and found that his car had been set on fire and destroyed. He has also received threatening messages, including one that said "I hope you die!" Picketers near his home have chanted "David Jentsch has blood on his hands!" to passersby.

"A garden hose was inserted into Dr. London’s home through a broken window, causing $30,000 in water damage. In claiming credit for the attack, the Animal Liberation Front (ALF) announced that it would have set her home on fire but for the fact that it was the dry season in Los Angeles and they did not want to start a wider fire. However, ALF did warn her that the next time they would not be so careful. True to their word, a few months later, a firebomb was set off on Dr. London’s front doorstep.

Masked activists banged on Dr. Ringach’s door and windows in the middle of the night, and he was subject to continuous harassment by ALF members.

From prior column ...

"Despite this horrible intimidation, Drs. Jentsch, London, and Ringach refused to be silent. Dr. London wrote an op-ed in the Los Angeles Times entitled "Why I Use Laboratory Animals" and has spoken out broadly on the importance of animal studies to potentially life-saving research. Dr. Ringach gave an interview to CNN on the value of animals in research. Drs. Jentsch and Ringach co-founded ProTest for Science, a group that solicits public support for humane animal research and counters false and inflammatory claims of animal rights extremists. Under its auspices, they organized a rally that attracted 700 faculty members, students, and members of the public and collected 10,000 signatures on a petition in support of humane animal research. Additionally, they partnered with a campus animal rights group to organize a peaceful public debate on the topic of animal-based research. They have also developed resources for researchers facing attack by animal rights extremists and are mentoring scientists on how to become advocates for humane animal research.

"Drs. Jentsch, London, and Ringach are recognized for their determination to defend the value of the use of animals in research and to ensure that extremists trying to prevent animal studies will not prevail."

UPCOMING MEETINGS AND TRAINING OPPORTUNITIES

April 16, 2012—Primate Safety Brown Bag Seminar: MSRB 1 Room 001, 12:00 to 1:00

May 2-3: NCABR IACUC 2012 Conference—Research Triangle Park

June 13-14: IACUC 101 and IACUC 201 Plus, Virginia Beach, VA.

October 13-17: Society for Neuroscience Annual Meeting, New Orleans
BILATERAL USE OF EYES FOR RESEARCH ACTIVITIES: Creation of visual disability as a consequence of ocular experimentation or disease development is a special animal welfare consideration that may apply to select research protocols. In its definition of major survival surgery, the Guide to the Care and Use of Laboratory Animals includes any surgical intervention that has the potential for producing a permanent handicap in an animal that is expected to recover. Hence, any experimental procedure that results in, or has the potential to result in, a level of visual disability sufficient to disrupt an animal’s normal daily activity should be considered a major survival procedure. Such procedures require appropriate justifications and suitable animal care accommodations. Protocols involving bilateral survival ocular procedures require special consideration and justification, with particular attention to any visual consequences. Such procedures include bilateral ocular surgeries, whether performed simultaneously or sequentially, and any other experiments with the potential to affect vision bilaterally. The Guide recommends that animals not be subjected to multiple major survival surgical procedures unless they are related components of a particular research project. Accordingly, a visually disabling procedure should not be performed bilaterally unless the two procedures are related components of a specific project. As noted in The Guide, cost savings alone is not an adequate justification for performing multiple survival surgical procedures. The privilege of using animals requires full attentiveness to humane care principles. Researchers must balance the scientific value of animals providing their own ‘control’ against the potential animal distress by having total sensation affected or destroyed.

The IACUC will consider proposals involving bilateral use of the eyes when bilateral use provides a necessary control to the experimental condition. Due to the potential risk to vision associated with bilateral eye use, any bilateral eye use will require scientific justification, similar to the requirement for multiple major surgery. Bilateral eye procedures are not considered multiple major surgeries, but will be treated in the same manner (requires scientific justification). Bilateral eye use will not require a Section K. Requests for bilateral eye use must be considered by either the SCSC or full Committee.

USE OF NON-PHARMACEUTICAL GRADE SUBSTANCES IN LABORATORY ANIMALS: The use of pharmaceutical-grade substances in laboratory animals ensures that the substances administered meet established documentable standards of purity and composition. This in turn helps ensure research animal health and welfare, as well as the validity of experimental results. The use of lower grade substances/compounds with undefined or higher levels of impurities or poorly formulated non-commercial preparations can introduce unwanted experimental variables or even toxic effects, and so should be avoided if at all possible. Although pharmaceutical grade substances should be used in experimental animals whenever possible, the use of non-pharmaceutical-grade substances in experimental animals is an acceptable practice under certain circumstances. For example, in the case of new investigational compounds, they would be the only grade and formulation available. The NIH Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture (USDA) both have determined that the use of non-pharmaceutical-grade substances should be based on (1) scientific necessity, (2) non-availability of an acceptable veterinary or human pharmaceutical-grade compound, and (3) specific review and approval by the institutional IACUC. Cost savings alone is not considered an adequate justification for the use of non-pharmaceutical-grade substances in laboratory animals. OLAW has also stated that while the possible implications of the use of non-pharmaceutical grade substances in non-survival studies appears less evident, the scientific issues remain the same and professional judgment, as outlined above, must still apply. It is important to understand that this guideline pertains to all components, both active and inactive, contained in the preparation to be administered. Therefore, the vehicle used to facilitate administration of a compound is as important of a consideration as the active compound in the preparation.

When selecting compounds the following order of choice should be applied:

1. FDA-approved veterinary or human pharmaceutical substances;
2. FDA-approved veterinary or human pharmaceutical substances used to compound a needed dosage form;
3. USP/NF or BP pharmaceutical grade substance used in a needed dosage form (also includes compounded products from any source);

For more details regarding this policy, and guidelines on selecting proper agents, visit the Duke animal program policy web page.
NEW PROCEDURES
FOR THE DUKE ANIMAL CARE & USE PROGRAM

COLLABORATING WITH OTHER INSTITUTIONS: The NIH Office of Laboratory Animal Welfare (OLAW) has clarified the roles that Duke may assume when participating with other institutions in PHS-assured collaborative research. The three inter-connected regulatory issues are:
- Certain species are USDA regulated species;
- PHS ‘follows the money’ when determining responsibly for oversight; and
- AAALAC focuses on ‘ownership of the animals’ as the overarching obligatory requirement for oversight obligations.

Duke researchers may collaborate with institutions which fall into one (or several) of the following categories:
- USDA Registered, and/or
- PHS Assured, and/or
- AAALAC Accredited.

The Duke Office of Animal Welfare Assurance (OAWA) shall serve as the coordinating agency for the Duke animal program. The OAWA shall partner with the Duke grants management activities (Office of Research Administration for the medical center and the Office of Research Support for the university) to assure all necessary requirements have been met prior to authorizing animal care or use in a collaborative arrangement.

The options for collaborative work between Duke researchers and researchers at other institutions involving animals are:

- **If Duke is the primary grantee of PHS funds which shall be used at another PHS-Assured Institution:**
  The NIH allows institutions to collaborate more freely if both institutions are PHS Assured. In these cases, the Duke IACUC shall review / approve a protocol. The subordinate institution may also require a protocol be reviewed / approved at their institution. An MOU between the two institutions shall be established identifying the responsibilities / obligations of each institution.

- **If Duke is the primary grantee of PHS funds that shall be used at a non-Assured subordinate institution (stateside):**
  Duke University will not generally extend its PHS Assurance to subordinate institutions, except in extraordinary circumstances as determined by the Institutional Official. To become an Assured institution, the subordinate institution shall contact the NIH Institutional Official. Once Assured, the Duke IACUC shall review / approve a protocol. The subordinate institution may also require a protocol be reviewed / approved at their institution. An MOU between the two institutions shall be established identifying the responsibilities / obligations of each institution.

- **If Duke is the primary grantee of PHS funds that shall be used at a non-Assured subordinate institution outside of the US (foreign institutions):**
  Duke University will not generally extend its PHS Assurance to subordinate institutions, except in extraordinary circumstances as determined by the Institutional Official. The NIH has a process for NIH Assurance of a foreign institution. The Duke animal program will assist the foreign institution in becoming Assured. Once Assured, the Duke IACUC shall review / approve a protocol. The subordinate institution may also require a protocol be reviewed / approved at their institution. An MOU between the two institutions shall be established identifying the responsibilities / obligations of each institution.

- **Duke is the subordinate institution using PHS funds for which the other institution is the primary grantee:**
  Duke shall review / approve a protocol for the work being performed at Duke. Duke shall provide the primary grantee any information requested to fulfill the obligations of the primary grantee. An MOU between the two institutions shall be established identifying the responsibilities / obligations of each institution.

In some cases, the funds may not be PHS funds. When this occurs:

- **When federal funds (other than PHS) are involved:** Federal granting agencies have differing requirements for oversight and management. Duke OAWA will check with the appropriate agency when such situations occur. Generally speaking, the Duke IACUC shall review / approve a protocol. The subordinate institution may also require a protocol be reviewed / approved at their institution. An MOU between the two institutions shall be established identifying the responsibilities / obligations of each institution.

- **When other than federal funds are involved:** Duke shall review / approve a protocol. The other institution may also require a protocol be reviewed / approved at their institution. An MOU between the two institutions shall be established identifying the responsibilities / obligations of each institution.

For more details on the process of collaborations, visit the Duke animal program website, Policy Page.