



# ANIMAL TRACKS



A newsletter for the Duke research community

July 2009

<http://vetmed.duhs.duke.edu>

## JAMES D. REYNOLDS, Ph.D. RE-APPOINTED AS IACUC CHAIRMAN

James D. Reynolds, Ph.D. has accepted re-appointment as Chairman of the Duke IACUC for an additional three year term, through 2012. Dr. Reynolds has been a member of the Duke faculty since 1996. He first served as an IACUC member representing the Department of Anesthesiology (he also holds a secondary appointment in the Department of Surgery). Dr. Reynolds served as the IACUC Vice-Chairman under Professor Emeritus Lee Tyrey, Ph.D. until Dr. Tyrey's retirement in June of 2006.

In addition to his service as IACUC Chairman, Dr. Reynolds also maintains an active research program at Duke. He holds a Ph.D. in Pharmacology from Queen's University in Kingston, Ontario and performed a post-doctoral fellowship with the Department of Anesthesia at the University of Iowa.

The IACUC and the Duke animal program leadership look forward to continued work with Dr. Reynolds in these next three years.

Please join us in welcoming James in his continuing tenure as Duke IACUC Chairman. It is with James leadership and your partnership we will be successful with the continued maturation and development of our world-class program of animal facilitated research at Duke University!

## REPORTING NON-COMPLIANT EVENTS TO THE NIH

The National Institutes of Health Office of Laboratory Animal Welfare (OLAW) interpretation of NIH Grants Policy has narrowed recently. The OLAW has begun reporting non-compliant activity to the federal grant agencies, when there is the potential for 'substantial' recoupment of federal funds, even when the resultant non-compliant activity does not result in animal welfare concerns.

NIH Notice Number: NOT-OD-07-044 (NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld) specifies the following:

- The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:**
- i. The conduct of animal activities in the absence of a valid Assurance on file with OLAW.**
  - ii. The conduct of animal activities in the absence of valid IACUC approval of the activity.**

While neither items i. or ii. are a change in NIH policy, OLAW's interpretation of item ii. **has morphed to a more narrow interpretation, and is now being applied to ALL aspects of animal utilization including unapproved anesthetic or analgesic use, unapproved methods of euthanasia, or changes in protocol specified husbandry without IACUC approval.**

Under federal regulation, the IACUC must report to OLAW any non-compliant activity which exceeds the minimums established by OLAW, or if an unapproved animal activity created an animal welfare concern. At that point, OLAW staff use 'professional judgment' to determine when the potential expense associated with the non-compliant activity is minimal (which they do not report to the funding agency) and when the non-compliant activity could have greater financial impact upon federal supplied research dollars (which they do report to the supporting granting agency). Since professional judgment is the basis for OLAW's reporting filter, there is no simple formula to determine what OLAW will or will not report to the funding manager.

### Upcoming Dates & Deadlines

July 23	New Protocol Meeting
July 27	Amendment Deadline
August 3	New Protocol Deadline
August 6	Amendment Meeting
August 10	Amendment Deadline
August 19	BB Seminar: AAALAC IS COMING!
August 20	Amendment Meeting
August 24	Amendment Deadline
Sept. 18	BB Seminar: AAALAC IS COMING!
October 1	BB Seminar: AAALAC IS COMING!

See NIH REPORTING .... On Page 2

## WHY IS DUKE AAALAC ACCREDITED?

Our society has many measures of quality, from the Underwriter Laboratories Safety Seal to the Good House-keeping Gold Seal. In the scientific community, we talk about having the AAALAC Seal. **AAALAC accreditation shows that an institution is serious about setting, achieving, and maintaining high standards for animal care and use.** With over 700 accredited institutions in 27 countries, AAALAC accreditation is recognized worldwide as evidence of quality animal care and compassionate animal use.



**Accreditation promotes scientific validity.** AAALAC engages scientists and veterinarians in an independent, rigorous assessment of the animal care & use program—an assessment that ultimately results in better research outcomes through enhanced animal care.

**Accreditation can be used as a recruiting tool to attract the best and brightest of researchers.** Talented professionals look for high quality programs, and seeing the accredited status of our campus, assures the candidate of our institutional commitment to progressive animal care and use in a strong research environment.

**Accreditation demonstrates public accountability.** Although animal based research can be a controversial issue, most people support biomedical research if it is conducted humanely. Accreditation demonstrates a willingness allow assessment of our program practices and confirms for the public and funding agencies that the Duke program is a program above reproach, which is compassionate toward animals, and provides a strong and secure foundation for cutting edge research.

**Accreditation documents fiduciary integrity.** Many granting agencies such as the American Heart Association, Kidney Foundation, the NIH, DOD, NASA, VA, and NSF regard accreditation as evidence of a commitment to program excellence and proper expenditures.

The bottom line? **Accreditation with AAALAC shows the world that Duke is serious about our commitment to humane animal care in a progressive and productive research environment!**

AAALAC will be visiting Duke later this fall for a routine accreditation site visit. Stay tuned for more news about this visit!

**Plan on attending a Brown Bag Seminar during August or September to learn how your laboratory can prepare for the accreditation site visit. (See page 7 & 8 for details).**

## From Page 1 ... NIH REPORTING

Funding agency grant managers have the discretion to pursue recouping funds associated with the unapproved or non-compliant procedure. Grant managers may also determine the level of funding which must be recouped. An informal survey of a number of federal agency grant managers indicated that if the affected funds are negligible and the research outcome was not changed, then the grant funds managers will not generally request reimbursement; but if the funds associated with the unapproved or non-compliant activity are substantial, or if the research outcomes were affected, then the federal funds used for the non-compliant activity must be returned. It is not clear at what point along the spectrum, that negligible becomes substantial.

The funds which could be required of researchers are funds specifically associated with a specific unapproved or non-compliant activity. For example, consider a case where an unapproved anesthetic was used for anesthesia of 100 mice. If we assume that this example meets the agency's definition of substantial, then the cost of the animals, anesthetic, surgical supplies, and personnel time for the animal surgery using the unapproved anesthetic could be recouped by the federal funding agency. Generally, federal funding agencies do not require recoupment of funds for other aspects of the research project or ongoing veterinary care not related to the specific non-compliant activity; such as standard institutional husbandry, or normal animal maintenance requirements.

Overall, Duke researchers do a wonderful job at maintaining compliance to approved protocols, but on occasion a deviation may unintentionally occur. The Duke IACUC is bound to abide by all terms and conditions of Duke's PHS Assurance and federal Grant Policy, and has little option in these cases except to report deviations to the NIH/OLAW. Once the IACUC determines a report is required, OAWA must prepare and report in a timely manner. As part of this process and prior to submitting the formal letter to NIH/OLAW, OAWA offers the PI an opportunity to self-report to their granting agency. If the PI self-reports, then OAWA can note the self-report in the letter to NIH/OLAW, and this notation will prevent NIH/OLAW's report to the grants manager. If the PI chooses not to self-report to their grants manager, then the NIH/OLAW staff will use professional judgment in determining when they will contact the grants manager and when they will not.

As is always the case, if you've any questions about what is approved in your protocol, you can contact the Office of Animal Welfare Assurance for assistance (668.6720) or send an email to [IACUC@duke.edu](mailto:IACUC@duke.edu). If you discover a protocol deviation has unintentionally occurred in the laboratory, either suspend future procedures or immediately submit an amendment to add the procedure, and call the OAWA for further recommendations.

Best wishes for a safe and productive research month,

## PHS ASSURANCE IS CAMPUS-WIDE

On 1 July 2009, the animal care and use program completed negotiations with the NIH's Public Health Service to consolidate the two existing Duke NIH/PHS Assurances into a single assurance. The consolidated assurance will use the existing Medical Center assurance number, but the name of the assurance will change to Duke University.

Grants managers need to begin using the new designation for all new grants submissions. Remember:

\* For the Medical Center side, the change is simply the name of the assurance.

\* For the University side, the change is simply the Assurance number.

Please note this new number and name for all submissions and reports.

Duke University: A3195-01

## ALCOHOL FOR SKIN DISINFECTION

The goal prior to surgery is to rapidly kill bacteria at the site of the planned incision or injection. Alcohols are well-suited for this. After application, their antibacterial effects result in falling bacterial counts that can last up to several hours. For example, a one-minute alcohol *immersion or scrub* (*this doesn't mean a simple wipe*) is as effective as a 4 to 7 minute scrub with Chlorhexidine or Iodophors. An article by Dr. Cunliffe-Beamer cited in the *The Guide* supports alcohol *for rodent skin* disinfection prior to surgery. The World Health Organization has designated alcohol "the gold standard against which all other skin disinfectants should be measured. *For these reasons, alcohol as a skin disinfectant for rodent survival surgery is permissible.* However, the use of alcohol as the sole disinfecting agent for USDA regulated species is not generally acceptable.

## ALCOHOL FOR INSTRUMENT DISINFECTION

Prior to surgery, instruments should be rid of all forms of microorganisms to prevent postoperative wound infections. But this is sometimes difficult due to the grooves on instruments that can trap protein-rich material. According to APIC (Association for Professionals in Infection Control and Epidemiology), ethyl alcohol and isopropyl alcohol are NOT effective in sterilizing instruments because they lack sporicidal activity and can't penetrate protein-rich materials. Isopropyl alcohol also lacks the ability to kill hydrophilic viruses. For these reasons, alcohol is classified as an intermediate level disinfectant, not suitable as the sole disinfecting agent for instruments.

## A CASE FOR PRE-EMPTIVE ANALGESIA

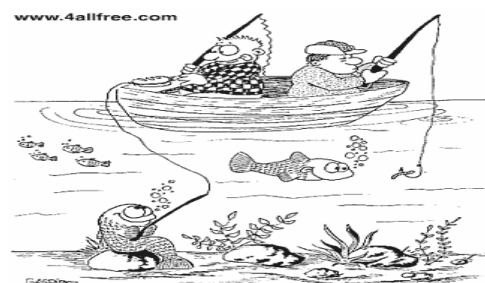
Pain and distress (P&D) modifies research outcomes. A simple statement, a true statement, but not quite so easy to quantify. When compounded with the core axiom of veterinary medicine to prevent or alleviate P&D in the animal patient, the situation may become paradoxical, complicated, or restrictive. An effective engagement of pre-emptive pain management will facilitate a strong and stable biologic platform from which animal facilitated investigation is valued and valuable.

On occasion, P&D prevention is not possible (e.g. studies involving inflammation). In these studies, P&D must be recognized, documented, and reported. But usually P&D is preventable, and it is the right thing to do for the well-being of the animal and the validity of the research. Studies such as 'Pre-Emptive Analgesia for Post-Operative Pain Relief in Lumbosacral Spine Surgeries: A Randomized Controlled Trial,' confirm that human patients given pre-emptive analgesia were more comfortable and had a more successful outcome than patients provided post-procedure analgesia.

While we do not accept the argument that animals are 'little furry people,' it is clear that animals are similarly constructed to humans (this similarity is the basis for biomedical research use of animals), and therefore if a process or procedure was successful in humans then there stands a high likelihood it will be similarly successful in animals—or it is was painful in animals it will probably be painful in humans. What many veterinarians report is that the use of pre-emptive analgesia smoothes the induction, maintenance, and recovery of animal patients—and limits signs of animal P&D requiring heavy analgesia.

Researchers can enhance their outcomes when they prevent the development of a cascade of inflammatory and pain mediators, and the best way to accomplish this is to use pre-emptive analgesia for procedures that might be painful or distressful. To prevent pre-emptive analgesia from serving as an experimental variable, all animals in an experiment should be provided with the same agent at the same dose—those animals that are likely to experience pain and those that are unlikely to experience pain.

The Duke animal care & use program requires the use of pre-emptive analgesia for animal based activity as an ethical imperative and scientifically sound method of maximizing the integrity of research data outcomes.



# Ask Labby

**Dear Labby:** I can't understand why it takes so long for my amendment to get approved by the IACUC? Why can't we get a process that is quick and responsive?

Tired of Waiting

**Dear Tired:** Compared to other institutions, processes used at Duke are both quick and responsive! The Duke IACUC uses a 3 tiered process for amendment reviews. Those amendments that qualify as a 'minor' amendment are generally reviewed and approved within 2-3 days after submission; those amendments which qualify as 'minor with veterinary review' are generally reviewed and approved within 3-5 days; and those amendments which qualify as 'significant' are reviewed by the IACUC's Amendment Subcommittee which meets every two weeks. Checking on your specific proposal, we noted that 2 of the members in your lab have not completed the required on-line training and therefore, the amendment has not received 'training clearance' and cannot be approved. Without 'clearance' for all lab members listed on the protocol, amendments and protocols cannot receive the final processing steps of issuing the approval letter. To help Duke researchers manage laboratory staff training requirements, OESO developed a system where PIs can check on the training status of all members of their laboratory, and can assure there are no interferences with a quick and responsive approval. Please contact Dr. Joan Catignani (joan.catignani@duke.edu or 668.3201) for details in establishing the training check option.



**Dear Labby:** I was bitten by a rat 2 months ago while performing research at Duke. It was a deep bite, but I decided to wash it off and go back to work. The bite didn't heal and last week I went to Employee Health; they said my department might have to pay for the treatment. Since it was a Duke rat and I was working on a Duke animal protocol, isn't Duke Workers Compensation responsible for the cost of treating my injury?

Dr. Bob Rattatoeey

**Dear Dr. Rattatoeey:** According to the Worker's Compensation regulations, if an employee fails to report an injury in a reasonable period of time, the costs of treating that injury is not covered by Workers Compensation, and the Department or the individual may be charged for the treatment. Most injuries will be minor and will never require any Worker's Compensation filing, but if there is a need for Worker's Compensation, then having reported the injury when it happened is critical! One another note, it seems you might benefit from 'Rat Handling' training. Please contacting Mr. Bill Wade at [w.wade@duke.edu](mailto:w.wade@duke.edu) to arrange for training in safe rat handling.

**Dear. Labby:** I am the department administrator supporting a new researcher in our department who will be arriving at Duke in about 2 months. She would like to get starting with her animal work soon after arriving. Can we get her protocol approved before she arrives at Duke?

Admin Annie

**Dear Ms. Annie:** There are many things a new researcher can do to get ready for research at Duke. They can complete the required animal handler training on-line. They can submit the employee health forms on-line, and if immunizations are necessary, they can get those where they are. They can submit a protocol for IACUC review. Even before a protocol is approved, they can arrange with DLAR to receive the animals from their present institution, and process the animals through quarantine and have them placed on a 'holding protocol.' If your researcher needs assistance with preparing the protocol, they can call the staff at OAWA who will be glad to walk them through the process and provide suggestions for writing their proposal. Yes, waiting to arrive at Duke will put their research behind the curve, so encourage them to get started 2-3 months before coming to Duke.



**Dear Labby:** Last month I sent a protocol to OAWA and was told it didn't require a signature. This month I dropped off a protocol on my way home and was told I needed to sign it. What gives? Why sometimes signatures and sometimes not?

Dr. S. Wordsmith

**Dear Dr. Wordsmith:** The Duke IACUC is bound by federal regulations which require knowledgeable consent from the Principal Investigator for consideration of protocol associated actions. Historically, this has meant that documents must be signed by the PI prior to processing by the IACUC. The Duke IACUC received federal agreement that a secure email system is as good as a hard signature. Therefore, any document submitted from the PIs 'duke.edu' email address is considered signed by the PI. Why? Because each of us have a unique password, and if it comes from the PIs Duke email account, then the PI must have agreed to submission of the form. This DOES NOT work for other email accounts (Hotmail, Gmail, EarthLink are not considered secure). Faxes and hand delivered copies do require a signature. So, if you would like to save yourself the signature, submit all animal program documents from your Duke email to the IACUC's email address ([IACUC@DUKE.EDU](mailto:IACUC@DUKE.EDU)). No signature required!

## USING PAIN MANAGEMENT SCORING FOR ASSESSING ANIMAL CONDITION

Dr. Doolittle could talk with the animals, but most of the rest of us are not so lucky. In fact, most of us are not terribly good at observing the animal's behavior and determining when they require veterinary intervention or additional medication. So, maybe the use of an assessment tool could assist us with knowing when intervention is required. The chart below is based upon Kirk's Current Veterinary Therapy: Acute Pain Management by Hendrix, Paul, Hansen, and Bernie. To use this chart, select a 'Criteria' for each 'Assessment.' Add up all of the selected 'Scores,' and if the result is 6 or greater, then a veterinary consultation and/or additional medication is required! Not quite the same as just talking, but overall a good tool to prevent unnecessary pain or discomfort.

Assessment	Criteria	Score
<b>Heart Rate:</b> Take a resting reading to determine baseline	0-15% > baseline	0
	16-35% > baseline	1
	36-40% > baseline	2
	Over 40% > baseline	3
<b>Respir.:</b> Take a resting reading to determine baseline	0-15% > baseline	0
	16-35% > baseline	1
	36-40% > baseline	2
	Over 40% > baseline	3
<b>Vocalization:</b>	None	0
	Crying but responds to voice	2
	Crying but not responds to voice	4
<b>Movement:</b>	Asleep / calm	0
	Position changes	1
	Frequent position changes	2
Response to Touch of the injury or surgery site	None	0
	Turns head, shows tenderness	2
	Protective, withdraws	4

This is a simple chart designed for a few select assessment criteria. This chart may or may not be useful to your study, but you can use this idea and create your own assessment tool to include in your protocol as a means to help assess animal discomfort and set specific milestones at which certain ameliorative actions will occur.

## PAINFUL Q & As

**Q: Why does the IACUC require me to assess pain and distress before the experiment is performed?**

**A:** It is the federally mandated responsibility of the IACUC to critically evaluate all research protocols for the potential to cause pain or distress, and assess the steps that are to be taken to enhance animal well-being. The IACUC accomplishes it's obligation in part by assuring the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal, and reviewing the investigator's written narrative of the methods and sources used to determine that alternatives were not available.

In addition to federal law, the IACUC is required to use the NRC Guide for the Care & Use of Laboratory Animals, which states that the IACUC should ensure the protocol addresses:

- appropriate sedation, analgesia, and anesthesia;
- criteria for timely intervention, removal of animals from study, or euthanasia if painful or stressful outcomes are anticipated; and
- details of post-procedural care.

Therefore, the protocol must provide adequate information for the IACUC to determine the potential animal pain and/or distress resulting from the study; and that effective measures to relieve pain or distress are engaged.



**Q: It would seem that some experiments are more likely to cause pain or distress more than other types of experiments. I am not sure if my proposed procedures would be considered painful, and therefore are not sure whether to consider my experiments as a CATEGORY 'E' type study. Are there guidelines on types of protocols where pain or distress would be more likely to occur?**

**A:** Examples of procedures which the NIH/NRC Guide for the Care and use of Laboratory Animals suggests may have the potential to cause pain or distress, include:

- Physical restraint
- Survival surgeries
- Food or water restriction
- Death as an endpoint
- Noxious stimuli
- Skin or corneal irritancy testing
- Tumor burden
- Intra-cardiac blood sampling w/o anesthesia
- Orbital sinus blood sampling w/o anesthesia
- Tail snipping of weaned animals
- Abnormal environmental conditions (hot or cold)

If you are performing work that includes these activities, then you should consider filing them as CATEGORY 'E' and include a justification why these procedures are scientifically necessary for your proposal.

## Duke ACUP Brown Bag Seminar

Tuesday July 28th, 2009

Noon – 1 p.m.

Bryan Research Building: Room 103

Sonja “Scout” Chou, VMD, MS, DACLAM

Director, Veterinary Services

Genetically Engineered Models and

Services

Charles River



### Will be presenting: Troubleshooting Production in Your Transgenic Colony

With the explosion of the use of genetically engineered models, this presentation will provide a background to better understanding the trials and tribulations inherent in breeding genetically manipulated animals, review factors that are known to influence mouse behavior and reproductive performance, and offer practical suggestions for troubleshooting strategies. This presentation is targeted towards laboratory animal technicians and managers as well as researchers involved in rodent production colonies.

The presentation will be on **Tuesday, July 28<sup>th</sup>, 2009** 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 snacks.

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**



# Duke ACUP's Brown Bag Seminar

Friday, September 18<sup>th</sup>, 2009

Noon – 1 p.m.

Hock Plaza Auditorium Room 0001

Ron Banks, DVM, Director of OAWA  
Will be presenting:

## “AAALAC is coming to Duke”

The Association for Assessment and Accreditation of Laboratory Animal Care International, AAALAC, will be coming to Duke in October to perform our triennial site visit. This site visit is necessary to maintain our accreditation. The following topics will be covered:

- What is AAALAC?
- Why is it important for Duke to be accredited?
- What does this mean for your research?

And most importantly...

- How to prepare your laboratory for the site visit.

It is important that as many people as possible from the laboratories attend, so that we all have a better understanding of what the expectations are and why they are important to your research as well as the accreditation of the Institution.

**Please visit AAALAC's website for more information:**

**<http://www.aaalac.org/>**

The session will be held in **the Hock Plaza Auditorium**, Room 0001, located on the lower level. From the lobby take the elevator **down** to level G. Go left and the auditorium will be down the hall on the right.

**Attendees are encouraged to bring a lunch.**

**OAWA will provide drinks and desserts.**

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# Duke ACUP's Brown Bag Seminar

Thursday, October 1st, 2009

Noon – 1 p.m.

Hock Plaza Auditorium Room 0001

Ron Banks, DVM, Director of OAWA

Will be presenting:

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