ANNUAL USDA INSPECTION RESULTS

By Kate Wiklanski
UCUCA

The United States Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) Animal Care program enforces the University of Michigan’s compliance with the Federal Animal Welfare Act (AWA); this is accomplished primarily through unannounced inspections, but also through educational and cooperative efforts and reporting.

The USDA conducted its annual compliance inspection of the University of Michigan’s animal care and use program and facilities in August 2006. While most everything that was inspected was found to be in compliance, the Veterinary Medical Officer (VMO) did cite the University for animal use protocols not accurately describing what is being done for post-operative pain relief.

Continued on page 2...

NEWSFLASH: Major Changes Ahead for UCUCA! See Page 9!

The Backbone is a quarterly publication of the University Committee on Use and Care of Animals (UCUCA)
USDA INSPECTION RESULTS, CONTINUED

The USDA VMO inspects animal housing rooms, individual animals, and records associated with the animals, such as surgical and post-surgical records, and UCUCA protocols. These records are compared to make sure everything is consistent. For example, if the UCUCA-approved protocol states that analgesics will be given every 12 hours for the first 48 hours after surgery, this must be done, and be reflected in the post-surgical record. If it isn’t, it is considered an item of noncompliance. Similarly, the drugs specified in the UCUCA approval are the only drugs allowed to be administered to the animals. If a different anesthetic or analgesic regimen is warranted, this has to be submitted to the UCUCA Office for veterinary and committee review and approval prior to implementing the change. It is imperative that everything that is done to a laboratory animal is included in the UCUCA-approved protocol, and is documented in the surgical records.

In addition to reviewing animal records, the facilities are also inspected. Items to which the VMO pays particular attention during inspections include, but are not limited to:

- Dust on horizontal surfaces in surgical rooms (especially overhead surgical lights)
- Dust and hair on exhaust grills (especially in rabbit rooms)
- Debris in food storage areas (especially where hay is stored)
- Open supplies of food and bedding not stored in a leak-proof container with a tightly fitting lid
- Storing husbandry or other chemicals (e.g., disinfectant, handsoap, etc) in animal rooms unless enclosed in a secondary container
- Expiration dates on all dated items (e.g., pharmaceuticals, feed, etc)
- Inadequate cage size (whether for animal size or number)
- Environmental enrichment for nonhuman primates

Based on the two citations received so far this year regarding post-operative pain relief, the UCUCA Office is dedicating this issue of The Backbone to post-procedural records and the administration of post-operative analgesics. As always, if there are any questions regarding the use and care of animals on campus, please do not hesitate to contact us by website (http://www.ucuca.umich.edu), email (ucuca.office@umich.edu), or phone (763-8028).

I love you, MUMMY!

HAPPY HALLOWEEN FROM THE BACKBONE!
WHAT IS ANALGESIA?
WHY IS IT IMPORTANT?

By Melissa Dyson, DVM
ULAM

Unrelieved pain can lead to unacceptable levels of stress and distress in animals. The proper use of analgesics, or medications to control pain, in laboratory animals is both ethically and scientifically necessary and is required by numerous organizations that regulate the care and use of these animals. Some of the challenges in providing appropriate analgesia to laboratory animals include the ability to recognize and evaluate pain in the various species used for research and the choice of appropriate analgesics for certain species and types of procedures.

Since animals cannot describe the pain that they are experiencing, we evaluate their behavior and physiology to assess levels of pain. Behavioral indicators of pain in animals include activity level, general appearance, temperament, vocalizations, and changes in food and water intake. Usually activity level decreases with pain, however pacing and restlessness may indicate pain in some species. Appearance of painful animals can include being in a “hunched” position and having a scruffy hair coat. They may also have discharge around the eyes and nose (i.e., porphyrin staining in rodents). Temperament changes may include increased aggression or reluctance to interact. Vocalization may increase or decrease and some species may grind their teeth (sheep or pigs) or chatter when painful. Painful animals may display anorexia and decreased water intake. Physiologic changes that can indicate pain include weight loss; decreased urination or defecation; and increase in heart and respiratory rate, blood pressure and body temperature.

It is also helpful to assess the appearance of surgical sites. Redness, swelling, or discharge indicates pain and/or infection. Abnormal behaviors related to a surgical site, including limping, guarding, licking, or chewing, also indicate pain. These signs can vary depending on the source of pain and the species in question. Pain scales can be developed to help objectively evaluate signs of pain. These scales involve assigning values to ranges of signs. Numeric values or ranges in degree (mild, moderate, and severe) or frequency (how many times a behavior occurs) are examples of ways to objectively evaluate pain.

The UCUCA has guidelines that require analgesics for certain procedures that are expected to be painful (see the UCUCA Policy on Analgesic Use in Animals Undergoing Surgery). It is important to remember that, like humans, individual animals may experience different levels of pain from the same procedure, and should be individually evaluated to assess the need for additional pain control.

Major categories of analgesics used in animals include non-steroidal anti-inflammatory drugs (NSAIDs) and opiates (narcotics). There are a wide range of drugs from these categories that have a variety of strengths, duration of efficacy, and potential side effects. Methods of delivery include orally or by injection via intramuscular, subcutaneous, intraperitoneal, or intravenous routes. Transdermal delivery of opiates like Fentanyl can be used in some species to deliver pain control over a long period of time. Local or regional nerve blocks are less commonly used but can be very helpful in providing pain control to specific regions without systemic effects. Local infiltration of drugs like lidocaine directly to a surgical incision or biopsy can provide some post operative pain relief for specific regions as well.

Continued on page 8...
During The University of Michigan’s 2005 AAALAC site visit it was noted that there was inconsistency in the way post-operative analgesia was evaluated during the animal use application review. Each review, done on a case-by-case basis, was dependant upon the procedures listed in the protocol and whether or not the reviewers felt that analgesia was warranted for those procedures. There could be disagreement among veterinarians, investigators, and IACUC members regarding the need for analgesics for specific procedures and species. In the Guide for the Care and Use of Laboratory Animals it specifically notes, “In general, unless the contrary is known or established it should be assumed that procedures that may cause pain in humans also may cause pain in animals.” Following the site visit it was suggested that our animal care and use program develop guidelines for post-operative analgesia.

The UCUCA Policy on Analgesic Use in Animals Undergoing Surgery was recently approved by the Committee. This policy categorizes surgical procedures based on required or recommended analgesia. For surgical procedures where analgesics are recommended, the investigator can request approval to withhold analgesics; however, adequate justification must be provided to the UCUCA. For surgical procedures where analgesics are required, the investigator can request approval to withhold analgesics, but scientific justification must be provided to the UCUCA. If the UCUCA approves the withholding of analgesics for procedures in the required category, the procedure will automatically be elevated to Use Category 7, 8, or 9 as is appropriate and, for USDA-covered species, will be reported to the USDA annually. It is considered good veterinary practice to administer analgesics prior to surgery (preemptive analgesia) to diminish pain an animal may experience following a potentially painful procedure.

Since all surgeries could not be included in this policy, if you need further assistance when completing your animal use application, please contact our office at ucuca.office@umich.edu or 763-8028. Additional guidance regarding appropriate analgesia for specific species can be found at http://www.ucuca.umich.edu/guideaa.htm. For further details of this policy please visit http://www.ucuca.umich.edu/guidesurg.htm.
ESIRIUS TIPS AND TRICKS: 
ANALGESIA COMPLIANCE IN THE PROTOCOL

By Jessica Durkin
UCUCA

With the new UCUCA Policy on Analgesic Use in Animals Undergoing Surgery in place, it may not be clear what is needed in the animal use application in order to remain compliant. The new policy provides guidance for investigators performing recovery surgeries and divides surgeries into two types: those that require analgesics post-operatively and those where analgesics are recommended post-operatively. The two following scenarios describe which pages of the protocol should be used to comply with the new policy.

OUR LAB WILL BE USING POST-OPERATIVE ANALGESICS:

In the online animal use application, you can enter your choice of analgesics that will be provided to the animals. On page 11.E.11 (Anesthetics, Analgesics, Tranquilizing or Neuromuscular Agents), select “Add Drug,” which will open page 11.E.11.A. In the instructions for page 11.E.11.A, web links are available for both the UCUCA Policy on Analgesic Use in Animals Undergoing Surgery and the Guidelines for Anesthesia, Analgesia, and Post-Operative Care for most species used at the University. Use these guidelines to select the most appropriate analgesic and dose for your animals. Be sure to also complete section B on this page for analgesic use to indicate whether or not preemptive analgesia will be provided. The policy indicates that as a general rule, analgesics should be given preemptively (i.e., shortly before or immediately after the animals are anesthetized). If analgesics will not be given preemptively, justification must be provided in question B.2.

OUR LAB WILL NOT BE USING ANALGESICS:

If your research will contraindicate the use of post-operative analgesics, this must be explained on page 11.E.15 of the online animal use application. Question 4 asks, “If analgesics would be given in human medicine for this type of procedure and will not be provided to animals in this project, please explain.” In addition, if you will not be using analgesics for a surgery where post-operative analgesics are required (such as thoracotomy or craniotomy), the Use Category placement must reflect this. Animals recovering from these surgeries without analgesics, even when scientific justification is provided, will automatically be elevated to Use Category 7, 8, or 9 as is appropriate. In situations where analgesics are recommended, rather than required, post-operatively for the surgery (such as subcutaneous cut-down or tracheotomy), scientific justification must be provided but it will not warrant a Use Category change.

If you have any questions regarding the online application, the eSirius program, or any UCUCA policies, please contact the UCUCA Office at 763-8028 or ucuca.office@umich.edu.

Download the Backbone!

http://www.ucuca.umich.edu/backbone.htm
REGULATORY COMPLIANCE:
GOT SURGICAL RECORDS?

By Steve Durkee
UCUCA

If you perform survival (recovery) surgeries on animals, then the UCUCA staff will be coming to see you soon. The visit is designed to review surgical records for animals undergoing survival surgery. Don’t panic! When the UCUCA staff arrives, we will simply review the records and make suggestions to improve the details kept. Due to the number of areas to visit, these visits will be unannounced. If you want to “pre-review” your own records, the following article provides a summary of record keeping information and where to find the complete documentation for these guidelines.

Surgical records are required for all non-rodent mammals. Rodents covered by the USDA’s Laboratory Animal Welfare Act Regulations also require surgical record keeping. Rodents that are covered by this act include guinea pigs, gerbils, degus, and hamsters. Information that should be recorded relates to three specific time frames for surgical procedures, namely the pre-, intra-, and post-operative periods.

The principal investigator is responsible for documentation and maintenance of the animal’s surgical (pre-, intra- and post-operative) record(s) for three years after the completion of the experiment.

Pre-surgical information should include: pre-surgical physical exam findings, such as a general gross examination, any abnormal behavioral or physical features, etc.; animal weight; pre-operative drugs; anesthetic induction time (including endotracheal intubation time, if applicable); and doses, volumes, and routes of administration for anesthetic agents.

Intra-operative information should include a brief description of the procedure and any complications. If anesthesia needs to be re-dosed, this should be noted in the record. Complications to record include abnormal structures/features, difficulty performing a particular portion of the surgery, etc.

Post-operative information should include: duration of anesthesia; time of endotracheal tube removal, if applicable; time when animal is returned to recovery cage and/or home cage; and any additional fluids and/or drugs given. The ULAM veterinary staff recommends providing analgesics prior to recovery from anesthesia. The doses, volumes, and routes of administration used should be noted. Monitoring of animals does not end immediately following the surgery. Animals must continue to be monitored, twice a day, for 3-7 days following surgery. A surgical record form should be kept in the room where the animal is housed. It must include the findings of each physical examination performed during the recovery period. Physical examinations should include a brief description of the clinical signs exhibited, or not exhibited, by the animal. Some questions to ask while performing these evaluations are: Is the animal grooming itself? Is it moving normally? Is it eating and drinking? Does the suture site appear infected? Has the animal chewed on the sutures or other body parts? Is the animal losing weight?

Continued on page 7...
REGULATORY COMPLIANCE:  
GOT SURGICAL RECORDS?

If pain relieving substances (analgesics) are provided after the surgery, these should also be noted on the surgical record form. Your approved protocol will provide specific guidance on this matter. The protocol will state whether analgesics will be given for a set time period, regardless of the animal’s appearance or behavior, or only administered if specific behaviors or physical (clinical) signs are observed. Typically these clinical signs include, but are not limited to: hunched postures; lack of grooming behavior; decrease in food or water consumption; weight loss; loss of mobility; and increased aggression. Additional species specific signs can be found in guidelines for anesthesia and analgesia, developed for each species by the veterinary staff. These guidelines can be accessed through the UCUCA website (http://www.ucuca.umich.edu/guideaa.htm).

Complete details of record keeping and a blank record form can be found in the ULAM document, Medical Care and Records for USDA-Regulated Mammals Following Anesthesia and/or Surgery (http://www.ucuca.umich.edu/forms/PostSx%20Care%20of%20Mammals04.doc).

For rats and mice, records are required for what is defined as a major survival surgery. Major survival surgeries expose a body cavity or cause permanent impairment of the animal. Some examples of major survival surgeries are: laparotomy, thoracotomy, craniotomy, joint replacement, and limb amputation. The ULAM document, Guidelines for the Performance of Survival Surgery on Rodents (http://www.ucuca.umich.edu/forms/Rodent%20Surgery%20Guidelines%202004.pdf), includes a surgical record form, which can be used to record information concerning the pre-, intra-, and post-operative information.

Reptiles and other cold-blooded animals should also have surgical records kept for them, consistent with information that is described above for other species undergoing survival surgeries. Information related to the pre-, intra-, and post-operative periods should be documented and available upon request.

The record keeping requirements can be confusing. As always, please feel free to contact the UCUCA staff for any questions you may have. General e-mails can be sent to ucuca.office@umich.edu or give us a call at 763-8028.
CONTROLLED SUBSTANCES, UNDER CONTROL

By Howard Rush, DVM
ULAM

As a service to investigators conducting animal research, veterinary drugs and controlled substances may be purchased through ULAM for use in their studies. The use of these agents must be included in the Application to Use Vertebrate Animals in Research, Testing, or Instruction and approved by the University Committee on Use and Care of Animals (UCUCA) before any controlled substance or veterinary drug can be purchased from ULAM.

Once a controlled substance is dispensed to an investigator, responsibility for recordkeeping and secure storage rests with the investigator. A record of utilization of controlled substances must be kept on the ULAM Form C. This record must show the date, species, purpose and amount administered. This form with the investigator’s signature must be returned to ULAM after all of the controlled substance has been utilized or when a partially filled bottle is returned.

Investigators utilizing controlled substances in the course of conducting animal research must maintain their own secure storage facilities. Controlled substances must be stored in a securely locked, substantially constructed cabinet or drawer within the laboratory which must be locked when unattended.

...Analgesics, continued from page 3

When planning a study that requires analgesics, investigators should be aware of the potential signs of pain for the procedures and species that they are working with. It is important to choose an analgesic that is appropriate for the species, will provide adequate pain control, and will not interfere with study results. Resources include the Anesthesia and Analgesia guidelines provided on the UCUCA website (http://www.ucuca.umich.edu/guideaa.htm) and consultation with ULAM veterinary staff. For additional information see the articles referenced below:

By Astrid Haakonstad
UCUCA

As the last rays of the summer sun finally set and we welcome in the brisk, cool breeze of autumn, here at the UCUCA Office things are in a state of flux as well. The changing of the color of the leaves outside coincides with a changing of the guard as we bid a fond farewell to Kate Wiklanski, the UCUCA Manager since 2001. She is returning to Boston, where she will be Director of IACUC Affairs for Boston University. Please join us in offering Kate a hearty congratulations, and thanks for a job very well done! We will miss her and wish her the best of luck in her new position. ULAM faculty veterinarian Dr. Karen Rogers will step into Kate’s shoes as interim UCUCA Manager. She will be holding the reins until we recruit a permanent UCUCA Manager.

The UCUCA Office will also be moving to a new location in mid-October. Our current office space is slated to be converted into animal rooms, and thus we will be moving to the 300 North Ingalls Building (300 NIB) on the 9th floor. Our new location will offer us much more office space, including a large laboratory room that we will use for hands-on training classes! Please note that although our office location will change, our campus mailing address (018 ARF 0614) will remain the same since the ULAM Office is staying where it is.

There may be some concerns as to whether these changes will affect the protocol review process or other areas of UCUCA business. Please be assured that it will be business as usual! The UCUCA Office and Committee will operate just as it is now, and there will be no increase in the length of time protocols will be reviewed and approved. We are committed to making this a smooth transition period for everyone. We will be posting new information on our website (http://www.ucuca.umich.edu) as it becomes available, and we will have more information in the next issue of The Backbone, due out by January. You are always welcome to give us a call (763-8028) or email us (ucuca.office@umich.edu) if you have any questions! 🚀

WHERE IN THE WORLD IS THE 300 NORTH INGALLS BUILDING?

“X” marks the spot!
HAPPY HOWL-O-WEEN!
**GOT FEEDBACK?**

Do you have questions, comments, corrections, or suggestions about *The Backbone*? Is there a topic you would like to see covered in a future issue? We want to hear from you! Email us at ucuca.office@umich.edu or call (734) 763-8028 and tell us about it!

**GET A BACKBONE!**

Readers wishing to receive future issues of *The Backbone* can be included on the mailing list by completing and returning the request form on the back page of the newsletter. Additional copies of *The Backbone* are also available from the UCUCA office, or you can download an issue from the web: www.ucuca.umich.edu/backbone.

**SNAIL MAIL**

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1301 Catherine St.
018 ARF
Ann Arbor, MI 48109-0614

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**BONE FRAGMENTS**

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**NEED HELP WITH YOUR ESIRIUS PASSWORD?**

If you forgot your eSirius password, or need to have it reset, please contact Julie Giordano by email (julesgi@umich.edu) or by phone (763-8028) and she will be happy to assist you!

**REMINDER: SPOT LABORATORY INSPECTIONS**

In accordance with the Public Health Service (PHS) Policy and AAALAC recommendations, the UCUCA will soon be coming to visit your laboratory space. We will be looking at areas in the lab where animals are used, reviewing records (controlled substances, surgical record forms), and reviewing protocol procedures. We are also available at this time, and always, to answer any questions you may have regarding your protocol, regulations, training, etc. Please feel free to contact the UCUCA Office with questions (3-8028, ucuca.office@umich.edu, or our website: www.ucuca.umich.edu).

**ANIMAL CONCERN HOTLINE**

Animal Concern Hotline Number:
(734) 763-8028

Animal Concern Online Submission Form:
http://www.ucuca.umich.edu/complaint.htm

**IF YOU SEE ANYTHING THAT TROUBLES YOU, PLEASE DO NOT HESITATE TO CALL OR SUBMIT AN ANONYMOUS REPORT ONLINE!**

**REMINDER: LAB PERSONNEL IN PROTOCOLS**

Do you have new personnel in your lab? Make sure to add them to your protocol if they will be using animals; EVEN IF THEY ARE TEMPORARY OR SUMMER PERSONNEL! Anyone who uses animals at any time under a UCUCA-approved protocol MUST be listed on that protocol.
Please complete and return to the University Committee on Use and Care of Animals (UCUCA):

Name ___________________________________ Department ______________________________
Telephone __________________________________ Fax ____________________________
Address ____________________________________________________________
Principal Investigator _________________________________________________
E-mail Address _______________________________________________________

Topics/areas of interest you would like to see explored in future issues:
____________________________________________________________________
____________________________________________________________________

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Editor:
Astrid Haakonstad