TOWN HALL MEETING

By Astrid Haakonstad
UCUCA Regulatory Compliance Associate

WHO: All principal investigators and laboratory staff members are encouraged to attend

WHAT: A “Town Hall” style presentation and dialogue with the UCUCA, UCUCA compliance staff, and ULAM veterinary staff. Refreshments will be served!

WHERE: Room M5330 Medical Science Building I

WHEN: Monday, May 18, 2009 at 3:00 PM

WHY: The UCUCA wishes to foster a collaborative relationship with the U-M research community and to provide guidance and assistance to investigators and laboratory staff members. This meeting is an opportunity to inform the research community of recent changes in UCUCA policies and guidelines, and to answer any questions or concerns you may have. By working together, UCUCA, ULAM and the research community will ensure that U-M maintains an animal use program that is fully compliant with all applicable standards and regulations.

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The Backbone is a quarterly publication of the University Committee on Use and Care of Animals (UCUCA)
POLICY & GUIDELINE UPDATES

ULAM GUIDELINES FOR ANIMAL MEDICAL RECORDS

By Megan Nowland, DVM
ULAM Resident Veterinarian

New guidelines have recently been released for the creation, storage and maintenance of animal medical records. The new guidelines can be found on the UCUCA website at http://www.ucuca.umich.edu/guidesurg.htm. Documents which are components of a medical record (defined in the guidelines) must now be maintained and stored in accordance with these guidelines.

A new concept to go along with these guidelines is that of a more-defined Health Contact. The Health Contact must be entered on the animal order form with accurate contact information. The information will in turn be printed on the cage cards for animals ordered through ULAM. This is the person that the veterinary staff will contact if a health problem is noticed with the animals and should have the decision-making authority for those animals in regard to medical treatment or euthanasia if necessary. This person is also responsible for upkeep of medical records for those animals.

For rats and mice (not covered by the Animal Welfare Act), record keeping is simple: for surgery and other procedures, the monitoring forms must be in the room with the animal for the duration of the post-procedural period (7-10 days, until sutures are removed, or the animal is euthanized). A sample form is located at the end of the ULAM document, Guidelines for the Performance of Surgery in Rodents. At the end of the post-procedural period, these documents can be filed by the laboratory staff if needed for research purposes or discarded if not.

For other rodents (such as hamsters, guinea pigs, etc.) records must be maintained in the room for the post-procedural period as described for rats and mice, but then must be stored for a minimum of six years (more detail regarding storage can be found in the guidelines). These records should be stored in a central place within the lab or housing area and be readily producible if requested by inspectors (UCUCA, USDA). Maintenance and storage of these records is the responsibility of the Health Contact for the animals.

All other mammals (rabbits, dogs, primates, etc.) must have any medical record components (as defined by the guidelines) submitted to ULAM. This does not include research records. If medical record components are created by lab personnel, they should be converted into PDF format and sent to ULAM-MedicalRecords@umich.edu for filing and storage. The Health Contact for these animals is responsible for this submission. When submitting documents, please be sure that the protocol number, Principal Investigator’s last name and the date are contained within the document as these are the parameters that will be used to organize records within ULAM.

Please contact the UCUCA office (763-8028 or email ucuca.office@umich.edu) for more information.

http://www.ucuca.umich.edu/backbone.htm
POLICY & GUIDELINE UPDATES

EXPERIMENTALLY INDUCED TUMOR MONITORING AND REPORTING

By Christine Alvarado, DVM
ULAM Resident Veterinarian/ Postdoctoral Fellow

The UCUCA Policy on Animal Procedure Records includes new standard operating procedures for experimentally induced tumor monitoring and reporting. A tumor monitoring sheet will be filled out by the PI (or designated laboratory member) for each protocol-specific end point. The monitoring sheet is to be kept in the animal room. In addition, each cage housing animals on protocols involving experimentally induced tumors will be identified by a yellow flag on the cage card. ULAM husbandry will also start reporting all animals with tumors that reach a specific size and any tumors which are ulcerated.

The new standard operating procedures are intended to assure compliance with protocol-specific endpoints, while helping investigators reduce the loss of data caused by unusual rate of tumor growth. The new guidelines are available on the UCUCA website at http://www.ucuca.umich.edu/guideproc. You can also contact the UCUCA office at 763-8028 or email ucuca.office@umich.edu for more information.

NEW/REVISED POLICIES AND GUIDELINES

The following policies and guidelines have been updated and are available for download from the UCUCA website (http://www.ucuca.umich.edu) or by clicking on the links below:

- UCUCA Policy on Animal Procedure Records (new)
- Guidelines for Animal Medical Records (new)
- Guidelines for the Performance of Surgery in Rodents (revised)
- Guidelines for the Performance of Surgery in Non-Rodent Mammals (revised)
- Experimentally Induced Tumor Monitoring and Reporting guidelines (new)
- Monitoring for Experimentally Induced Tumors presentation (new)
- UM Methods of Euthanasia by Species (revised)
- Guidelines for Monitoring Rats in Aging Studies (new)
- Sheep Quarantine & Conditioning (revised)
- Recommended Dose Volumes for Laboratory Animal Species by Route of Administration (revised)
- Plan for Environmental Enrichment of Nonhuman Primates (PEEP) (revised)
- ULAM Animal Containment Policies & Procedures plus appendices (see www.ucuca.umich.edu/osehhaz) (revised)

Please don’t hesitate to contact the UCUCA office at 763-8028 or ucuca.office@umich.edu if you have any questions about the updated policies and guidelines.
CONTROLLED SUBSTANCE LICENSING CHANGES AHEAD

By Patrick Lester, DVM
ULAM Faculty Veterinarian

The U. S. Drug Enforcement Agency (DEA) and the State of Michigan Bureau of Health Professions have informed the University of Michigan that changes are required in our compliance approach to controlled substance use in animal research so as to appropriately manage the risk of diversion and abuse.

To that end, the Office of the Vice President for Research (OVPR) and the Unit for Laboratory Animal Medicine (ULAM) will be implementing a transition plan to a new structure consisting of a central program coordinator assisting researchers and research units to organize and manage controlled substance licensing, registration, acquisition, distribution, laboratory storage, record keeping, transfer, and disposal. Guidance documents and related forms will be posted on the UCUCA website to assist in these matters (this information will soon be available under the “Controlled Substances” tab).

The main change required is to replace the current centralized method of controlled substance purchasing and distribution through ULAM with departmental level or individual state controlled substance research licenses and DEA researcher registrations. The regulations now require a separate DEA research registration and a State of Michigan research controlled substance license for each laboratory or principal place of business (i.e., laboratory building street address) where research controlled substances are received, stored, and administered. Controlled substance research licenses and research registrations are separate from clinical practitioner controlled substance licenses and registrations.

Departments will be contacted to determine whether to vest responsibilities in departmental registrations or to have research investigators obtain individual registrations. Departmental registrants will be fully responsible for all controlled substances used by all laboratories within their department as documented in their registration application.

ULAM will continue to supply controlled substances until licensing, registration, and other necessary program details are functional and complete. A target date of January 1, 2010 has been proposed. The controlled substance program coordinator and OVPR will provide more information to departments as specific details are developed and outlined.

http://www.ucuca.umich.edu/complaint.htm
EFFECTS OF NONCOMPLIANCE ON NIH-SPONSORED PROTOCOLS

By Astrid Haakonstad
UCUCA Regulatory Compliance Associate

As part of its mission to ensure the humane care and justified use of animals used in research and instruction at the University of Michigan, the UCUCA reviews concerns involving animal use and regulatory noncompliance at its convened meetings. Some instances of noncompliance may be considered serious or continuing, and therefore reportable, noncompliance. If this involves projects sponsored by National Institutes of Health (NIH) grants or contracts, the institution may be responsible for reversing some charges to the NIH institute or center that was used to fund the noncompliant activity.

According to the NIH Public Health Service (PHS) Policy, an institution cannot charge NIH grants or contracts for animal activities conducted under the following circumstances:

- The activity was never approved by the Committee
- The activity was conducted after the protocol’s expiration date
- The activity was conducted during a time when the activity or protocol was suspended by the Committee

When the UCUCA reviews animal concerns at its convened meetings and determines that an instance of noncompliance involving an NIH-funded study is serious or ongoing, the U-M is required to report the incident to the Office for Laboratory Animal Welfare (OLAW) and to the granting institute or center, and to ensure that NIH funds are not charged for any unapproved, expired, or suspended activities.

In cases of reportable noncompliance, the UCUCA will contact the investigator to find out what source of funds sponsored the activity. UCUCA also works with OVPR and DRDA to find out what contractual obligations are applicable. If NIH funds were charged, UCUCA will contact the PI and work with OVPR and the Office of Sponsored Projects to find alternate sources of funding in order to reverse unallowable charges against NIH awards.

For more information, see the FAQ page for the PHS Policy: http://grants.nih.gov/grants/olaw/faqs.htm.

NEED HELP WITH YOUR PROTOCOL? YOUR REGULATORY COMPLIANCE ASSOCIATE IS HERE FOR YOU!

All of the principal investigators (PIs) are alphabetized by their last names, and each compliance associate is responsible for a section of the alphabet. Here are your regulatory compliance associates, by PI last name:

A-F: Astrid Haakonstad (764-6850)  M-R: Sara Waugh (764-9122)
G-L: Marie Cornell (764-2187)  S-Z: Matt Taylor (615-8791)

For help with facility-related issues, contact Dawn O’Connor (936-9329).
MEET THE UCUCA OFFICE STAFF

By Astrid Haakonstad
UCUCA Compliance Associate

The UCUCA is supported by a talented and hard-working group of administrative professionals, which includes the compliance staff and the office support staff. The UCUCA office staff provides administrative support to the Committee as well as assistance to investigators and laboratory members regarding their animal use protocols.

The UCUCA Manager, Jessica Durkin, is the principal administrator for the Committee and the manager of the entire UCUCA office staff (compliance and administrative). She is also the liaison between the University and regulatory bodies such as OLAW and USDA. Julie Laundree is the manager for the administrative office staff. Along with responsibilities such as organizing Committee functions and reports, she assists investigators with eSirius access and training, and corrections or queries regarding animal use category deductions and negative balances.

In the October 2008 issue of The Backbone, you were introduced to the UCUCA compliance staff: Dawn O’Connor, Astrid Haakonstad, Marie Cornell, Sara Waugh, and Matt Taylor. The following are mini-biographies of the administrative staff!

CLAIRE WHITTAKE-SMITH

After receiving a degree in hotel management in South Africa, were I was born and raised, I decided to expand my horizons and moved to London, England. During my time in London I worked for an internet start-up company and eventually moved into property management & acquisitions.

After marrying, I moved to the US and joined the University of Michigan. I first started in business finance and then moved to the UCUCA office where my organizational skills are put to good use everyday.

HAZEL SCHROEN

Since I love people, I am very happy to be the front desk and main telephone receptionist. Much of my work involves personnel and their moves onto or off of protocols and all of the responsibilities for each person, ULAM, the Training Core, UCUCA and OSEH surrounding these changes.

My interests outside of work include my wonderful family and pets, pottery, knitting, cooking and walking.

KAREN REVILL

Before coming to the University of Michigan in 2000, I taught early elementary school and preschool. When I first started at the University of Michigan I worked with medical students for seven years and then from there I worked in a Clinical Scholar Program before starting in the UCUCA office.

I love working with people and enjoy spending time with my husband and two children. I also look forward to pursuing a Master’s Degree in either Social Work or Educational Leadership.
NEED HELP WITH YOUR ESIRIUS PASSWORD?

If you forgot your eSirius password, or need to have it reset, please contact Julie Laundree by email (julesgi@umich.edu) or by phone (936-9328) and she will be happy to assist you!

REMINDER: CHECK YOUR CAGE CARDS!

Before working with any animal, please ensure that you have the right cage and the right animal by checking the cage card and/or tag on that animal. Make sure that the principal investigator and protocol number are both correct, and also ensure that the expiration date is still current. This will ensure that you do not use another investigator’s animals by mistake, and that your protocol remains in compliance. If you see a cage card that looks like it has incorrect information, or a cage that is mislabeled, please notify your husbandry supervisor as soon as possible, or if you have questions you can also contact the UCUCA office at 763-8028 or ucuca.office@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.
IF YOU WISH TO BE REMOVED FROM THE BACKBONE EMAIL LIST, PLEASE CONTACT ucuca.office@umich.edu

Download This Issue

http://www.ucuca.umich.edu/backbone.htm