THE NINE USE CATEGORIES: WHAT DO THEY ALL MEAN?

By Matt Taylor  
UCUCA Regulatory Compliance Associate

When filling out an animal use protocol, the investigator must place their animals into a pain category relevant to the procedures they are performing. The UCUCA has elaborated on the use categories (UC) and have separated them into 9 different sections. Category 1 is for those animals undergoing no manipulations, and category 9 is for painful or distressful experiments that do not include anesthetics or analgesics because of the effects these drugs can have on the experimental outcomes. What you can interpret from the table found in the eSirius animal use application on page 11.E.16 is the category number, a description of what defines placement in that category, and then examples of what procedures would fall into that category. Of course there are too many procedures to name, but all animals must be accounted for in one of the UCs when filling out a protocol. If you are still not sure of which category to use, please feel free to contact your UCUCA compliance associate for assistance. Below you will find answers to some of the most common questions we receive in the UCUCA Office in regards to UCs:

I breed animals for my protocol and do tail biopsies for genetic testing...which category would they fall into?  
Since the animals experience minimal pain, they would be placed into category 2. However, if tail biopsies are performed on animals over 21 days of age, this means they need to be anesthetized, and therefore would be placed into category 3.

I'm performing a thoracotomy and the animal never recovers from anesthesia. This would be category 3, right?  
No. Animals that go through a major non-recovery procedure, with anesthesia, would require category 4. This means that the procedures that are being performed are painful, but the animal is under anesthesia and is not allowed to recover.  

Continued on next page...
THE NINE USE CATEGORIES
EXPLAINED

...Use Categories, continued from previous page

I know that the UCUCA Policy on Analgesic Use in Animals Undergoing Surgery was updated recently. How does that affect which category my animals are in?

Surgery types are separated into three different categories depending on level of invasiveness and tissue/bone manipulation. Type I surgical procedures are performed with appropriate anesthesia and do not require the use of additional analgesics. Type II surgical procedures require the use of pre-emptive analgesics. Type III surgical procedures require the use of analgesics pre-emptively, for a minimum of 24 hours post-operatively for mice and rats (48 hours for all other species), and then as needed for pain. Any recovery surgical procedure would place the animals in category 3 or 6 assuming the use of analgesics. If analgesics cannot or will not be given in accordance with the policy, this will automatically place animals into category 7, 8, or 9 regardless of the scientific justification.

I’m afraid that if I place my animals into a higher use category (7, 8, or 9) that my protocol will not get approved... is that true?

Not at all! Animals can be used in the higher categories as long as scientific justification is provided. An investigator should not be afraid of asking for approval. The review process is not designed to hinder research, but to make procedures and experiments compliant with all applicable policies, guidelines, and laws. We want to help you design your protocol in order to benefit the outcomes of your experiments without compromising the welfare of the animals.

UC 9: Painful or distressful experiments for which anesthetics, analgesics, tranquilizers are purposefully withheld because their use would adversely affect the experimental results. Examples: Trauma or burn on unanesthetized animals.

UC 8: Procedures conducted require the animals to feel pain in order to fulfill the aims of the study. Examples: Noxious stimuli, death as an endpoint, inflammation.

UC 7: Procedures that cause distress, however no method is available which would alleviate these effects without interfering with the experimental results. Examples: Prolonged/chronic restraint, stress experiments, paralysis, prolonged food/water restriction.

UC 6: Procedures that cause pain and/or distress, however anesthetics, analgesics, or tranquilizers are used to alleviate these effects. Examples: Major recovery surgical procedures (thoracotomy, craniotomy, laparotomy).

UC 5: Procedures that cause pain and/or distress which is alleviated by euthanasia. Examples: Debilitating tumor growth, toxicity tests, ascites production (Note: Animals are not permitted to spontaneously die, but will be sacrificed when showing signs or morbidity).

UC 4: Procedures that cause pain and/or distress, however anesthesia is used and animals are not allowed to recover. Examples: Major surgical non-recovery procedures (organ/tissue removal, thoracotomy, perfusion under anesthesia, etc.).

UC 3: Procedures that cause some minor pain and/or distress but anesthetics and/or analgesics are used to alleviate these effects. Examples: Tail biopsy requiring anesthesia, implantation of peripheral catheters, subcutaneous implants, intracardiac injections.

UC 2: Procedures that cause only slight or no pain or distress. Examples: Injections, breeding, tail biopsy (before 21 days of age in mice), non-debilitating tumor growth, anesthesia for chemical restraint, oral gavage, decapitation.

UC 1: No manipulations or procedures conducted on the animals. Examples: Observation without euthanasia at the end of the study.
REGULATORY COMPLIANCE
NEWS & NOTES

POST-APPROVAL MONITORING

By Sara Waugh
UCUCA Regulatory Compliance Associate

The monitoring of protocols that have been approved by the UCUCA is an important facet of the University of Michigan’s program for the care and use of animals. In 2003, the UCUCA office staff employed a post-approval monitoring program as a way to cultivate a collaborative relationship between UCUCA and the research community and to further ensure compliance with regulations, policies, and standards. Post-approval monitoring (PAM) visits are now being conducted on an annual basis with every investigator whom has an active animal use protocol. Your designated UCUCA compliance associate is responsible for scheduling and conducting PAM visits.

The visit entails a general review of the written protocol and discussion of the actual activities occurring to determine regulatory and policy compliance. Protocol-related documents and records such as surgical records, training records, and controlled substance logs, may also be assessed. These meetings are informal and serve as an educational opportunity for researchers to ask questions regarding their responsibilities in conducting research with animals. Post-approval monitoring is intended to be facilitative, with an emphasis on education rather than investigation, while helping the investigator to prevent noncompliance to the greatest degree possible and to remain consistent with regulatory and institutional reporting and enforcement requirements.

VAPORIZER MAINTENANCE

By Marie Cornell
UCUCA Regulatory Compliance Associate

Keeping your anesthetic vaporizer and anesthesia system properly maintained is very important. Upon our most recent AAALAC, Intl. site visit there were several incidences of vaporizers in use that had not been currently certified. As a result of these findings the UCUCA office has started to closely monitor vaporizer maintenance.

If you have not already provided the location of your anesthetic machine and the date your vaporizer and anesthetic circuit were last serviced to the UCUCA office, you may do so by emailing Marie Cornell at mhaeussl@med.umich.edu.

In addition the ULAM Training Core offers several classes on the use of anesthetics and vaporizers in research. Please email ULAM-Trainingcore@med.umich.edu for more information.

Here are some tips to help keep your vaporizers up to date:
 ✓ Vaporizers must be serviced yearly unless otherwise stated in the manufacturer’s guidelines.
 ✓ ULAM offers a maintenance service every June and December. (email alss@umich.edu for more information.)
 ✓ Anesthetic vaporizer and anesthesia circuit must be clearly labeled with most current date of service.
 ✓ Any vaporizer found to be in use while not properly maintained will be identified and reported to OSEH.
NEW FACULTY & STAFF
MEET DR. INGRID BERGIN

By Linda Stegmeyer
ULAM Administrative Specialist

For some of us, there are inklings of our future career path even at an early age. This was certainly true for Ingrid Bergin, who recently joined the ULAM faculty as a veterinary pathologist. From her first pet, a spider she kept in a bug house for a year, her curiosity grew to include other animals and a keen fascination with the diversity and variety they represent. Today, her career as a veterinary pathologist in the field of biomedical science is predicated on the assumption that different species are variations on a theme: whether at the anatomic, microscopic, or molecular level. By this understanding, the study of disease manifestations in one species can lead to insights about disease in other species. Veterinary pathologists like Dr. Bergin are uniquely situated to apply their broad comparative biology background to the study of animal models in human disease.

It’s interesting to consider that Dr. Bergin didn’t always know pathology was a career option. Ingrid received her V.M.D. from the University of Pennsylvania in 1998 and her M.S. in toxicology from the Massachusetts Institute of Technology in 2002. While at MIT, Ingrid got her first real experience with laboratory animal science. It was working with laboratory animals that initially led her to think about comparative pathology. For this reason, she chose to undergo further training as a veterinary pathology resident at the College of Veterinary Medicine at Michigan State University from 2005 to 2008 and became board certified in veterinary pathology in 2008. Additionally, Dr. Bergin is also board certified in laboratory animal medicine. Veterinary specialty board certification requires passing rigorous certification exams and is a relatively rare achievement—there are only approximately 1,450 boarded veterinary pathologists and 525 boarded laboratory animal veterinarians. Both laboratory animal veterinarians and veterinary pathologists are now in urgent demand across the country, particularly because of an almost universal explosion of genetically-engineered mouse populations reared for the study of human disease. Genetically-engineered mice can have unexpected pathological findings, and individuals knowledgeable in both mouse biology and human disease are a much needed asset to researchers in determining whether these findings are significant.

The University of Michigan is among those institutions fortunate enough to have veterinary pathologists on staff who can provide assistance to researchers using animal models. Dr. Bergin joins ULAM veterinary pathologists Dr. Erby Wilkinson, who has over 20 years experience in the evaluation of mouse models, and Dr. Kate Eaton, who has research interests in bacterial gastrointestinal pathogens and has a joint appointment in the Department of Microbiology and Immunology. Together, this core group of pathologists can provide pathology support to University investigators or direct them to additional resources.

Outside of work, Ingrid the pathologist can relax when Ingrid the mom takes over. Together with husband, Edwin, she is raising two daughters, 6-year-old Lia and 5-month-old Elena. They all share a house with Lacey, a Basset/Labrador mix (her “Bassador”), and a blue-crowned Conure parrot named Sydney.

Dr. Bergin began her work with ULAM on December 1, 2008 with several roles: diagnostic (necropsy) service, teaching the unit’s veterinary laboratory animal residents, and research pathology. She is excited to be part of a strong laboratory animal program in a university setting and is looking forward to becoming a contributing member of the university family.
POLICIES & GUIDELINES

DISPOSITION RECORDS: WHICH SPECIES REQUIRE THEM?

By Dawn O’Connor
UCUCA Senior Regulatory Compliance Associate

According to the regulations of the Animal Welfare Act, research facilities must maintain records regarding the transportation, sale, euthanasia, or other disposition of dogs and cats in the possession of the facility. At the University of Michigan, these records are the responsibility of the principal investigator and must include:

☑ USDA identification number
☑ Description of animal (species, breed, markings, sex, age)
☑ Date and manner of disposition (donation, euthanasia, transfer, etc.)

These records must be maintained for three years and must be readily available for review during federal inspections. Principal investigators leaving the university must forward their records to the UCUCA office for retention during the remainder of their protocol’s three-year UCUCA approval period. Disposition records can be found at the following address: www.ucuca.umich.edu/forms/Disposition_Dogs_Cats.doc.

UPDATED POLICIES AND GUIDELINES

Note: The following policies and guidelines have been updated and are available for download from the UCUCA website (www.ucuca.umich.edu).

☑ Recommended Dose Volumes for Laboratory Animal Species by Route of Administration (new document)
☑ Quarantine & conditioning guidelines for sheep, swine, and non-human primates
☑ UCUCA Policy on the Use of Expired Medical Materials and Non-Pharmaceutical Grade Compounds
☑ UM Program for Reviewing the Housing of Different Species In the Same Room.
☑ UM Program for UCUCA Review of Exceptions to Regulations, Policies, and Nationally Accepted Standards

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.

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)
THE FUNNY BONE

PLAY THE USE CATEGORY MATCH-UP GAME!

By Dawn O’Connor and Astrid Haakonstad

How well do you know the nine use categories (UC)? Put your knowledge to the test by matching up the procedures on the left with the categories on the right. Then, check the answer key below to see how well you did!

A: A mouse is anesthetized, then the chest is opened and organs are perfused. The animal is euthanized as a result.

B: A small defect is created in the tibia of a mouse in order to insert a pin and create a fracture to study bone healing.

C: Birds are observed in the wild without capture.

D: A rat is placed in a standard tube restraint device for over 30 minutes.

E: Mice in a cancer study grow large tumors, but are euthanized before becoming moribund.

F: Chimpanzees in a wildlife park are observed and given primate chow.

G: Rats in a study involving opiate drugs cannot be given analgesia for survival surgery because use of analgesics will negate the results of the study.

H: Mice in a cancer study grow large tumors and must be followed until death in order to study the progression of the disease.

I: Tail biopsies are being performed on mice to determine genotype, but the mice are over 21 days of age and therefore they must be anesthetized.

UC 9: Painful or distressful experiments for which anesthetics, analgesics, tranquilizers are purposefully withheld because their use would adversely affect the experimental results.

UC 8: Procedures conducted require the animals to feel pain in order to fulfill the aims of the study.

UC 7: Procedures that cause distress, however no method is available which would alleviate these effects without interfering with the experimental results.

UC 6: Procedures that cause pain and/or distress, however anesthetics, analgesics, or tranquilizers are used to alleviate these effects.

UC 5: Procedures that cause pain and/or distress which is alleviated by euthanasia.

UC 4: Procedures that cause pain and/or distress, however anesthesia is used and animals are not allowed to recover.

UC 3: Procedures that cause some minor pain and/or distress but anesthetics and/or analgesics are used to alleviate these effects.

UC 2: Procedures that cause only slight or no pain or distress.

UC 1: No manipulations or procedures conducted on the animals.

Answers: A-4, B-6, C-1, D-7, E-5, F-2, G-9, H-8, I-3
BONE FRAGMENTS

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.

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
University of Michigan
UCUCA
1301 Catherine St.
018 ARF
Ann Arbor, MI 48109-5614

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

University of Michigan
University Committee on Use and Care of Animals (UCUCA)
018 ARF SPC 5614
763-8028 (Telephone)  936-3234 (FAX)
ucuca.office@umich.edu (e-mail)

Add my name to your mailing list.
Remove my name from your mailing list.

THIS IS THE LAST PRINTED ISSUE OF THE BACKBONE!
FUTURE ISSUES WILL BE SENT BY EMAIL AND AVAILABLE FOR DOWNLOAD FROM HTTP://WWW.UCUCA.UMICH.EDU/BACKBONE.HTM