



ANIMAL TRACKS



A newsletter for the Duke research community

August 2007

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

New Protocol Template Approved by the IACUC

At the July 27 IACUC meeting, the Committee approved a new Duke animal program protocol template. This new template must be used for all new animal use applications submitted after (_____). Until that date, animal use applications may be submitted on either the current form or the new template.

During the next few months, the OAWA is providing a number of training sessions through the 'Brown Bag Seminar Series.' These sessions focus on helpful hints in completing the new template. For project specific help, you can contact the Office of Animal Welfare Assurance (668-6720) for additional assistance.

The new template addresses a number of problems with the present process. For example, presently every protocol must contain all pages of the template, even if all pages are not necessary for the desired use. The new template will consist of Part I (administrative information and regulatory required questions) and those sections of Part II (procedure specific sections) that are applicable to your study. The old template required a signature, where as the new protocol may be signed or may be emailed from the PI's Duke Email account. The old protocol asked open-ended generic (and sometimes confusing) questions, the new template uses check boxes and menu options extensively and only requires narrative when necessary to describe or define the proposed activity. Using the Adobe form version (it is also available in hard copy or Microsoft Word), users will find that the new template can be expanded to meet the needs of the individual project, and most of the template can be completed by checking the appropriate box. To access a copy of the new protocol template, visit the animal program web site, click the link for 'FORMS' and select the protocol form.

The process for amendments and facility housing approvals will remain the same (those template were updated just last year).

Any new process has an associated learning curve, please contact the OAWA / IACUC with any problems you encounter in using the new temple.

Wishing you a productive research month,

New Web Training Opportunity for Animal Care and Use Community

The Duke Foundation has provided funds to establish a group enrollment for the Duke animal care & use program to the AALAS Learning Library web training modules! This web training resource is open to all PI's with animal protocols, research associates, part time lab members, visiting staff (e.g. researchers or students). The only requirement to participate in the web training resource is to be listed on a Duke animal care and use protocol.

The AALAS Learning Library provides training that is essential for investigators, laboratory managers, research associates, animal technicians and others working with animals in a research or education setting. The Learning Library emphasizes the appropriate handling, care, and use of animals and is designed to provide another avenue to obtain important training and improve skills of those working in the animal research arena.

(CONTINUED ON PAGE 3 SEE 'NEW WEB TRAINING')

Are You Tired of Having Your
 Protocol Held Up Because
 Someone Has Not Completed
 Their Required Training?

Did you know that PIs can check people listed on your protocol (or prospective protocol / amendment) and their training status **on-line prior to submitting the protocol (or amendment) for IACUC review?** Call Cackie Joyner at 684-2794 or email at joyne004@mc.duke.edu to set up access rights to review your protocol personnel status.

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Tips For A Smooth Hazardous Drug/Chemical Safety Review by OESO

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Occupational Hygiene and Safety Division
Occupational and Environmental Safety Office

A required component of using animals at Duke is 'clearance' of the animal protocol (or amendment) by Duke's Occupational and Environmental Safety Office (OESO). When OESO staff members review animal protocols for chemical safety and hazardous waste, we are interested in employee and environmental safety during all aspects of chemical use during the research, not just the steps involving live animals. **To speed the chemical safety/hazardous waste review process, please describe employee safety precautions and waste handling methods for any particularly hazardous chemicals used during the research, including steps that don't involve the animals.** Additionally, please describe the quantities used and frequency for each step. Here are some tips:

- Any particularly hazardous substances (PHS) that you plan to use **MUST** be identified to OESO. For 'live animal' PHS use, list the 'live animal' related hazardous agents in the Hazardous Agents section of the animal protocol. For PHS use not involving 'live animals' but necessary for the performance of the animal activity (e.g. formalin, other fixatives, etc.), a brief supplemental narrative to the protocol, or listing the agents in the animal protocol may be used. In either case, a description of safety practices for working with the PHSs must be included. **This description should include employee safety measures for all uses of these chemicals – including preparation, especially if you purchase the substance in powder form (see the box at the end of this article for more recommendations on handling powdered PHS), spill clean-up, and waste disposal.**

- The most common chemicals omitted in animal protocols (and will delay clearance of the protocol) are paraformaldehyde and formalin, both of which emit formaldehyde, a PHS. (For many uses of these materials in labs, the online formaldehyde training is also required.)
- Certain drugs used in research are particularly hazardous substances.
- A full list of PHSs by CAS number can be found at http://www.safety.duke.edu/LabSafety/Docs/PHS_by_CAS.pdf.
- If you are exposing animals to PHSs (including chemotherapeutic and other hazardous drugs), we will also be interested in minimizing chemical exposure to animal handling staff working with the animals or their bedding in the 48 hours after the animals have been exposed.

NEXT COLUMN ... THIS PAGE

For additional information, see the SOP for the use of Toxic Chemicals in Animals at <http://www.safety.duke.edu/LabSafety/Animals.asp>.

As you are describing personal protective equipment, please be aware of the dual meaning of the word "mask", which is used to refer to surgical masks and some types of respirators. Use of respirators (including N-95s and other filtering facepieces) requires time-consuming compliance with the OSHA respiratory protection standard. If you are planning to use surgical masks, please be specific – otherwise, we may email you for clarification. Hazardous chemical waste, including unused chemotherapy drugs or materials used to absorb a spill, should be collected by OESO. If you have specific chemical waste questions, or to register with OESO as a waste generator, please call 684-2794.

Please fill out the hazardous agents section of the protocol for all hazardous agents. If the dosing and administration information does not apply, just leave these boxes blank or type "N/A". If you have questions, you may contact Courtney Stanion at 684-5709 or Courtney.Stanion@duke.edu.

Recommendations for safe handling of powdered PHSs and other sensitizing or highly irritating powders

Consider purchasing the material in liquid form so that you avoid handling powder altogether.

- OR -

Purchase in pre-weighed amounts, preferably in a sealed vial with a septum so that diluent can be injected directly into vial.

- OR -

Use a balance located inside a fume hood or biological safety cabinet (BSC).

- OR -

- If your balance cannot be located in a fume hood or BSC:
 - Tare an empty container with a lid.
 - Go to the fume hood or BSC, add an approximate amount of powder to the container and close the lid.
 - Return to the balance and determine the mass of powder.
 - Calculate the necessary amount of liquid to produce the desired concentration.Return to the fume hood or BSC to mix solution.

New BMBL Edition

Courses and Libraries: The AALAS Learning Library has two 'Libraries' that may be used:

The Animal Care and Use Library: This library will be of principal interest to most members of our research community. Web courses in this Library include:

- ⇒ Introduction to Mice (or Rats, or Guinea Pigs)
- ⇒ Introduction to Rabbits
- ⇒ Introduction to Hamsters / Gerbils
- ⇒ Introduction to Swine
- ⇒ Introduction to Nonhuman Primates
- ⇒ Introduction to Amphibians
- ⇒ Working with the Laboratory Mouse
- ⇒ Mouse Breeding Colony Management
- ⇒ Genetically Engineered Mice
- ⇒ Aseptic Technique for Rodent Survival Surgery
- ⇒ Maintaining Animal Procedure Areas
- ⇒ Pain Recognition and Alleviation in Laboratory Animals
- ⇒ Inhalation Anesthesia Systems for Rodents
- ⇒ Post-Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress
- ⇒ Syringes and Needles
- ⇒ Selection of Cage Cleaning Products - Chemistry Driven
- ⇒ Nutrition
- ⇒ Biosafety in Microbiologic and Biomedical Laboratories
- ⇒ and many others ...

Certain of these modules (e.g. Intro to ...) would be most beneficial to new hires or visiting students, while other modules (e.g. pain recognition or aseptic technique would be of greater value to active research associates. All modules are available to all Duke animal program participants.

The **JAALAS CEU Test Library** offers the opportunity to earn continuing education units (CEUs) by taking the self-administered test based on the scientific articles in *Contemporary Topics* online. These tests are published six times a year. The online test questions are the same as the questions published in each issue of the hardcopy version of *Contemporary Topics*. New questions will be posted online after each issue has been printed and mailed to subscribers. The Test Library for each issue will remain available for two months, after which the questions for the next issue will be posted. Answers to the previous issue's questions are also posted.

While enrollment to you and your laboratory staff is free (thanks to the Duke Foundation), you need a username and password. Send an Email to: IACUC@DUKE.EDU. On the SUBJECT LINE, say: "ACCESS TO DUKE / AALAS LEARNING LIBRARY." In the body of the message, list: FIRST NAME; LAST NAME; DUKE NET ID for the individuals in your laboratory who would like access to the Learning Library web modules.

In February 2007, the US Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health published the 5th edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The BMBL provides guidelines applicable to both *in vitro* and *in vivo* work with human and zoonotic pathogens.

The BMBL includes 'agent summary statements' that describe the appropriate biosafety levels for working with various microorganisms, as well as recommendations for proper handling, safety equipment, and facility safeguards that should be in place when conducting research on particular agents. Agent summary statements are included for microorganisms based on the criteria:

- ⇒ "the agent is a proven hazard to laboratory personnel working with infectious materials;
- ⇒ "the agent has a high potential for causing [laboratory-associated infections] even though no documented cases exist;
- ⇒ "the agent causes grave disease or presents a significant public health hazard¹."

Updates since the last edition include the addition of new or updated agent summary statements for those agents now classified as 'Select Agents', including an updated Agent Summary Statement for influenza viruses, and a new chapter on biosecurity, defined as "the discipline addressing the security of microbiological agents and toxins and the threats posed to human and animal health, the environment, and the economy by deliberate misuse or release¹."

1. DHHS, CDC & NIH. *Biosafety in Microbiological and Biomedical Laboratories*, 5th edn. (US Government Printing Office, Washington, DC, 2007). <http://www.cdc.gov/OD/OHS/biosafety/bmb15/bmb15toc.htm>.

Upcoming Dates & Deadlines

August 2	Significant Change (SC) Deadline
August 6	New Protocol & SC Deadline
August 16	IACUC SC Meeting
August 17	Brown Bag Seminar: New Protocol Hints
August 23	IACUC Full Committee Meeting
August 27	Significant Change (SC) Deadline
September 6	IACUC SC Meeting
September 10	New Protocol & SC Deadline
September 20	Brown Bag Seminar: New Protocol Hints
September 27	IACUC Full Committee Meeting

Deadlines are 5 PM on the date listed! No exceptions!

RODENT SURVIVAL SURGERY

Post-operative infections in rodents can and do occur. Such infections, which may not be apparent on casual observation, may cause distress to the animals and may affect the results of the study. Duke's institutional position is that aseptic surgical conditions and procedures must always be used in animal surgeries, regardless of species. These conditions and procedures are somewhat species specific. For example, aseptic conditions for rodent surgery does not necessarily mean a complete surgical gown and mask in a dedicated surgical operatory — the use of a dedicated space with a surgical mask, a lab coat, sterile gloves, and sterile instruments is sufficient. Skin disinfection with a detergent in aquatic species is prohibited because of the injurious nature of this disinfectants to aquatic species. The specific design of the aseptic environment is tailored to the risks associated with that species under consideration.

Since the majority of the surgery at Duke centers on rodents, let's look at the requirements for aseptic rodent surgery.

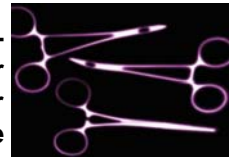
The minimum standards for aseptic procedures in rodents done in investigator laboratories are:

- **A clean uncluttered work area, away from break areas and out of the human traffic flow.** The space for the pre-procedure (patient prep activities), the surgical procedure, and post-procedure recovery can be the same or proximate area. The *preferred* option is to have a surgical area separate from the pre-procedure and post-procedure areas.
- **A disinfected work surface.** Use Clidox, Chlorhexidene, Clorox, quaternary ammonia, or hydrogen peroxide as a surface wipe down prior to placing the animal on the work area. *Alcohol, as a sole surface disinfection, is not acceptable!*
- **Use only in-date anesthetics and analgesics.** If volatile (inhaled) anesthetics are being used, an appropriate scavenging system must be in use.
- **Monitoring the depth of the patient's anesthesia must be part of the process.** Remember, the palpebral reflex is not consistent in rodents and should not be a primary means of assessing depth of anesthesia. Use the pedal reflex instead.
- **Supplement anesthetic, as necessary, to maintain anesthesia.** Remember, if using Ketamine and Xylazine as your anesthetic regimen, you do not supplement with Xylazine as this drug has a long metabolism and additional supplementation will likely delay recovery or could kill the animal. If using Ketamine/Xylazine anesthesia, supplement only with Ketamine.



should occur at 25—50% of the original dose.

- **Appropriate preparation of the surgical site** including removal of the hair and disinfection of the skin. The 'standard of care' for the Duke animal care program includes the use of an iodine (or chlorhexidine) skin scrub followed by an alcohol rinse a total of three times (scrub-rinse-scrub-rinse-scrub-rinse).
- **Draping the surgical site with sterile toweling avoids contamination of the incision,** instruments, and supplies. In case where it is not reasonable to drape the patient, then use sterile toweling to rest surgical instruments between uses.
- **Rinse the surgeon's gloves with a sterilant between rodents** (if appropriate precautions are taken to minimize contamination of surgical gloves). If surgical gloves become contaminated by handling non-sterilized items, they must be replaced with sterile gloves.
- **A surgical mask should be worn by the surgeon and any assistants working in the immediate surgical field.** Additional personal protection equipment (PPE) may also be used if people working in the area are allergic rodents.
- **A hair cover (surgical cap) should be worn by the surgeon to prevent loose hair from falling into the open wound.**
- **Heat supplementation (for the animal) for procedures lasting more than 15 minutes is usually required.** Do not lay the animal directly on any heating blanket, especially an electric one, but place 2 or more layers of toweling over the heating pad, and then place the animal on the toweling. This prevents severe burns that can occur with heating devices. *Delta Phase heating pads or warm saline bags also work, and are the preferred option to electric heating pads.*
- **The use of sterile instruments, sterile supplies (for internal use), and proper wound closure materials are required** (See below for proper methods of sterilization).
- **Post procedural recovery should include a quiet location, that is warm (may use heating pad or lamp), and where the animal can be readily observed by the technician (in case of distress during recovery).** This location may or may not be the surgery area.
- **Analgesic (pain control) should always be provided, a scientific exemption from pain control has been IACUC approved.** The level of analgesia is based upon the degree of invasiveness of the procedure. Always follow the protocol.



CONTINUED ON PAGE 5 ... SEE RODENT SURGERY

For all anesthetics, intra-operative supplementation

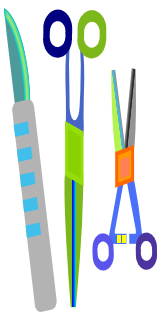
Controlled Substances: For procedures involving the use of controlled substances (e.g. Ketamine, pentobarbital, are examples of controlled substances), maintain proper control and administrative record keeping by recording the date, time, animal identification, dose, resulting balance, and a signature of the individual administering the dose. Maintain the drug in a locked storage drawer, cabinet, or safe.

Multiple Patient Surgeries in Rodents: Surgical procedures may be performed on multiple rodents during a single session using one sterile surgical pack, providing care is taken to minimize contamination and re-sterilization of the instrument tips between animals (as long as you do not touch the tips). The tip is the part of the instrument that actually touches the tissue / organ, therefore, for rodent surgery, the tip **MUST** be sterile, the rest of the instrument **MUST** be clean. Your 'sterile' gloves may be used for multiple animals, if you use a sterilant on the gloves between animals.

Methods to sterilize the instruments (tips) are:

◆ **Initial Instrument Preparation:**

- Autoclave instruments using appropriate wrapping material and heat sensitive tape / indicator, or
- Wash the instrument with standard kitchen detergent and dry with a clean cloth. 'Flame' instrument tips with 95% alcohol or heat the instrument tips in a glass bead sterilizers (approximately 15 seconds) and then cool the instrument tip using sterile saline or sterile air for 30 – 45 seconds before use. Store with tips sterile until use.
- Soak instruments in a 'cold' sterilant:
 - Benz-all (single use size): Mix one bottle in one gallon of water. Soak for a minimum of 5 minutes before use.
 - Amerse: Mix 1 ounce per gallon of water. Soak for a minimum of 5 minutes before use. Be sure and rinse with sterile saline prior to use.
 - Cidex: Active ingredient: 2% Glutaraldehyde. The manufacturer's instructions indicate that a minimum of 10 hours is required for sterilization. Cidex comes in two formulations, Cidex and Cidex-7 (long-life). The shelf life of activated Cidex is 15 days and of activated Cidex-7 is 28 days.
 - Clidox: Active ingredient: Chlorine dioxide. 1:5 mixture must be mixed daily. 1:18 mixture is good for 14 days. 1:5 is a good sterilant; 1:18 is a disinfectant. Be sure and rinse with sterile saline prior to use.



- Alcide: Active ingredient: Sodium hypochlorite 1.37%. The manufacturer's instructions indicate that a minimum of 6 hours is required for sterilization. The shelf life of the activated solution is 14 days. Be sure and rinse with sterile saline prior to use.

Soaking instruments in alcohol IS NOT APPROVED! Alcohol is not a high level sterilant!

- ◆ **Between Animal Re-Sterilization of instruments:** Surgical procedures may be performed on multiple rodents during a single session using one sterile surgical pack, providing care is taken to minimize contamination and re-sterilization of the instrument tips between animals. The methods to accomplish this include:
 - 'Flame' instrument tips with 95% alcohol or heat the instrument tips in a glass bead sterilizers (approximately 15 seconds) and then cool the instrument tip using sterile saline or sterile air for 30 – 45 seconds before use. Store with tips sterile until use.
 - Benz-all: Soak for a minimum of 5 minutes between uses. Be sure and rinse with sterile saline prior to use. Be sure and rinse with sterile saline prior to use.
 - Amerse: Soak for a minimum of 5 minutes between uses. Be sure and rinse with sterile saline prior to use
 - Cidex: Soak for a minimum of 5 minutes between uses. Be sure and rinse with sterile saline prior to use.



OAWA's Brown Bag Seminar

Friday, August 17th, 2007

Noon – 1 p.m.

Bryan Research Building: Room 103



Dr. Ron Banks
Director of the Office of Animal Welfare
Assurance will be presenting:

The New Duke IACUC Protocol Template: The “How To’s” for the new system

The Duke IACUC has been working for over a year to develop a new animal use protocol template. The new template has several goals:

1. To develop a ‘back-bone’ document for the soon-to-be-coming web-submission for animal use applications;
2. To have a protocol that asks the questions necessary for the IACUC to make an informed decision;
3. To have a protocol that is easier for researchers to follow;
4. To decrease the number of clarification questions required; and
5. To allow reviewers to be able to review efficiently and completely.

At this seminar, the Office of Animal Welfare Assurance will give a preview of the animal use protocol template and discuss how to use it. The protocol template has a core document that will be completed with each new protocol submission, and then additional sections will be completed and submitted as they apply to the proposed research plan and procedures. We will discuss:

1. General overview of the purpose of a protocol template;
2. General overview of the Duke IACUC’s actions in developing the new template; and
3. General overview of the structure of the new template and the concept of how it will work, by Part and Section.

Hard copies of the template core will be available at the seminar with a web-link for the various appendices for specific sections of the protocol. Dr. Banks will briefly touch on each of the appendices of the template. P.I.s, laboratory managers, and research associates are strongly encouraged to attend to minimize speed bumps during the transition to the new template.

The presentation will be on **Friday July 20th, 2007** 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 desserts. The session will begin promptly at noon. Please arrive early to sign-in and find a seat.

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>