

Animal Care and Use Newsletter

November
2013



IACUC
Institutional Animal Care and Use Committee
ULAR
University Laboratory Animal Resources
ORRP
Office of Responsible Research Practices

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Inspections

...didn't we just do this?

With IACUC inspections twice a year, annual EH&S inspections, and external site visit inspections from AAALAC and the USDA, it seems like one inspection has barely ended before the next one starts. In 2013 the IACUC conducted spring semiannual inspections in conjunction with the AAALAC site visit in March, and then the USDA arrived on campus for an unannounced inspection during the last week of the fall semiannual inspections in September. Some areas on campus had an IACUC inspection in the morning followed by a USDA inspection in the afternoon!

The results of the USDA inspection were excellent. The USDA Inspector had many positive things to say about our program and facilities, and the inspection report indicated no citations. USDA inspections are very straightforward: there are either citations for non-compliance to the Animal Welfare Regulations and a deadline by which to correct the deficiency, or there are not. While there is an appeal process that sometimes allows for a citation reversal, the university is typically not required to respond to a USDA inspection with corrective action or a management plan.

AAALAC results and the ensuing follow-up, on the other hand, are more similar to the follow-up investigators experience after the semiannual IACUC inspections here at OSU. Just like labs are notified about deficiencies noted and a response and/or management plan is requested, AAALAC provided the university with several findings for which a response was mandatory as well as some suggestions for improvement. Senior leaders of the Animal Care and Use Program, the IACUC, and ORRP and ULAR staff have been working hard over the past nine months incorporating actions and management plans in response to the AAALAC findings. The investigators and animal users may have noticed increased interaction with and questioning from IACUC members during the fall semiannual inspections, a rash of new policies and procedures, or an effort to clarify and revise older policies to provide additional guidance. All these activities enhance opportunities for information exchange at all levels of the Animal Care and Use Program.

The IACUC has introduced five new policies and revised three in response to the AAALAC site visit. In addition, major improvements in the Occupational Health and Safety Program are on the horizon and will be featured in the next newsletter. Until then, read on for information about new and revised policies since the August newsletter...

Resources

**Animal Care & Use
Newsletter Online:**
<http://orrp.osu.edu/iacuc>

e-Protocol:
<https://eprotocol.osu.edu>

**University Laboratory
Animal Resources:**
<http://ular.osu.edu>

**Office of Responsible
Research Practices:**
<http://orrp.osu.edu>

**Institutional Biosafety
Committee:**
<http://orrp.osu.edu/ibc>

**Office of Environmental
Health and Safety:**
<http://ehs.osu.edu>

IACUC Policies

All new and revised policies developed by the OSU Institutional Animal Care and Use Committee to assist investigators and staff with their research are available on the [IACUC Policies and Procedures](#) page of the [Office of Responsible Research Practices](#) website. These policies are reviewed and updated on a regular basis to ensure that they still meet regulatory requirements.

- ***New*** - [Inhalation Anesthesia Machine](#): Anesthesia machines include many components, including rebreathing bags, tubing, hoses, valves, gaskets, flow meters and vaporizers. **All components** of ULAR or lab-owned machines should be evaluated **by the user** prior to each use to ensure proper function. In addition, the following requirements must be met (please note that ULAR owned machines are maintained by ULAR):
 1. **Machines must be inspected annually by qualified personnel** - this inspection includes validation of the vaporizer, which ensures that the delivery of anesthetic gas is within 10% of the metered concentration
 2. **Vaporizers must be calibrated at least once every three years** - calibration is performed by a qualified vendor who checks, adjusts or determines the vaporizer function by comparison to a standard
 3. **Passive charcoal/carbon filter canisters must be monitored** - a log documenting weight or hours of use must be kept



Remember to document the annual inspection / validation and the triennial calibration. This is usually accomplished by affixing a tag to the machine from the person / vendor providing the service.

- ***New*** - [Autoclave Verification and Validation for Survival Surgical Equipment](#): Autoclaves used for sterilization of surgical equipment must be **verified** each time items are being sterilized and **validated** at least every six months.
 1. **Verification** - chemical indicator controls (autoclave tape and/or indicator strips) must be present on the inside and outside of surgery packs for every autoclave cycle; items must be resterilized prior to use if the chemical control indicates a failure to reach required temperatures (i.e., does not change color). In addition, all autoclave packages must contain the initials of the user and date of sterilization, and packages must be resterilized if left unused for more than one year
 2. **Validation** - biological indicator controls must be used to ensure proper microbicidal activity every six months
- ***New*** - [Movement of Animals Outside the Animal Housing Location](#): This policy provides expectations for the discrete and safe movement of animals outside the housing location and methods to reduce the risk of zoonosis and allergen exposure to personnel. Requirements of particular note include use of appropriate containment to prevent external viewing, avoiding public areas, elevators and corridors when possible, and restrictions against movement via public transportation. In addition, **use of personal vehicles is strongly discouraged** and must be described in the animal use protocol and approved by the IACUC.

- **New** - **Reporting of Environmental Problems in Animal Housing Locations:** This policy describes the reporting requirements for temperature excursions outside the **Guide** recommended temperature ranges or the approved housing SOP/SMP. Requirements include documentation of action taken (e.g., reporting to the building coordinator, FOD, or other personnel on the approved housing emergency plan), and reporting to the IACUC if the excursion results in the need to move animals to a safe or appropriate location.
- **Revised** - **Validate Sanitization Effectiveness:** This policy was revised to include language that the manufacturer's instructions must be followed when using products that have been validated and approved in the policy. In addition, Roccal D was added to the list of pre-validated and approved products.



Wex-Cide Spor-Klenz Opti-Cide Roccal D

- **Revised** - **Use of Pharmaceutical and Non-Pharmaceutical Grade Compounds in Animals:** The revision in this policy provides guidance for investigators on the requirements for properly labeling of any compounds stored in secondary containers. All compounds used in animals must be labeled with the following information:

1. **Name of the compound**
 2. **Final concentration**
 3. **Diluent (if applicable)**
 4. **Date of Expiration**
- **Single compounds** - record the expiration date listed on the original bottle or label
 - **Mixtures/Compounds** - record the earliest expiration date listed on any of the agents in the mixture or compound*
 - **Experimental Compounds** - compounds with no expiration date will be discarded based on performance evaluation of the agents



* **Note** - dilutions or mixtures of anesthetics or analgesics must be prepared using sterile technique. In some cases, compounds may interact resulting in an expiration date that is very short and should be discarded based on performance evaluation of the agents. Multiple-dose injectable vials should not be used if they contain particulate matter, precipitates, turbidity, or discoloration.

- **Revised** - [Changes to Approved Animal Use Protocols \(Amendments\)](#): This policy was revised to add changes in animal use location as an additional type of amendment that may be considered minor when submitted to the IACUC. In addition, the review process for minor amendments and the process for making changes in study personnel were clarified.

e-Protocol Tips

Tip #1: *Required Documents for Satellite Housing* - "Standard Operating Procedures for Husbandry" and "Emergency Plans" are two additional documents that are required for all satellite housing locations. The IACUC has created template documents for each of these required forms, which can be found on the [Investigator Guidance](#) website.

Tip #2: *New Feature - Check Study Team Requirements* - Any person listed on an approved protocol now has the ability to check the training requirement for all study team members *and* members for which a study team change has been proposed by clicking on the "Check Study Team Requirements" link under "My Activities" in e-Protocol.

 **Check Study Team Requirements**

Tip #3: *Finding Your Renewal Protocol* - The "Create Renewal" link under "My Activities" creates a copy of the protocol that can be edited and updated for the triennial *de novo* renewal. However, the system does not automatically take the user to the newly created copy. The renewal copy can be accessed by clicking on the "e-IACUC" tab at the top of the webpage, then clicking on the link to the renewal protocol found in the "History" of activities.

Tip #4: *"Additional Contact" vs. "Key Personnel"* - Study team members other than the PI and Co-PIs can have a role of "Additional Contacts" and/or "Key Personnel." The difference between these two roles is that "Additional Contacts" receive *all* of the same notifications that the PI receives, while "Key Personnel" typically receive limited notifications about the protocol or amendments throughout the review process and some annual review and triennial renewal notifications. "Additional Contacts" do not necessarily perform animal activities and may not necessarily be listed as key personnel when strictly functioning in an administrative capacity. However, a lab manager who performs administrative functions *and* animal activities, *and* should receive all notifications sent to the PI should be listed as both an "Additional Contact" and "Key Personnel." PIs themselves should not be listed as "Additional Contacts."

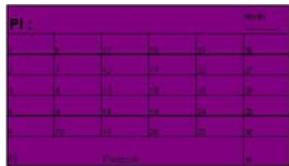
Staff Profile

Jennifer Spohn is an IACUC and IBC Analyst in the Office of Responsible Research Practices. She assists researchers with biosafety submission, guides investigators through the e-Protocol system, and provides administrative support for the IACUC. When proposed research involves recombinant DNA, transgenic animal strains, or other biohazards, Jennifer forwards the proposals through the review process with the IBC. She is currently serving as the secretary/historian for the Association of Staff and Faculty Women. Jenny earned her Bachelor degree in Psychology from The Ohio State University and has been with the ORRP since 2007.



REMEMINDERS

- **Documentation** - deficiencies in documentation accounted for almost 25% of the findings in the most recent semiannual inspections. Examples include everything from having the wrong animal use location listed in the approved protocol to inadequate or missing documentation of special food or water to inadequate surgery records. Clarification and guidance for each of these examples are detailed below:
 - Remember to submit an amendment when the animal use location changes, when the lab moves, or when a space is no longer being used. The [Changes to Approved Animal Use Protocols \(Amendments\)](#) policy states that changes in animal use location may be considered a minor change when submitted to the IACUC.
 - Remember the [Documentation of Husbandry Procedures](#) policy requires documentation of food and/or water modification at the cage level (**purple cards**) or room level (calendar in room binder) in the vivarium. You may document in a notebook or on a calendar in the lab, but documentation must be accessible to IACUC members during inspections and ULAR staff on a day-to-day basis.



Purple Cage Card



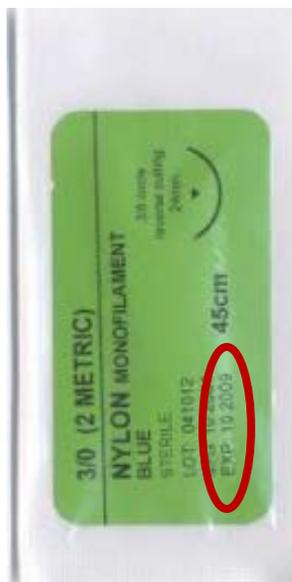
Room Calendar

- Remember the [Rodent Surgery](#) policy requires surgery records document accurate records of anesthesia, the procedure performed, the date and surgeon, and post-operative care including analgesia administration. Surgery and post-operative care records can be downloaded from the [ULAR Forms](#) website or the ORRP QI Specialist can help create custom records specific to the procedure being performed.
- **Sanitization** - deficiencies in sanitization also account for nearly 25% of the findings during the fall semiannual inspections. The majority of these findings involved improper storage of brooms, mops, squeegees, etc. The [Guide](#) calls these tools “cleaning implements” and states that they “should be stored in a neat, organized fashion that facilitates drying and minimizes contamination.” The IACUC has interpreted this to mean that cleaning implements should be stored off the floor on a wall-mounted utility rack such as the example provided below.



REMEMBERED REFRERS

- **Aseptic Surgical Technique** - lab personnel reporting improper aseptic technique accounted for about 5% of the findings on the semiannual inspection. Remember that ULAR provides animal handling and technique classes **free of charge** to personnel listed on animal use protocols. Visit [ULAR Training](#) for information and scheduling, or review the IACUC [Rodent Surgery](#) policy and ULAR [Best Practices for Rodent Survival Surgery](#) for a refresher.
- **Expired Materials** - expired agents, compounds and materials accounted for approximately 15% of the findings on the semiannual inspection. Not only should personnel check expiration dates on injectable agents and compounds before each use, but also research materials such as sterile gloves, packages sutures, PE tubing, and even sterile water. These materials may not be used in live animals, and if they are not discarded they must be clearly labeled and kept in a separate location so that they will not be inadvertently used in live animals.



- **Confirmation of death** - a secondary physical method of euthanasia is required to confirm death after CO₂ euthanasia and prior to disposal of carcasses. Acceptable secondary methods for confirmation of death include creation of a pneumothorax, removal of a vital organ, decapitation, exsanguination, or cervical dislocation. Remember that cervical dislocation may not be performed in rats weighing more than 200 grams.
- **Avoid recapping needles** - recapping needles is dangerous because the needle could miss the cap and stab the hand holding it. Remember that if recapping is required you **must** use tongs, a recapping device or a one-hand scoop method. EH&S has provided a Sharps Safety Fact Sheet that can be downloaded [here](#) and posted near lab sharps containers.



Recapping device



One-hand scoop