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

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## Preventing Protocol Drift and Maintaining Compliance

All PI's are encouraged to spend time with their study teams and laboratory personnel to be sure research activities do not deviate from the activities described in approved animal use protocols or amendments.

Here are some common things to consider:

1. Personnel working with animals must know what is in the approved protocol(s) – (animal procedures, anesthetics, analgesics, early removal criteria, euthanasia methods, blood collection quantities and frequency, etc.). **Any one listed in a protocol has access to the protocol by logging into <https://eProtocol.osu.edu>. A hard copy of the approved activities should be available in the lab where it is easily accessible to personnel, including the PI.**
2. Confirm that the protocol number listed on an animal's cage card corresponds with the approved protocol before conducting any activity on that animal.
3. Ensure that personnel do not modify protocol activities without IACUC approval. Examples of unacceptable "protocol drift" include:
  - Change in the type of euthanasia or anesthesia
  - Collecting more blood or tissue or using an altered collection method or schedule
  - Change in the type or dose of drug administered
  - Failure to adhere to early removal criteria defined in an approved protocol
  - Involving personnel not listed on the protocol
  - Conducting pilot studies or practicing procedures without prior IACUC approval



## Resources

### Animal Care & Use Newsletter Online:

[http://orrrp.osu.edu/  
iacuc/index.cfm](http://orrrp.osu.edu/iacuc/index.cfm)

### e-Protocol:

<https://eprotocol.osu.edu>

### University Laboratory Animal Resources:

<http://ular.osu.edu/>

### Office of Responsible Research Practices:

<http://orrrp.osu.edu/>

### Institutional Biosafety Committee:

[http://orrrp.osu.edu/  
ibc/](http://orrrp.osu.edu/ibc/)

### Office of Environmental Health and Safety:

[http://www.ehs.ohio-  
state.edu/](http://www.ehs.ohio-state.edu/)

As always, if you have questions or need assistance with amending your approved protocol, contact the IACUC office at 292-4494 or 292-0409.

## Animal Handling & Technique Training

Classes are provided by ULAR staff FREE OF CHARGE and are highly encouraged!!

ULAR offers scheduled classes, as well as individually scheduled sessions.

Before you register for training, please be sure that you are listed in the protocol and have completed all of the required training listed on our website, [www.ular.osu.edu/training](http://www.ular.osu.edu/training).

### CLASS: Introduction to the Laboratory Mouse

This class is an introduction to handling & restraint and covers basic techniques. This course will combine both lecture and hands-on techniques. All techniques will be demonstrated, and students will then have the opportunity to practice these skills under the supervision of our experienced trainers. Topics and techniques to be covered include: handling & restraint, health assessments, subcutaneous injections (SQ), intra-peritoneal injections (IP), sub-mandibular blood collection, proper micro-isolator use, and euthanasia/secondary methods.

**Location/Day and Time** - Wiseman Hall 110

Second Thursday of every month 10 a.m.

Fourth Tuesday of every month 1 p.m.

**Attire** - Business casual/Scrubs.

Class size is limited to 15 people.

To register for this class, e-mail [ulartraining@osu.edu](mailto:ulartraining@osu.edu)



### Individual Sessions

ULAR also offers individually scheduled sessions for you to learn techniques specific to your protocol. To schedule training for specific techniques or for species other than mice, or for a complete list of topics, please visit our website: [www.ular.osu.edu/training](http://www.ular.osu.edu/training).

Allow a minimum 5 days advance notice for training to ensure animals are available. If you would like information, contact the ULAR training coordinator at 292-5094 or [ulartraining@osu.edu](mailto:ulartraining@osu.edu).

## Recent News from the IACUC

Donna McCarthy, IACUC Chair

It has been over one year since we went live with the electronic protocol system for both the IACUC and IBC. In December, the IACUC office released an Animal Care and Use Newsletter which provides tips on adding personnel to the system along with information on new and revised guidelines. In addition, the National Research Council of the National Academies released a revised "Guide for the Care and Use of Laboratory Animals" in January. This is the document used by regulatory and accrediting agencies and the OSU IACUC to evaluate our program. The IACUC will be reviewing the guidelines published on our website to be sure they are congruent with the revised "Guide." This spring, we also launched our new Quality Improvement Program and hope to accomplish several visits to PI labs in the coming months.

I encourage you to periodically check the IACUC website for recent news, past newsletters, links to the new "Guide," as well as the IACUC guidelines and policies for animal care and use (<http://orrrp.osu.edu/iacuc/>). This is also the place to find guidance on preparing documents for submitting or amending animal use protocols. As always, if you have suggestions on improving the program or questions about e-Protocol or IACUC policies, please contact the IACUC office.

### ***Don't forget...***

If hiring students to work with animals during the summer, they need to be added to the protocol and all training completed before work with animals begins.



## IACUC Policies Updated During the Past Year

All of the policies developed by the OSU Institutional Animal Care and Use Committee to assist investigators and staff with their research are available on the Policies Page on the ORRP Website. These policies are reviewed and updated on a regular basis to ensure that still meet regulatory requirements.

### Updates During the Past Year:

- **Biological, Chemical and Radiological Safety** - clarifies the process for obtaining OASIS forms.
- **Changes to Approved Protocols (Amendments)** – makes any change of anesthetic agent now a significant change. This was changed to meet regulatory agency requirements.
- **Transfer/Adoption of Research Animals** - clarifies the process for communicating the availability of animals for adoption
- **Mouse Breeding Cages** - Updates the procedures for documenting litters and weaning animals. In addition, it requires a ULAR veterinarian review of any IACUC approved weaning age extension beyond 21 days to help ensure that animal welfare of the animals are not compromised.
- **Genotyping of Rodents** - clarifies procedures for genotyping rodents.



### New Policies:

- **Housing and Veterinary Care of Aquatic Species** - The Guide for the Care and Use of Laboratory Animals has a new section on using aquatic species. This Guideline provides guidance on the use of these animals in research.
- **IACUC Member Conflict of Interest** – Provides information concerning requirements that IACUC members follow to ensure that there are no conflicts of interest during the review of protocols.



A full listing of IACUC policies is available at <http://orrrp.osu.edu/iacuc/osupolicies/>.

## What is Early Removal Criteria?

Early Removal Criteria (ERC) are specific, predetermined indicators of pain and distress used to establish early study endpoints without loss of scientific quality of data. ERC should be developed by the primary investigator (PI) based on pain and distress due to the animal model or experimental procedures outlined in the animal use protocol.

There are some common clinical signs, such as lethargy or weight loss, which are often used as ERC. Additionally, as a PI, it is essential to also include clinical presentations or parameters that are specific to the project. In order to implement the ERC, animals on study should be monitored at appropriate frequencies to permit timely termination of the experiment once the endpoint has been reached. This may require weekly, daily or even hourly observations. You will be asked to provide these proposed time-points in the ERC section of your animal use protocol.

It is important to understand that once the ERC are approved by IACUC, they must be followed. As such, it is essential that the ERC accurately reflect when animals can and will be removed from study. It is understood that adverse effects may occur that were not anticipated at the study onset. ERC should be updated to reflect these changes via an amendment.

University Laboratory Animal Resources (ULAR) veterinary staff can help you to develop your ERC such that it enables you to remove animals from study at the appropriate time-points to minimize pain and distress without compromising the quality of scientific data. Additionally, if necessary, training can be provided to help staff recognize signs of pain and distress.

Want to learn more:

Organization for Economic Co-operation and Development (OECD) Guidance Document No.19 on “*The Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluations*”, 2000.

CCAC Guidelines on Choosing Appropriate Endpoints

[http://www.ccac.ca/en/CCAC\\_Programs/Guidelines\\_Policies/GDLINES/ENDPTS/APPOPEN.HTM](http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/GDLINES/ENDPTS/APPOPEN.HTM)

## Need help with preparing your animal use protocol?

All animal use protocols and amendments at the Ohio State University are now prepared and submitted electronically in the e-IACUC system. These documents must undergo an online veterinary consultation prior to IACUC review. A ULAR Protocol Consultant is available to provide assistance with document preparation including assistance with inputting renewal protocols into the electronic format and guidance for new investigators and their research teams.



For assistance please contact: Angela J. Phillips, Protocol Consultant, ULAR, at 614-292-3633 or [phillips.270@osu.edu](mailto:phillips.270@osu.edu).

Additional services available from Angela or the IACUC office include individual or group training on use of the e-Protocol (e-IACUC) system and guidance regarding all aspects of the consultation and review process.

Don't forget, training guides are also available at research online to help you navigate in the e-Protocol system.