OFFICE OF ANIMAL CARE AND USE (OACU)
INFORMATIONAL MEMO
February 2016

The purpose of this memo is provide Principal Investigators (PI), research staff, and administrative managers with updates about the UNC Animal Care Program. New or recently revised IACUC Guidelines/SOPs/Policies can be found at the bottom of the memo. Please share this information with your research staff and feel free to contact the OACU staff if you have questions about any items in this memo.

Prevent Non-Compliance and Protocol Drift – Review Your Animal Care Application (ACAP) Before Conducting Procedures and Amend ACAP Before Starting New Procedures

Personnel working with animals must be familiar with the procedures described in the approved ACAP. Researchers may only conduct new procedures after describing those changes in an amendment and receiving Institutional Animal Care and Use Committee (IACUC) approval. Non-compliance with the approved protocol is reportable to the Vice Chancellor for Research and the NIH Office of Laboratory Animal Welfare (OLAW).

Examples of past reportable protocol non-compliance include:
- Unapproved toe clipping or toe clipping after 10 days of age in mice
- Euthanasia in animal housing rooms when it is not described in the protocol
- Allowing personnel not listed on the ACAP to work with live animals
- Unapproved changes in the type of euthanasia, anesthesis, or analgesia
- Failure to use analgesics/anesthetics according to frequency and duration described in ACAP
- Failure to document administration of analgesics and/or anesthetics
- Use of expired agents and/or materials in live animals
- Failure to use a secondary physical method to ensure death
- Use non-pharmaceutical or non-veterinary grade agents without prior approval
- Failure to adhere to early removal criteria (humane endpoints) defined in an approved ACAP
- Conducting pilot studies and unapproved procedures, surgeries, or techniques
- Surgeries not performed as described in the approved protocol

Plan carefully when completing your ACAP. The IACUC must approve any changes before they can be implemented. Submit an amendment to describe any anticipated changes to your ACAP. Initiate new practices only after you have received written IACUC confirmation that the amendment is approved. Be sure to include all potential techniques to be utilized as well as different anesthetic and analgesic options and dose ranges to provide flexibility. The purpose of amendments is to allow investigators the opportunity to request changes or minor additions to the application that were not anticipated when the application was initially submitted. If you are unsure whether an amendment is needed, please refer to the [Guidelines for Amendments and Other Protocol Changes](#) or contact OACU at 919-966-5569 for assistance. Please review your current application frequently and at the time of its annual review to ascertain that all necessary information is contained in the application.
ACAP Updates

The ACAP Home Screen page has been redesigned to improve ease of use. All applications can now be viewed or accessed directly from this page. Select the IACUC ID number or title of the approved protocol on the Home Screen to initiate DLAM Requests (such as an animal orders, transfer, import, export or cage card requests) or submit an ACAP Change Request (such as an amendment, title/funding change, or annual renewals).

Within the application form there have been improvements to several sections.
- The Literature Search Section 4.1 has been revised to better address federal requirements.
- The Pain Category definitions in the Animal Numbers Section 4.0.3 have been expanded.
- The questions in the Euthanasia Section 6.0.8 have been updated for clarity. The use of the Euthanex Smartbox chamber can now be added and an associated technique is now available in the Personnel Section 1.0.
- While previously only 3 surgeons could be listed in the surgical Sections 5.2 and 5.3, the application form now permits the addition of unlimited names.
- Several sections now generate pop-up error messages for missed items to cut down on the number of reviewer comments.
- The Title Funding page now gathers additional information and displays more details from RAMSeS.

Also, to assist researchers with application submissions we have produced 2 new documents.
- Creating Animal Care Applications in ACAP outlines some of the dos and don’ts of application submission and is recommended reading for anyone using ACAP.
- Tips for Generating Continuation Applications Using Templates compiles the most common issues cited by reviewers for revision when using application templates. Anyone submitting a continuation for an ongoing project in this manner should consider referencing this document as they prepare their application.

If you have questions or need assistance filing a new or continuation application, an amendment, an annual renewal or a title funding change, please call the Office of Animal Care and Use at 919-966-5569.

Grant-Protocol Congruency Updates

The Grant Congruency section of the IACUC website has been edited and streamlined for clarity. Visit it at: http://research.unc.edu/offices/iacuc/grant-congruency/

Grant-Protocol Congruency is currently required for the following funding agencies and should be completed either at JIT Notice or Notice of Award before funds are distributed:
- National Institutes of Health (NIH)
- All NIH subdivisions (e.g. NCI, NHLBI, NIAID, NIDDKD, NIAAA, etc.)
- National Science Foundation (NSF)
- American Heart Association (AHA)
- American Cancer Society (ACS)
- Veterans Affairs (VA)
- March of Dimes (MOD)

Due to some technical issues that are still being mitigated, the web form to request a Congruency Review has been temporarily relocated to: http://research.unc.edu/offices/iacuc/forms/request-for-review/
The Title/Funding Change (TFC) page in ACAP has been updated with additional information to clarify when a TFC should be filed for incoming grant awards. TFCs should be filed only after Notice of Award is received. The input fields have also been adjusted to capture only relevant information. The approval page will now display both the protocol title and grant title separately so that the protocol title does not need to be changed each time a new funding source is added. Most funding agencies DO NOT require matching grant and protocol titles.

**UNC-CH Center for Bioethics**

Through the North Carolina Translational and Clinical Sciences (NC TraCS) Institute, the Center for Bioethics offers confidential research ethics consultation, including consultation regarding ethical issues in the design, conduct, and dissemination of animal research. To read more about these services or find out how to request a consultation, please see the website: [http://bioethics.unc.edu/research-consultation/](http://bioethics.unc.edu/research-consultation/).

**Reminders to Researchers Regarding Work in DLAM Animal Facilities**

**Emergency Contact Information** - It is imperative that you regularly check to ensure that you have provided a current emergency contact phone number in each DLAM space where your animals are housed. DLAM staff utilize these numbers to contact labs when an urgent matter arises. Too often, weekend DLAM Vet Services calls go unanswered, leaving DLAM staff to make decisions on behalf of the lab.

**Photographs, Audio Recordings, and Video Recordings in DLAM Animal Facilities** - Taking any type of picture, or recording any audio or video within the animal facilities without prior approval from the DLAM Director, Dr. Craig Fletcher, is strictly prohibited. To acquire approval contact DLAM at 919-843-7992. In addition, the procedure and need to record should be described in the approved Animal Care Application.

**New and Updated IACUC Policies, Procedures, Guidelines and Standard Operating Procedures**

All policies and guidelines described below are accessible via the IACUC website on the *Policies and Procedures* page. Please check this site frequently as policies and guidelines are updated on a regular basis.

**Animal Procedural Space Exception (APSE) Guidelines**

The IACUC has revised the APSE guidelines to allow holding of non-USDA regulated species outside of a DLAM-maintained space for up to 24 hours without a request for exception. Previously, the maximum time period was 12 hours. The justification for holding the animal outside of DLAM must still be described in the appropriate protocol and approved by the IACUC. Holding non-USDA regulated species outside of DLAM for greater than 24 hours requires an exception.

An exception is still required in order to house USDA-regulated species outside of the DLAM facility for greater than 12 hours.

ACAP Sections 3.2 and 3.3 have been updated to document the changes described above. Also, these changes should clarify locations where procedures are conducted to better facilitate the IACUC inspection process.
Guidelines For Satellite Animal Facilities

We have revised the Guidelines for Satellite Animal Facilities by reorganizing the document and combining the previous version with the IACUC Satellite Facility SOP form. This more comprehensive document should clarify the approval process and streamline documentation for current and prospective satellite PIs and their staff.

All aspects of the previously approved IACUC Satellite Facility SOP form have now been incorporated into the revised version. In addition, the form includes details required by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALACi) in the institution’s Program Description. This addition may ultimately help reduce investigator time when the IACUC is collecting information for the AAALAC Program Description.

Cage Population Densities, Housing, and Breeding – Mice

The revisions simplify the policy by removing the differences between blue and green line Techniplast cages.

Additionally, this revision requires that cages marked with a yellow ‘Action-Required’ card to be addressed within 48-hours (including weekends and holidays). In the past, this policy has allowed researchers an extended period of time to address potential overcrowding when cages were marked on a Thursday, Friday, or over a holiday. According to this revision, cages must be addressed by the researcher within 48-hours of card placement or DLAM will be authorized to separate for the lab and charge the standard fee. This aspect of the revision was discussed and was supported by the DLAM Advisory Committee (which is comprised of UNC-CH faculty researchers, IACUC members, Office of Animal Care and Use staff, and DLAM Veterinary and Husbandry staff).

Tumor Burden Policy

This policy was revised to clarify humane endpoints and allowable tumor sizes, dependent upon tumor type and location. Researchers are encouraged to reference language in this policy when writing or amending protocols.

Rodent Euthanasia Policy

The policy now allows euthanasia in rodent housing rooms as long as the room contains Individually Ventilated Caging and/or animals are euthanized in a vented hood. The euthanasia method used must be described in the protocol.

Additionally, in response to changes in the 2013 AVMA Guidelines for Euthanasia, the policy now allows cervical dislocation without anesthesia to be included in protocols without scientific justification. The OACU Training and Compliance Team will continue to train in this technique and only highly proficient PIs and LACs will be certified to train others. If you would like to be certified in this technique, please contact OACU personnel at iacuc@unc.edu to schedule a one on one session.

Veterinary Care for Research Animals

The document was updated to include a statement that unexpected hatching must be reported to DLAM Veterinary Services so that humane euthanasia can be arranged.
Guidelines for Administered Agents

This is a newly created document that consolidates information from several sources and should help with the vet verification process.

Anesthesia/Analgesia drug log template

This document has been revised and can be printed or updated electronically.

Animal Welfare Concern or Animal Protocol Noncompliance Reporting

This revised flier replaces the lime-green version currently posted in laboratory spaces with updated contact information. *Please print and post in spaces on campus where live research animals may be present.*

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