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OFFICE OF ANIMAL CARE AND USE (OACU)
INFORMATIONAL MEMO
June 2015

The purpose of this memo is to 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 call the OACU staff if you have questions about any items in this memo.


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 recent reportable protocol drift/non-compliance include:
- Unapproved toe clipping or toe clipping after 10 days of age in mice
- Euthanasia in animal housing rooms
- Allowing personnel not listed on the ACAP to work with animals
- Unapproved changes in the type of euthanasia, anesthesia, 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 animals
- Failure to use a secondary physical method to ensure death
- Use of agents that are not pharmaceutical or veterinary grade
- 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 are 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 a variety of 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, many of which were not anticipated when the application was initially submitted. If you are unsure whether an amendment is needed or not, 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 at the time of its annual review to ascertain that all necessary information is contained in the application.

Use of Toe Clipping in Mice
If your approved ACAP describes toe clipping in mice, please review the UNC Policy on Rodent Toe Clipping with your laboratory members and ensure that they are performing the technique as described in the policy and in your approved protocol. Some relevant aspects of the policy are described below.

- **Toe clips must be performed on or before 10 days of age** with the ideal time being between 5-7 days of age. If tissue for genotyping is required beyond 10 days of age, contact DLAM veterinarians for alternative methods of collecting tissues.
- **Toe clipping** must be scientifically justified in an approved IACUC protocol.
- The IACUC allows **toe clips on a maximum of 4 toes** and no more than 2 toes per foot.

**ACAP Updates**

There have been recent ACAP updates to reduce approval time and simplify submitting and revising applications. The most notable change links the ACAP attachment section to the EHS Lab Safety Plan. IBC Schedule forms can now be uploaded directly to an application. Also, ACAP has also been moved to a new server in an effort to increase performance speed.

In April 2015, to be more in line with regulatory expectations, the IACUC implemented a more robust Section 4.1 *Literature Search for Alternatives to Painful Procedures*. If your ACAP has animals in Pain Category D or E, Section 4.1 is required. Investigators working with non-USDA-regulated species must update Section 4.1 when preparing new or continuation applications. However, investigators working with USDA-regulated species must submit an amendment to update Section 4.1 before July 23, 2015.

Plans for further improvements in 2015 include streamlining the funding information within the application and full integration of the *Animal Services* form into the body of the application. The latter will make the current forms obsolete.

The OACU Administrative team will soon be joined by Tayler Gentle, who will be the point person for post-IACUC meeting processing of new and continuation applications. Tayler will fill the role vacated by Colleen Fritsche who was promoted to Assistant Director & Administrative Manager. Tayler joins Rita Williams, who you may know from processing your amendments, and Pam Miles and Vanessa Gunn, our highly skilled and always helpful Administrative Assistants.

**Grant-Protocol Congruency Updates**

*Grant-Protocol Congruency Review* is the process by which the primary awardee institution verifies that all animal studies proposed in a grant are covered under approved animal protocols before funds are awarded by the sponsor. It is required under PHS Policy and NIH Grants Policy Statement and applies to funding agencies that follow NIH guidelines [NIH, NSF, American Heart Association (AHA), and American Cancer Society (ACS)]. ACAP approval does not mean congruency. These are separate reviews.

Below are some helpful tips regarding **Grant-Protocol Congruency Review**:

- All protocol information should be submitted to sponsors via the appropriate admin office (e.g. Sponsored Programs Office, Office of Sponsored Research, etc.), not by the PI.
- To facilitate the process, the PI can initiate a congruency review by submitting a request on the IACUC website at [https://apps.research.unc.edu/_misc/iacucGrantCongruency/grantCongruency.cfm](https://apps.research.unc.edu/_misc/iacucGrantCongruency/grantCongruency.cfm)
  - NIH and NSF grants must be reviewed for congruency before submission of JIT/protocol information to sponsor. Congruency reviews are automatically initiated for NIH awards when grant status is changed to JIT Request Received in RAMSES.
AHA grants must be reviewed for congruency within 90 days of the start date; generally, the application should be submitted to AHA with IACUC information labeled as "pending"

ACS grants must be reviewed for congruency before funding is issued to UNC; again, IACUC info should probably be submitted as "pending" until notice of award

Grants will not be changed to "Funded" status and funds will not be released unless congruency has been confirmed (except grants where the proposed animal work will not be conducted in the first year. These will be reviewed in renewal years when animal work is added.)

Subcontracts and Collaborations:

- When UNC is the primary grant awardee, any subcontracts/collaborations employing animal studies must have a Memorandum of Understanding (MOU) in place before the sub-award can be released. The MOU serves to:
  - declare the subcontractor's ownership and responsibility for animal work proposed in grant
  - confirm congruency for the subcontracted studies

Title/Funding Changes (TFCs) is the process of denoting funding sources for protocol activities.

- NIH, NSF, and ACS DO NOT require matching titles.
- AHA prefers matching titles, but will accept non-matching with an explanatory letter.
- A previously approved TFC does not mean congruency
- A TFC should be filed after Notice of Award from the sponsor and creation of the award account in RAMSES. This is now indicated in the ACAP.
- Information required to file a TFC:
  - Funding type
    - Grant
    - Departmental funds
    - Private industry contract
  - Parent IPF# and/or Award Project #
  - Prime sponsor (automatically populated)
  - Sponsor (automatically populated)
  - Grant title (automatically populated)
  - PI on grant (automatically populated)
  - Option to edit protocol title (for agencies that require matching titles like AHA)

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 and at http://research.unc.edu/offices/iacuc/important-notices/. Please review frequently as the OACU posts revised documents and other important information here on a regular basis.

Policies:

**Tumor Burden Policy:** This policy was slightly revised to address non-treated induced tumors. These tumors did not fit any category in the prior version. A wording change was made from “Animals with experimental,
therapeutic intervention and their corresponding controls” to “Animals with induced experimental tumors and their corresponding controls”. This conforms to the NIH Guidelines for Endpoints in Animal Study Proposals.

**Action Required Cards for Rat Cage Density:** In January, 2015, the IACUC approved the implementation of a cage density “Action Required” card for rat cages, similar to the mouse cage density card system. This system identifies rat cages that exceed the recommended cage density to control and alleviate overcrowded rat cages.

**Social Housing of Research Animals (Terrestrial and Aquatic):** Following August 2014 AAALAC site visit the IACUC revised the policy to address single housing of social USDA-regulated species. All singly-housed USDA-regulated species must have a ‘Single Housing’ card on the cage to indicate the reason for non-social housing. It is the PI’s responsibility to place and maintain these cards to accurately reflect the current status of each animal. For animals without a permanent record, this card serves as a social housing record/history for the life of the animal. If the animal has a permanent record, the PI must indicate the reason for single housing in each animal’s record. The cards and/or the records must be readily available for review by IACUC, DLAM and outside regulators upon request.

*Note: For both USDA-regulated species and non-USDA-regulated species (i.e. purpose bred rodents) Section 6.0.5b in ACAP now addresses single housing of social animals. An exception request is no longer required.

**Rodent Euthanasia Policy:** The policy now includes information regarding euthanasia in animal housing areas. We incorporated information, previously posted on our website, into the current policy and edited the statement for clarity (see page 2 of the policy).

**Environmental Enrichment Program for Animals:** The minor revision addresses the replacement of PVC tubes with red huts as the default enrichment provided by DLAM in rodent cages.

**Toe Clip Policy (Rodents):** Due to multiple reports of non-compliance with this policy, some resulting in Animal Concern Reports, the IACUC revised the rodent toe clipping policy to emphasize the most salient points and decrease the potential for confusion.

**Guidelines:**

**Rodent Identification Guidelines:** This guideline was reformatted from its previous version and the description of several techniques were updated. A full list of all IACUC Policies and Guidance Documents can be found here: [http://research.unc.edu/offices/iacuc/policies-procedures/](http://research.unc.edu/offices/iacuc/policies-procedures/)

**Links to June 2015 Network for Laboratory Animal Coordinators (NLAC) Presentations:**

- NLAC June 2015 – EHS – AAALAC One Year Out – Safety Update
- NLAC June 2015 – IACUC Updates
- NLAC June 2015 – Mouse Cage Density Presentation
- NLAC June 2015 – Use of Expired Materials
- NLAC June 2015 – Vet Care Guidelines

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