OFFICE OF ANIMAL CARE AND USE (OACU)
INFORMATIONAL MEMO
February 2010

In order to provide better service to our Principal Investigators (PI), research staff, and administrative managers, the Office of Animal Care and Use (OACU) has compiled this informational memo. Please feel free to call the OACU staff if you have any questions about any items in this memo.

ACAP ADMINISTRATION

New Investigators and Research Personnel

OACU personnel are available to assist you and to answer questions about the application and amendment submission, review, approval, and renewal process. You may also consult with OACU personnel regarding preparation of your Animal Care Application (ACAP). Please do not hesitate to contact the office at 966-5569 if you have any application related questions. We will direct you to the correct individual if our office is unable to answer your questions.

ACAP Items

Thank you for your patience as OACU waits in the cue for computer programming time. As soon as the programmers responsible for ACAP are able, they will be putting ACAP on an improved platform and OACU will be able to address many of the issues research personnel have raised over the past three years. OACU is anxious to make the suggested improvements, although much is out of our control at the moment. Please continue to inform us of issues you have with the content of ACAP and we will implement changes as soon as we have the capability.

1. Submission of Amendments and Annual Renewals:

When submitting an amendment close to the time of the annual renewal or at the same time as an annual renewal, please submit your annual renewal first. If the investigator submits the amendment first, the current ACAP programming logic keeps the amendment expiration date rather than the annual renewal date. The office rarely encounters this problem. However, when it occurs, it causes confusion.
2. Completing Amendments

When starting a new amendment for your protocol, a window will pop up in ACAP that states, “Please wait while your amendment form is generated.” You will also see an hour glass on this window while the amendment form is loading. Please ensure that you do not close this window or enter any information for your amendment until ACAP closes the window and takes you to the Amendment Item List. Failure to do so may result in the deletion of some text or complete sections of your ACAP application.

3. Creating a New or Editing an Existing Application in ACAP:

When creating a new application or editing an existing application, please do not have more than one ACAP screen open simultaneously. Should more than one ACAP screen be open, data will be transferred between the various applications, resulting in random changes in all open applications. This is particularly true when copying and pasting between applications, which is generally not recommended.

4. Copying or making a template of an existing application

If you wish to make a copy of the entire application, go to the Application Management screen, activate the Approved tab and click on the Make a copy link next to the required PDF logo. Then, complete the next screen and click the Generate a Copy tab. The copy is now available for editing in the Application Management screen, under the unsubmitted tab.

Delayed review of Animal Handler forms

Please note that as soon as an individual submits their ‘Animal Handler’ form electronically, it becomes part of the Animal Handler Registration database. However, there is a time lag (sometimes considerable) before the ACAP ‘Personnel’ section registers completion of the ‘Animal Handler’ form by a red check. As long as you have submitted your form electronically, you have satisfied the requirement. At the time of application review, if the ACAP ‘Personnel’ section does not reflect that an individual has completed the animal handler form, OACU personnel know to look in the Animal Handler Registration system to verify submission.

Environment Health and Safety (EHS) and the University Employee Occupational Health Clinic (UEOHC) are currently working to tackle the backlog in animal handler forms.

Summary of Application and Amendment Review Process

Some researchers have raised questions about the ACAP application/amendment review process. OACU wants to take this opportunity to briefly explain the review process and hopefully answer questions you might have.
When an application/amendment is submitted, OACU personnel administratively review the following aspects of the application/amendment.

- Personnel listed on the application/amendment are assessed to determine if they have completed the necessary on-line orientations, EHS requirements, and the occupational health ‘Animal Handler’ form. Also, the handling techniques listed for each individual are assessed to determine if the individual has the necessary training and certification.
- The funding portion of the application is reviewed to determine if the investigator has associated the application with a particular grant so that congruency between the grant and the application can be assessed.
- The survival surgical section of the application is reviewed to determine if researchers have adequately described aseptic technique.

Applications at UNC undergo Full Committee Review and are presented to the IACUC at a convened meeting. The IACUC meets monthly. Each application is assigned to a primary reviewer, who will present the application to the full committee at a convened meeting. Also, a veterinarian reviews the application. Additional questions may be raised by any of the committee members attending the meeting. These comments are compiled and sent to the investigator after the meeting.

The investigator revises the application to address all comments prior to re-submission. The reviewers are responsible for evaluating the revised application. Many times, the revised application stimulates new questions that were not thought of during the initial review because many of the experimental aspects were not clear at the time of review. Thus, the reviewers may ask additional questions that arise in response to the revisions and clarifications. Each reviewer must be comfortable that all aspects of the application have been addressed before approving the application. This may sometimes require additional questions and several iterations. Amendments are addressed the same way except they are handled by Designated Review and do not typically go to a fully convened IACUC meeting.

IACUC members are all volunteers and have other constraints dictating their time. All members do their best to respond to revised applications in a timely manner and OACU personnel work hard to facilitate the review process. However, in the case of complicated applications with many comments, the process can be time consuming.

Changing Principal Investigator Techniques and Roles in ACAP

Once an application is submitted, the PI’s name, role(s) and technique(s) can only be changed by OACU. Please call 966-5569 if additions or modifications to the PI role(s) and technique(s) are needed.

Changing Principal Investigator on an Application

Once an application has been approved, changing the PI requires the submission of an amendment requesting a PI transfer.
Submission of Continuation Applications

In order to designate an application submission as a “continuation application”, the PI must indicate the application’s previous ACAP identification number in the General Information Section of the updated application. If the PI is unable to finish the online form, he/she should save the application until it can be completed and submitted. When resuming work on the “continuation application”, please do not create another NEW application. Instead, go back to the unfinished online form previously saved, complete the form, and then submit it when ready. Creating multiple copies of “continuation applications’ causes problems in ACAP and prevents administrators from determining which application needs to be continued.

Grant and ACAP Submission and Renewal Schedules

UNC-Chapel Hill began a program requiring NIH grant applications to be reviewed for congruency with the corresponding ACAP application(s). Currently, OACU is reviewing a sampling of NIH grant applications for which an investigator has received “just in time” notification. If any discrepancies are noted between the two documents, Michelle Denning, the IACUC Manager and Grants Specialist, will contact you to obtain additional information to resolve the discrepancies. Please note that this congruency review is conducted only on new or continuing NIH applications. NIH grant applications that are in a non-competing cycle will not be reviewed as part of this program.

Because the PI signature on the Application Certification page of the ACAP application certifies that all animal activities on the grant application have been included on the ACAP application, please ensure that you have received IACUC review and approval of all animal activity outlined in your NIH application no later than receipt of your “just in time” notification.

As the program continues to develop, we will continue to provide you with further information about the program. OACU has plans to widely publicize the details of the new program and to hold meetings to allow for discussion with the UNC research community. In the meantime, should you have any questions about the Grant/IACUC Application congruency review, please contact Michelle Denning at 966-5569 or via email at michelle.denning@unc.edu.

TRAINING AND COMPLIANCE

New and Revised Standard Operating Policies and Guidelines: Effective February 11, 2010

- Amendment Guidelines

Please contact the OACU Training and Compliance Coordinators at 966-5569 if you have any questions regarding these documents.
Semi-annual Inspection

The IACUC is federally mandated to inspect the following at least semi-annually:

- Satellite facilities (animals housed in investigator maintained area greater than 12 hours)
- Areas in which surgical manipulations are performed

Laboratories in which routine procedures, such as immunization, dosing and weighing, are conducted may be evaluated by other means such as random inspections. However, the institution, through its IACUC, is still responsible for all animal-related activities regardless of where animals are maintained or the duration of the housing. Training/Compliance Coordinators (TCCs) are responsible for coordinating and conducting the semi-annual laboratory inspections. TCCs have many other responsibilities, such as investigating animal concerns and conducting hands on training. The requirement to respond quickly to investigate potential animal concerns and other compliance issues does not allow notification of all inspection visits. When time and schedules permit, TCCs will notify labs prior to inspecting. The TCC team currently conducts 25 – 40 laboratory inspections per month.

Use of Fabric Chairs in the Laboratory

The Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition [Section VI-Principles of Laboratory Biosecurity page 44 item D4b] http://www.cdc.gov/od/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf specifies that “Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.” If inspectors note the use of fabric chairs in the laboratory during IACUC semi-annual inspections, the investigator will be advised to remove the chair(s) before the next six month inspection. If the chair(s) have not been removed at the time of the next inspection, IACUC will note the deficiency in the inspection report.

Laboratory Animal Coordinator (LAC) and Personnel requirements when animal breeding is approved on an application:

1. For all applications involving MOUSE breeding:

   - The mandatory Mouse Breeding Policy Lecture must be indicated in the Technique(s) Profile for all personnel involved with breeding.
   - The voluntary Mouse Colony Management Lecture is available to all researchers and attendance can be indicated by listing it in the relevant personnel Technique(s) Profile.
   - New technique
     - Weaning – Mouse: This new Technique will encompass proficiency in sexing, basic husbandry, weighing and measuring, tooth trimming, nail trimming.
2. For all applications involving RAT breeding:

- New technique(s)
  - Rat Breeding: This new Technique must be listed in the Technique(s) Profile of all personnel involved with breeding.
  - Weaning –Rat: This new Technique will encompass proficiency in sexing, basic husbandry, weighing and measuring, tooth trimming, nail trimming.

**DLAM INFORMATION**

**Use of Tecniplast cages outside the Division of Laboratory Animal Medicine (DLAM) animal facility**

Disconnected from the ventilated rack, Tecniplast cages allow mice to be safely housed in the blue and green line ventilated cages, without compromising respiration, for approximately 24 hours. If you remove blue and green line cages from the DLAM facility to another location, be sure to adhere to the 12-hour maximum time period animals are allowed to be kept outside the DLAM animal facility. Keep the cage intact. Do not remove the filter or pop the wheel. Return the cage to the appropriate designated dirty cage return in your facility. Contact Randy Allen of DLAM at 843-0737 if you have questions.

**Vaporizer Training in Research Animals**

DLAM Veterinary Services provides researchers with the required isoflurane vaporizer training. Before DLAM will provide training, the individual must have completed the following requirements:

- IACUC on-line Orientation
- DLAM on-line Orientation
- Research Profile
- Lab Worker form
- Receive certification in Handling and Restraint (for the pertinent species)
- Obtain DLAM facility access

For questions regarding vaporizer training or to schedule an appointment, please contact DLAM Veterinary Services at 966-2906.

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