Animal Care Matters

An IACUC and ARF e-Newsletter

Fall 2008

From the IACUC Administrator — Stephanie Cook

As mentioned in last quarter's newsletter, many of the IACUC's forms, policies, and procedures are being updated. Below are updates regarding forms and usage:

- **NEW AUP FORM AND INSTRUCTIONS.** The new AUP form and instructions are now available from the website and supersede all previous versions. It becomes effective as of the November IACUC meeting. Please print out a set of instructions for future use, as they provide guidance as to what information is to be provided. Please note that the form and the instructions are posted separately. If you are planning to submit a new AUP for consideration in November, be sure to use the new form as there is a significant change in the form—**both PI and Department Chair signatures are now required on page 1.** PIs will continue to sign the Investigator Assurance on page 2.
- **PLEASE USE CURRENT FORMS** to reduce approval delays. Some PIs continue to submit AUPs or changes on old forms, requiring resubmission on current forms.
- **ARE YOU ADDING THE SAME PERSONNEL TO MORE THAN ONE AUP?** Utilize the "multiple" amendment! If you are adding the same personnel to two or more AUPs, you can fill out one amendment form and simply list the pertinent AUPs in the "AUP Number" box. Once approved, both the amendment and the approval letter are filed with each AUP. The advantage here is that there is less paperwork for all concerned.

Use of old forms continues to be an issue. Old forms require resubmission on current forms. All AUP forms and most policies can be found and downloaded from the ARF webpage under the IACUC link: *http://uscm.med.sc.edu/ARF/iacuc.html*. If you need help finding the information or guidance you need, please let us know. The ARF/IACUC phone number is 777-8106.

INSIDE THIS ISSUE:

Daylight Savings Time begins Sunday, November 2. Remember to set your clocks back !

ANIMAL ORDER DEADLINE

Thursdays @ 2:00pm is the cutoff for ordering animals needed the following week. This allows the ARF sufficient time to clarify any issues that may arise due to incomplete information from the PI as well as unforeseen vendor problems. If you are ordering animals, please make someone familiar with the order available on Thursdays to answer questions. Charlotte wants you to have your animals when you need them.

FROM THE IACUC CHAIR

With the Fall semi-annual inspections completed, a few of us have received letters regarding what were, I hope, minor deviations from IACUC policies. This round of inspections resulted in many fewer deviations of any kind. This leads me to think that we are all getting better at our work, especially regarding the regulatory end of things.

Although no one enjoys seeing his or her name on an inspection or compliance letter, we must agree that, without these inspections, some of us might not take animal care and use as seriously as we should. As it is, we are sure that our labs will be in good order at least twice a year. This is the lead-in to my next point.

It has been mentioned before that regulations are always changing and the USDA, OLAW, etc. always have their favorite areas of focus. Every few years, AAALAC or another agency begins to take a harder look at what is being overlooked in facilities around the country. Well, guess what? Post-approval monitoring and compliance are the items really being pushed these days, or so we are told by those at other universities. It really is as it should be. In terms of regulatory compliance, getting an AUP approved is the easy part.

In the upcoming months, expect more activity from the IACUC in terms of information-gathering, lab visits, verification of personnel, and so forth. View increased monitoring activities as opportunities to educate us on what is happening in your lab and any problems you are having.

- Ken Walsh

If you fax your animal order form to the ARF, you must still mail in both pages of the hard copy.

Got Compliance?

According to Dr. Andrew Jefcoat in the most recent edition of *Lab Animal* magazine (v. 37:10, Oct. 08), most noncompliance incidents can be traced back to one of three factors: 1) **lack of information**, usually rooted in a lack of training or communication among research, veterinary and regulatory personnel; 2) **desperation** due to circumstances that cause a party to knowingly neglect protocol and/or standard operating procedures, etc.; or 3) **disregard** for policies and requirements by one or more individuals who may believe that the regulatory environment is either a) increasingly unnecessary or b) interferes with the freedom to determine the "right" way to design or carry out a study. (To be fair, IACUC members and staff are sometimes believed to be petty, nit-picking "bean counters" who enjoy stopping researchers in their tracks.)

On a more positive note, there are also three components that facilitate compliance and cooperation among the various stakeholders in animal research. All of us need to keep in mind that the researcher/IACUC relationship is a two-way street with three lanes: 1) **Education** – of investigators; veterinary, research and regulatory staff; students; and IACUC members (you probably belong to more than one group). It is the responsibility of regulatory staff to educate researchers on legislative requirements and it is researchers' responsibility to educate non-researchers on the what, when and why of their needs. 2) **Assistance** – via veterinary and IACUC policies/procedures that incorporate means of handling urgent requests or issues quickly, while providing adequate monitoring to retain investigator/institutional compliance. Researchers help the IACUC by providing access to their labs as well as information regarding how the committee facilitates or impedes their work. Again, each side needs to help the other reach goals. 3) **Anxiety Reduction** – this is accomplished by seeing things from the other's point of view and realizing that neither "side" is out to thwart the other. Developing non-adversarial relationships and working as a research/regulatory to restructure processes, resolve issues and make it easier to get and keep research going.

Transgenic Animals and the Use of Recombinant DNA in Animals

FAQs for Research Subject to the

NIH Guidelines

The University of South Carolina recognizes that the use of laboratory animals for teaching and research is fundamental to advances in biology and medicine. The use of laboratory animals is subject to a multitude of laws, policies, regulations and standards. The NIH Office of Biotechnology Activities has policies regarding the use of transgenic animals and recombinant DNA in animals which may require some investigators to obtain both IACUC and IBC approval.

1. Under which section of the *NIH Guidelines* does the generation of transgenic rodents fall?

The creation of transgenic rodents falls under one of two portions of the *NIH Guidelines* depending on the containment level required to house the rodents. Experiments involving the creation of transgenic rodents that can be housed under Biosafety Level conditions are covered under Section III-E-3. Experiments involving the generation of transgenic rodents requiring BL2, BL3 and BL4 containment are covered under Section III-D-4.

2. Under which section of the *NIH Guidelines* does the generation of transgenic animals other than rodents fall?

The creation of all transgenic animals (other than rodents that can behousedunderBL1containmentconditions) is covered under Section III-D-4 of the *NIH Guidelines.*

3. Would the breeding of two different strains of knock-out mice require IBC approval under the *NIH Guidelines?*

The techniques used initially to create knock-out animals involve the stable introduction of recombinant DNA into the animal's genome, and thus these animals are considered transgenic. As the breeding of two different strains of knock-out mice will potentially generate a novel strain of transgenic animal, the work is covered under the *NIH Guidelines* and as such requires !BC review and approval. Sections in the *NIH Guidelines* that cover work with rodents include III-E-3 for work that requires Biosafety Level (BL) 1 containment and III-D-4 for work that requires BL2, BL3 and BL4 containment.

4. Is IBC registration and approval needed for the maintenance of a transgenic animal colony?

The maintenance of a transgenic rodent colony (i.e. breeding within a particular transgenic strain) at BL 1 is an activity that is exempt from to the *NIH Guidelines* and, as such, does not require mc registration and approval. The maintenance of a transgenic rodent colony at BL2 or higher falls under Section III-D-4-b and requires !BC approval. The breeding of all other transgenic animals is subject to the *NIH Guidelines* under Section III-D-4-a or III-D-4-b depending on the containment level required.

5. Is the purchase and transfer of transgenic rodents exempt from the *NIH Guidelines?*

Under Appendix C-VI of the *NIH Guidelines,* the purchase or transfer of transgenic rodents may be maintained at BLI containment are exempt from the *NIH Guidelines.* The purchase or transfer of transgenic rodents that require 8L2 or higher containment is not exempt from the *NIH Guidelines.* These animals are covered under Section III-D-4, and purchase and transfer of such animals requires mc registration and approval. It should be noted that the subsequent use of transgenic rodents may not be exempt from the *NIH Guidelines.* Experiments using transgenic rodents at BL 1 are exempt from the *NIH Guidelines* if the experiment does not involve the use of recombinant DNA. If the protocol does involve the use of recombinant DNA or is conducted at BL2 or higher then the work falls under III-D-4 of the *NIH Guidelines* and as such requires mc review and approval prior to initiation.

6. Is the purchase and transfer of transgenic animals other than rodents exempt from the *NIH Guidelines?*

No, only the purchase or transfer of transgenic rodents that may be maintained at 8LI containment is exempt from the *NIH Guidelines.* The purchase or transfer of any other animal for research purposes at any biosafety level (including BLI) is not exempt, nor is the purchase and transfer of transgenic rodents that require BL2 or higher containment.

7. Are gene ablation studies covered by the *NIH Guidelines?*

The answer to this question depends on the technique employed in the study. If recombinant techniques are used to knock out the gene, then work would be covered under the *NIH Guidelines.*

8. Who has the responsibility to review the generation of transgenic animals if an institution is generating animals for investigators who are not affiliated with that institution?

The generation (creation) of transgenic animals is an activity covered under the *NIH Guidelines.* The mc at the institution where that activity is occurring has the responsibility to review and approve that activity (if the institution is subject to the requirements of the *NIH Guidelines).* The subsequent use of the animals by investigators not at that institution would need to be reviewed and approved by the mc at the investigator's institution if that institution conducts or supports recombinant DNA research that receives NIH support and the activity covered under the *NIH Guidelines.*

9. When a core facility generates transgenic mice as a "fee for service" for Principle Investigators (PIs), is it the responsibility of the PI or the core facility to register the generation of the mice with the IBC?

Section IV-B-7-a-(1) of the *NIH Guidelines* articulates one of the responsibilities of the PI as 'initiating no recombinant DNA research which requires mc approval prior to initiation until that research has been approved by the mc and has met all other requirements of the *NIH Guidelines.'* It would be acceptable for either the PI of the core facility or the PI purchasing the transgenic ani-

mals to fulfill the responsibility to register the generation of the animals. In many cases, the animals being generated will be subsequently used in experiments that are subject to the *NIH Guidelines,* and the registration of the research with the mc may encompass both the generation and subsequent experimentation with the animals.

10. When existing transgenic animals at an institution are purchased or transferred to an investigator outside the institution, who should review and approve the use of these animals?
An institution's mc does not need to review and approve the use of transgenic animals at another institution. If the receiving institution is subject to the *NIH Guidelines* (i.e. conducts or supports recombinant DNA research that receives 1\,rrH support), then the purchase and transfer of animals (other than rodents that can be housed under BL1 containment), along with any experiments subject to the *NIH Guideline,* would require review and approval by the mc at that institution.

11. What are the *NIH Guidelines* requirements for research with large transgenic animals (sheep, pigs, etc.), or research with recombinant DNA microorganisms in such animals?
When conducting recombinant DNA work with large animals, the work is covered under Appendix Q of the *NIH Guidelines.* Appendix Q specifies containment and confinement practices when animals are of a size or have growth requirements that preclude the use of laboratory containment of animals. The *NIH Guidelines* include provisions for tracking and inventorying these animals (Appendix Q-I-B-2 states that a permanent record must be maintained of the experimental use and disposal of each animal). Animal carcasses must be disposed of as to avoid their use as food for human beings or animals unless food use is specifically authorized by an appropriate federal agency (Appendix Q-I-B-l). An acceptable method, for example, would be incineration.

12. Are recombinant DNA modifications to the somatic cells of non-transgenic animals subject to the *NIH Guidelines?*
Yes, these experiments are subject to the *NIH Guidelines.*
a) Sections III-D-l-a through III-D-l-d cover experiments using Risk Group 2, 3, 4, or restricted agents in whole animals. See the *NIH Guidelines* for the appropriate containment for such experiments
b) Section III-D-4-a covers experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. DNA from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any animal and propagated under conditions of physical containment comparable to BLl or BLI-N and appropriate to the organism under study.
c) Section III-D-4-b covers recombinant DNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals that are not covered by Sections 111-0-1 or III-D-4-a. The appropriate containment for these experiments is determined by the me.
d) Experiments not included in Sections III-A, III-B, III-C, III-D, III-F, fall into Section III-E. Experiments covered by Section III-E may be conducted at BLI containment. -The End

UNIVERSITY OF SOUTH CAROLINA

ANIMAL CARE MATTERS

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Animal Resource Facilities
School of Medicine
Graduate Science Research Center, Ste. 102
Columbia South Carolina 29208

Phone: 803/777-8106 Fax 803.777.2849 Email: stephanie.cook@sc.edu

We're on the Web !!
http://uscm.med.sc.edu/ARF/index.htm

NEW (and not so new) FACULTY attend the RESEARCH RESOURCES @ USC SYMPOSIUM

Sponsored by the Early Career Faculty Network

THURSDAY, OCTOBER 30, 2008

9:30AM-11:30AM

Russell House Ballrooms A & B

RSVP by Oct. 10 to Dr. Matt Kostek 777-1462

mkostek@gwm.sc.edu

FINE PRINT (BAD NEWS)

ARF is NOT happy that animal vendors are now adding a fuel surcharge to each shipment. These surcharges must be passed on to PIs. Please make adjustments needed in your budgets as there will notice slightly higher charges.

Animal Care Matters is published four times a year by the Institutional Animal Care and Use Committee (IACUC) and Animal Resource Facilities (ARF) of the University of South Carolina (USC).

The IACUC is an institutional body appointed by the USC President to oversee the program for the humane care and use of all vertebrate animals used for research, teaching, and training. Any investigator who intends to use laboratory animals must submit an Animal Use Proposal (AUP) to the IACUC for its review and approval.

The ARF provides care and maintenance of all animals used by investigators. Preventive care is provided through vendor animal health evaluations, quarantine programs, and sentinel animal diagnostics. Special care and services can be provided upon request.

Comments and submissions for **Animal Care Matters** are welcome and should be directed to Stephanie Cook, IACUC Administrator, at 777-8106 or *stephanie.cook@sc.edu*.

IACUC Meetings 2008

Meeting Date	AUP Deadline
Jan 10	Dec 19
Feb 7	Jan 30
Mar 6	Feb 27
Apr 3	Mar 26
May 1	Apr 23
Jun 5	May 28
Jul 10	Jun 25
Aug 7	Jul 30
Sep 4	Aug 27
Oct 2	Sep 24
Nov 6	Oct 29
Dec 4	Nov 25

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