



Animal Care Matters

An IACUC and ARF Newsletter

A New IACUC Administrator is Hired

For those of you that do not know, Benilda Pooser has left her position as IACUC Administrator at USC for a similar position at Clemson University. We would like to take the time to wish her well in her new endeavors. Animal Resources would now like to announce the hiring of Elizabeth Thames as the new IACUC Administrator/Program Coordinator for USC. Elizabeth received her Masters degree in Molecular Biology from USC in 1999. She has worked in the Department of Biological Sciences for the last 4½ years as a Research Specialist. For the last 3½ years, Elizabeth worked with Dr. Mike Dewey, where she became enthralled in animal research.

What are the responsibilities of the IACUC Administrator/Program Coordinator (IA)? One part of the job is to make sure things run smoothly at IACUC meetings. The IA is actually the first person to see your Animal Use Proposal (AUP) after you turn it into Animal Resources. The IA is likely to ask you to make changes to your AUP if she finds sections have been left blank and/or she feels like the IACUC committee will ask you to change some part of the AUP. One of the goals is to have an AUP passed the first time the IACUC committee reviews the proposal. The IA is a non-voting member of IACUC but may make comments if clarification of guidelines is needed. The IA is responsible for the minutes of the IACUC meetings and making sure the rules and regulations of OLAW, USDA, and other governing bodies are being followed. Another part of the IA's job is to publish the Animal Care Matters Newsletter. The goal is to make the Newsletter as informative and useful as possible. If you have any ideas or questions or comments about any part of the Newsletter, please contact Elizabeth (see back page for contact info).

Significant Changes to an AUP

Is a change in lab personnel a "Significant" change? A change in lab personnel has been classified as a minor change to an AUP. What does this mean for investigators? First, it means that all new personnel must contact ARF before they begin working with animals. ARF will then advise you as to the appropriate training (on-line and/or hands-on) required for your AUP. Once the training is complete then the investigator need only to make the necessary changes on the Annual Update form. One thing to keep in mind is that if a person is listed on the Annual Update form but has not gone through the appropriate training, that person **can not** be approved to work with animals. This in turn could delay your research efforts.



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Important Dates To Remember

Thanksgiving- Tues.
Nov 25- All animal
orders for delivery
the week of Dec. 1st
must be in by 2 pm.

Christmas-
Tues. Dec. 16- All
animal orders for
delivery the weeks
of Dec. 22 and Jan.
6, 2004 must be in
by 2 pm. There will
be no animal delivery
during the Christ-
mas break (week of
Dec 29).

A recent article by Moshe Shalev in the Oct. issues of *Lab Animal*, discusses the recent appropriations bill whereby Congress asked the NIH to investigate allegations of noncompliance with federal policy on animal research. The bill states "The Committee is concerned about allegations that several institutions receiving NIH funding may not be in full compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. The Committee encourages NIH to determine the extent and scope of any such allegation and notify the Committee of its findings". The bill does not mention any one institution but it does aim to strengthen the oversight of animal research institutions by both Congress and the NIH.

Research institutions are required to comply with PHS policies and provide appropriate Assurance documents to NIH before receiving PHS funds. The USDA animal welfare regulations apply regardless of the funding source. FDA regulations under the Federal Food and Drug and Cosmetics Acts must be followed as a requirement for the release of new products.

NIH Grant Policy Statement, Part II, Subpart A: 1 of 7 states "The grantee is responsible for the actions of its

employees and other research collaborators, including third parties, involved in the project." Subpart A 2 of 7 states "No NIH awards for research involving live vertebrate animals will be made unless the applicant organization and all performance sites are operating in accordance with an approved Animal Welfare Assurance and provide verification that the IACUC has reviewed and approved those sections of the application that involve use of vertebrate animals, in accordance with the requirements of the Policy."

What does all this mean for USC? In a sentence, we always need to be careful to dot our "I"s and cross our "T"s. Be sure your entire staff is trained properly. Be sure your staff follows the guide lines set forth by NIH, USDA, etc. Be sure all the appropriate paperwork has been completed. Turn in your AUPs early for a pre-review. If guidelines are unclear, ask the Animal Resource office. It is their job to help guide investigators through all the mud. Some numbers that might be of some use to you are:

- USC's PHS/NIH Assurance No. A3049-01
- USDA Registration No. 56-R-003

Rats vs. Mice

The approved AUP used Rats, but the actual work being done used mice. Is it okay to substitute one animal for another animal without an amendment to the original AUP? The answer is NO.

OLAW states "change of species is an example of a "significant change" requiring prior IACUC approval". You must submit an amendment to your original protocol or have a new AUP approved by IACUC. It is the responsibility of the primary investigator (PI) to know which animal is approved for experimental use. It is the responsibility of the PI to make sure his/her staff knows which animals are listed on the approved AUP.

Noncompliance with the above regulation can and will lead to a suspension of animal use. In addition, the investigator will most likely need NIH (Grants Management Officer) approval before the research is allowed to continue. The same may apply also to other funding agencies. Save time, money, and grief, plan ahead!

Meet the ARF Staff

Main Office- 777-8106

Dr. Robert Beattie-Director

Peg Rentz-Manager Jeff Mell- Secretary

Elizabeth Thames- IA Tim Hearn-Busi. Office

Animal Care Employees- 777-2226; SOM 733-3268

USC Main Campus

Pam - Hands-on animal training, etc.

Charlotte - Supervisor

Ann Christana

Christie Freda

Ginger Jeff

Jessica Machaka

Rebekka

SOM Campus-



Frequently Asked Questions

1. Does the IACUC need to require that the investigator submit the grant application, or portions thereof, along with the IACUC animal use protocol form for review by the IACUC? Is the IACUC required to compare the two for consistency? US Public Health Service (PHS) *Policy (Policy on Humane Care and Use of Laboratory Animals)* requires the institution to verify, before award, that the IACUC has reviewed and approved those components of grant application and contact proposals related to the care and use of animals. This position is reiterated in NIH Grants Policy Statement under Part II, Terms and Conditions. Most institutions have developed an IACUC protocol form and require investigators to provide detailed information about the proposed use to the animals on this form. The signature of the authorized institutional official on any PHS application or proposal indicates the organization's commitment to comply with the laws, regulations, and policies to which an activity is subject. Institutional submission of IACUC approval, subsequent to submission of the application/proposal, must represent approval of the information originally submitted in the application/proposal, or include notification of any significant changes required by the IACUC.

Although there is no explicit requirement for the IACUC to do a side-by-side comparison of the application/proposal and the IACUC protocol review form, it is an institutional responsibility to ensure that the information the IACUC reviews and approves is consistent with that contained in the application/proposal to be funded. Institutions are free to devise a workable mechanism to accomplish this end. One excellent way to prevent problems of inconsistencies between the information submitted to the PHS and that on the IACUC protocol review form is to implement a procedure for direct comparison. If a procedure of direct comparison is adopted, the individual(s) charged with conducting the comparison should be appropriately qualified to identify inconsistencies. Some institutions have delegated this responsibility to a particular office or position (e.g. sponsored programs office, compliance office); others have asked Departmental Chairs to verify consistency.

2. Are the scientists at our institution allowed to use non-pharmaceutical-grade chemical compounds in physiological preparations involving laboratory animals? Please clarify whether this is an allowable practice and whether it makes a difference if the compounds are used in survival versus nonsurvival experiments. The use of non-pharmaceutical-grade chemical compounds in ex-

perimental animals under certain circumstances has been, and will continue to be a necessary and acceptable component of biomedical research. OLAW and the USDA have determined that their use should be based on (1) scientific necessity, (2) nonavailability of an acceptable veterinary or human pharmaceutical-grade compound, and (3) specific review and approval by the IACUC. In preparing and reviewing proposals to use non-pharmaceutical-grade products, investigators and IACUCs should consider a number of related animal welfare and scientific issues including safety, efficacy, and the inadvertent introduction of research-complicating variables. Although one can assume that issues such as sterility, pyrogenicity, stability, pharmacokinetics, and quality control have been addressed during the course of producing pharmaceutical-grade drugs, one cannot say the same for substance produced in the research laboratory using non-pharmaceutical-grade chemical compounds. Cost savings alone do not adequately justify the use of non-pharmaceutical-grade compounds in animals. Although the potential animal welfare consequences of complications are less evident in nonsurvival studies, the scientific issues remain the same. The principles and need for professional judgment just outlined still apply.

3. Our IACUC has encountered a problem with investigators who do not submit their protocols for review in time to gain approval before the three-year expiration date. Is it permissible to grant an administrative extension of IACUC approval so as to avoid expiration?

No. For PHS purposes, IACUC review following the provisions at IV.C.2 of the PHS *Policy* must be accomplished at least once every three years. The IACUC may not extend the three-years approval by any means other than IACUC review and approval using the procedures of IV.C.2. When IACUC approval expires, it is no longer valid. Continuation of animal activities beyond the expiration is a serious and reportable violation of PHS *Policy*.





UNIVERSITY OF
SOUTH CAROLINA

Campus Mail

ANIMAL CARE MATTERS

An IACUC and ARF Newsletter

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

Phone: 803-777-8106
Fax: 803-777-2849
E-mail: elthames@gwm.sc.edu

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

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 Elizabeth Thames IACUC Administrator, at 777-8106 or elthames@gwm.sc.edu.

IACUC Meetings 2003-2004

Meeting Date	AUP Deadline
Dec 4	Nov 24
Jan 8	Dec 22
Feb 5	Jan 26
Mar 4	Feb 23
Apr 1	Mar 22
May 6	Apr 26
Jun 3	May 24
Jul 1	Jun 21
Aug 5	Jul 26
Sep 2	Aug 23
Oct 7	Sep 27
Nov 4	Oct 25
Dec 2	Nov 22

IACUC MEMBERSHIP

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Donald Allen, Ph.D.

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Joe Hick, M.D.

CONSULTANTS

Tommy Coggins
Charles Jeffcoat