

When you have finished reading this newsletter, please pass it along to others in your lab or office.

Please have all personnel in your lab initial here as evidence of continuing education and keep this newsletter in your logbook.

- AAALAC Site Visit Scheduled for UCSF in October
 - More Protocol Facts
 - IACUC Review Process
 - Who Can Authorize Modifications?
 - Expedited IACUC Policy on the Oversight of Procedure Areas
- In this Issue:

#820
Laboratory Animal Resource Center
Box 0564

Closure of a protocol (MI): IACUC professional staff in collaboration with LARC Director regarding disposition of remaining animals

Transfer of a protocol to another PI (MI): IACUC Chair.

Administrative Changes
Name additions (MI): IACUC professional staff (conditional upon successful completion of required training). Name deletions (MI) and Reduction in number of animals (MI): IACUC professional staff

Notes:

- Investigators are strongly encouraged to email their modifications (including attachments) to modifications@research.ucsf.edu
- All modification requests and approvals must be in writing.
- A signed approval memo or letter must be received by the PI before any modifications are initiated.
- An investigator requesting major changes to the experimental procedures will be asked to incorporate the changes into a complete application. ❖

(Continued from page 2)



Minor (MI): applies to changes such as a change in the PI, study title or location, addition or deletion of personnel, and minor procedural changes. **Major (MA):** in general, these apply to studies involving regulated species and/or category C, as well as major procedural changes in non-USDA regulated species or change or addition of any species to a study.

The following examples specify designated reviewers for modifications, however, the IACUC Chair may assign specific requests to any member of the IACUC:

Some examples:

Laboratory housing (MI): LARC or IACUC Veterinarian or Committee Chair/Vice Chair

Change in therapeutic medication (anesthetics, analgesics, antibiotics, etc.) (MI): LARC or IACUC Veterinary staff

Change in experimental procedure (MA or MI): IACUC

ANIMALIA

A Quarterly Newsletter for the UCSF Animal Research Community

University of California, San Francisco

Fall 2003 - Special Edition

Volume 03, Number 2

AAALAC SITE VISIT SCHEDULED FOR UCSF IN OCTOBER

AAALAC, the Association for Assessment and Accreditation of Laboratory Animal Care International, is an international organization committed to promoting humane treatment of animals in science. AAALAC accreditation is similar to the mandatory JCAHO accreditation for hospitals; however, it is voluntary and covers organizations that use animals in research, teaching or testing. Accredited organizations include universities, hospitals, government agencies, pharmaceutical and biotechnology companies, and other types of research organizations.

The voluntary application program consists of a comprehensive, strict internal and external evaluation. Before the AAALAC inspectors visit our University, UCSF must conduct a comprehensive self-evaluation and program review in order to produce a thorough Program Description document. The AAALAC program reviewers, a team of highly qualified professionals, will thoroughly review our written Program Description document prior to and during their site visit. During the final program review, UCSF will be provided with a confidential, on-site evaluation of the institution's animal care and use program.

Once accredited, UCSF must be re-evaluated every three years to maintain its accredited status.

Why attain AAALAC Accreditation?

✓ AAALAC accreditation means that an institution is serious about setting, achieving and maintaining high standards for animal care and use; AAALAC accreditation is recognized internationally as a symbol of quality.

✓ When scientific research involves animals, reliable results *depend* on superior animal care. By involving all parties in animal research (scientists, managers, staff and administrators) in

the thorough assessment of our institution's animal program, the result is improved research practices and outcomes.

✓ Our colleagues and the public want UCSF to have a well-run animal research program; voluntary AAALAC accreditation assures them and demonstrates UCSF's willingness to go above and beyond the minimums required by law to uphold a responsible and humane animal research program.

✓ Some private biomedical organizations may recommend grantees using animals in their studies be part of an AAALAC-accredited program; government agencies also view AAALAC accreditation favorably. Both private and public funding sources view accreditation as an assurance that animal use will be justified and humane, and that appropriate regulations and policies will be followed. ❖

MORE PROTOCOL FACTS

◆ Protocols may be easily *modified* by notifying the IACUC (by letter or appropriate form) and explaining the changes you need to make. Forms are located at: <http://www.iacuc.ucsf.edu/forms/awForms.asp>

◆ Protocol approval is for a one year period. If a protocol is not renewed on time, all experimental procedures must stop and animals will be transferred to the Laboratory Animal Resource Center (LARC). You cannot access your animals until you submit a new protocol for full IACUC review and approval (6 - 8 weeks process time). Accrual of per diem charges will continue and are the responsibility of the Principal Investigator.

◆ Addition of personnel cannot be completed (i.e., individual will not be added to protocol) until the person to be added has completed both the BRER and Species-Specific training requirements. ❖



IACUC REVIEW PROCESS

There are many procedures and review processes that take place from the time a protocol is submitted for pre-review, until it is approved by the Institutional Animal Care and Use Committee (IACUC). It is hoped that this article will provide insight into the activities that take place behind the scenes (e.g., packet distribution, committee review, information dissemination) during the average six weeks from protocol receipt at the IACUC Office to approval. If you have any questions, please contact the IACUC Office at 476-2197.

Approval Period

Federal regulations mandate a maximum of one year for study approvals. The IACUC will send courtesy reminders to PIs approximately 75 days before the expiration date of an approved study to allow sufficient time for renewal processing. Note: If renewal applications are not renewed and approved by the expiration date, animals will be immediately transferred to the LARC Holding Protocol for routine care. The Principal Investigator and his/her staff will not have access to the animals until the application has been approved.

Types of Review

UCSF-IACUC has adopted formalized procedures, known as "Designated Reviewer", approved by the USDA and PHS. This process allows for review of proposed activities (protocols) by less than a full Committee.

Full Committee Review: Initial applications, renewals every three years thereafter, and major changes (see below) in approved protocols are reviewed by the full committee and require completion of the Full Committee Application Form.

Designated Subcommittee Review: Applications for continuing review, that is, second and third year after initial review and approval, are reviewed by an IACUC subcommittee and require completion of the Short-Form Renewal Application Form (unless a major modification to the protocol is involved).

Urgent Reviews: Under certain rare circumstances the IACUC Chair may use the Designated Reviewer process for urgent reviews. The investigators must provide compelling reasons for these types of reviews.

Tissue Collection: The IACUC Chair may use the Designated Reviewer process for Category A protocols proposing tissue collection only.

Modification Review: If the PI wishes to make modifications to the approved protocol during its one-year approval period, these changes must be approved before they are initiated. Approval for a modification does not change the existing expiration date.

Types of Review Outcome

After IACUC review, one of the following determinations is made for each application:

Full Approval is granted when the Committee has no concerns about the application. The investigator is sent a letter with a IACUC approval number, valid for one year, and may begin the project.

Revisions Requested prior to approval is given when the members require a written response from the investigator. The members may ask the investigator to clarify a point, provide further information, or make revisions in the protocol. The investigator's response is normally reviewed by the IACUC Chair. No approval is given until the questions and/or concerns of the Committee have been satisfactorily addressed and approved by the Chair. This category was formerly known as Contingent Approval.

Returned for Additional Information prior to committee re-review is requested when serious concerns are raised and the members agree that additional information and/or justification is needed before approval can be reconsidered. The investigator's response must include a point-by-point letter addressing all concerns, as well as a revised application. The response is then reviewed by the Full Committee.

Disapproval is given when the Committee completely refuses to approve a protocol.

On rare occasions, the Committee may encounter major difficulty in making an assessment and an outside consultant with special expertise may be asked to evaluate the protocol. ❖

WHO CAN AUTHORIZE MODIFICATIONS?

UCSF-IACUC had adopted formalized procedures, known as "Designated Reviewer", approved by the USDA and PHS. This process allows for review of proposed activities (protocols) by less than a full Committee.

Modifications

Modifications are classified as one of the following two categories: (Continued on page 4, see Modifications)

EXCERPTED IACUC POLICY ON OVERSIGHT OF PROCEDURE AREAS FOR USDA COVERED SPECIES

Important: For complete policy, see IACUC website: <http://www.iacuc.ucsf.edu/Policies/awPolProcArea.asp>

Policy

Effective June 1, 2003 the Laboratory Animal Resource Center (LARC) will have oversight authority over all procedures and procedure areas for USDA-covered species. This includes animal surgical preparation, surgical, and post-surgical care and animal anesthesia for imaging and other non-surgical procedures. LARC staff will monitor or perform animal anesthesia and post-procedural recovery. Research groups may apply for laboratory staff certification. Certified staff are not subject to the requirements specified in *Oversight and Notification* below. Such staff may perform procedures for which they have been specifically certified.

Certification

IACUC and LARC recognize that there are certain circumstances in which it is acceptable to delegate provision of anesthesia, monitoring, post-procedural care and/or record keeping to the investigator or other PI designated personnel. Certification may be granted by the IACUC to qualified individuals. Certification may contain conditions or be limited by procedure or species.

Application Process

Existing Protocols and Personnel
The Principal Investigator must submit a "Request to Obtain Approval for Personnel to conduct Procedures" form to the IACUC for review and approval.
Note: Upon implementation of the Policy only individuals with a written IACUC approval may conduct any surgical or anesthetic procedures or post-procedural care on USDA covered species.

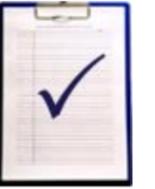
Addition of New Personnel to Existing Protocols
Complete Request to Add Study Personnel form to add personnel to your approved protocol and submit to IACUC Office.

New Protocols

In order to obtain a delegation of authority for new protocols, the Principal Investigator must complete the Part 2-A of the "Application to Use Vertebrate Animals in Research and Instruction" providing all the relevant information for each individual and procedures.

IACUC Review

The IACUC will review each application for parameters that include:



- Training and experience of personnel
- The type and complexity of procedures for which exemption is requested
- Frequency with which the laboratory conducts procedures
- Compliance history of both the laboratory and individual(s) involved
- Special circumstances (e.g. need to transport animals, etc.)

Based on the criteria listed above, the IACUC may:

- Approve the request subject to specific conditions
- Disapprove the request. The IACUC will notify the PI in writing as to the reasons why

Monitoring

IACUC staff have been authorized to conduct unannounced audits of all animal procedure and post surgical-care activities at UCSF. Therefore, investigators with approval to conduct anesthesia, monitoring, and/or post-procedural care are required to notify IACUC at least 24 hours prior to initiation of a surgical procedure. Notification can be made by calling the IACUC Office at 476-2197.

Oversight and Notification

LARC procedural oversight requires that Investigators **MUST** obtain an approved surgical time through LARC. At least **three business-days** before the surgery, a LARC veterinary professional and the investigator should meet to discuss and agree upon procedure planning, suggested diagnostics, post-procedural care, proper documentation and adequate LARC staffing.

For purposes of this policy IACUC veterinary professionals are included within the definition of LARC. Note: Deviation from this policy or approved exemptions is considered a serious violation of UCSF policy and will be subject to disciplinary action by the IACUC.

