

In This Issue

(CTRL + click to follow link)

- Notes from the Chair: Jawed Fareed, Ph.D.
- Hot Topic - AAALAC
- PRIM&R 2007 Conference
- IACUC Protocol to Grant Proposal
- Post-Approval Monitoring (PAM)
- IACUC Semi-Annual Inspection Report
- IRB/IACUC Seminar
- IACUC ACORP Form
- IACUC Training Info
- Upcoming Meetings
- ALTBIB
- OLAW
- USDA
- LAWTE
- CMF News
- Questions

Useful Links

(CTRL + click to follow link)

OLAW
Frequently Asked Questions (FAQs)

NABR
National Association for Biomedical Research

Notes from the Chair - Jawed Fareed, Ph.D.

The academic year 2006-2007 is near term on June 30th, 2007. Usually at this time, we have many of our faculty colleagues relocate and incoming faculty join us. The IACUC is required to keep a record of the outgoing faculty and the appropriate paperwork for the closure or transfer of the outgoing faculty protocols. At times these ACORPS are transferred to another faculty member to assure the animal research continuation for a graduate student or an ongoing program. There are specific guidelines for the closure as well as transfer/qualified continuation of the ACORPS. The IACUC office is prepared to assist our faculty colleagues to facilitate any transition related to their ACORPS.

For the incoming new faculty, the IACUC will conduct a special session to brief on the institutional policies and procedures at Loyola for the use of animals in research. Loyola IACUC is federally mandated oversight for the proper use of animals in research with the following responsibilities:

- Reviewing of animal use protocols.
- Reviewing significant changes to protocols.
- Evaluating institutional compliance with PHS policy, USDA, (US Department of Agriculture).
- Animal Welfare Regulations and our Institutional policies.
- Periodic monitoring of the institutional animal care and use programs, including inspecting animal facilities at Loyola and satellite facilities.
- Reviewing concerns related to animal care use.
- Reporting non-compliance and suspect ions to the Office of Animal Welfare, OLAW.

In addition, the IACUC with CMF (Comparative Medicine Facility) will organize training programs in a specific area for the investigators to facilitate their animal research application processing and approval. The following tips may be helpful:

- Describe proposed use of animals in grant/contract applications.
- Obtain IACUC approval prior to using animals and prior to implementing significant changes.
- Insure research is conducted in accordance with the protocol.
- Comply with institutional policies and procedures.
- Address significant changes to the use of animals in progress reports.
- Address the use of animals that may be a potential change in the scope of project.

The following website can be used to get additional information regarding the writing of an application involving animal research:

<http://www.niaid.nih.gov/ncn/clincial/researchchanimals/tutorial/index.htm>

The current ACORP form has undergone revisions with the input of our faculty colleagues. This form has incorporated several of the suggestions made by our colleagues to streamline the submissions. Dr. Ginsburg and his subcommittee have done a lot of work to revise the

NIH

Comparison of IACUC Protocols to Grant

TRAINING

Online Training Website

Contact Us



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ACORP and make it user friendly. Hopefully, this form will be investigator friendly and will facilitate the submissions. The IACUC welcomes any suggestions on the newer form which will be made available soon after initial testing.

In the last week of March 2007, the animal PRIM&R meetings were held in San Diego, CA. Dr. Valero and other members of ORS attended this meeting and have brought copies of educational materials and important educational documents. In particular, post-approval monitoring, grant matching, managing qualifications and biohazard topics were highlighted in these meetings. Some of this information is available on CDs in the IACUC office. The investigators are welcome to review these.

We wish Dr. Jody Brewer all the best for his new position at the University of Alabama. Dr. Brewer has served the IACUC for the past several years in various capacities. He was a member of the CC Subcommittee and contributed to several of our programs including the inspections. The IACUC is thankful for all the good work. We look forward to our continued collaboration with him.

[Return to top](#)

Hot Topic - AAALAC International

AAALAC International (the Association for Assessment and Accreditation of Laboratory Animal Care International) is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. More than 700 institutions around the world have earned AAALAC International accreditation, demonstrating their commitment to responsible animal care and use. They include universities, hospitals, government agencies, pharmaceutical and biotechnology companies, and other types of research organizations. AAALAC has been working to promote animal well-being and enhance life sciences research and education since 1965.

AAALAC International will be visiting our institution on Thursday, July 26, 2007 to renew our accreditation. The AAALAC inspectors will visit the CMF areas and PI laboratories, interview CMF and research personnel, meet with IACUC members over lunch and finally, conduct an exit interview with Drs. Lee and Kennedy. More details to follow.

Link: <http://www.aaalac.org/index.cfm>.

"AAALAC International i-brief" - (short for "Issue Brief"), a new publication from AAALAC International. The i-brief is designed to help clarify specific elements of one of AAALAC International programs, and is published as a service to accredited institutions.

The first issue addresses the "Suggestions for Improvement" (SFIs) that are sometimes offered by AAALAC's Council on Accreditation in their final site visit reports. This publication is helpful in answering common questions related to SFIs, what they are, their purpose, how to deal with them, and how they can benefit our program.

Link: http://www.aaalac.org/ibrief/AAALAC_i-brief_SFIs.pdf

[Return to top](#)

PRIM&R Conference

Public Responsibility in Medicine and Research (PRIM&R) is dedicated to creating, implementing, and advancing the highest ethical standards in the conduct of research.

Acknowledgement

Special Thanks to:
Rose Buesing, BS

Since 1974, PRIM&R has served the full array of individuals and organizations involved in biomedical and social science/behavioral/educational research. Members of the PRIM&R community include professionals representing human and animal research protection programs, as well as researchers, institutional officials, government personnel, subject advocates, ethicists, policy makers, pharmaceutical and biotechnology leaders, and attorneys. Materials and Handouts from the PRIM&R conferences held in San Diego, CA, March 24-27, 2007 can be found at:

Link: http://www.primr.org/education/2007_IACUC/handout_center_IACUC07.html
(password – “iacuc07”)

[Return to top](#)

Comparison of IACUC Protocol to Grant Proposal

As part of the Office of Research Response to an OLAW letter dated March 13, 2007, a link has been added in the Portal Research Channel for IACUC reviewers and staff so that information in the grant and the protocol is congruent.

“PHS Policy and the NIH Grants Policy Statement ([Part II, Terms and Conditions](#)) require the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. There is not an explicit requirement for the IACUC to do a side-by-side comparison of an application/proposal and the IACUC protocol. However, institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with what is in the application/proposal.”

[Return to top](#)

Post-Approval Monitoring (PAM)

Post-Approval monitoring will be implemented to assist the IACUC and PI's in maintaining compliance. Details will be sent in a separate announcement.

“Monitoring of animal care and use is required, though neither the PHS Policy nor the [Guide](#) explicitly address or require specific or separate post approval monitoring (PAM) procedures to compare the practices described in approved protocols and SOPs against the manner in which they are actually conducted.

IACUCs are charged, however, with program oversight and as such are responsible for program evaluations, reviews of protocols, reporting noncompliance, ensuring that individuals who work with animals are appropriately trained and qualified, and addressing concerns involving the care and use of animals at the institution. The veterinarian with program authority and responsibility for animal activities along with the animal care and technical staff, add another important level of program supervision.

Related components of institutional programs provide monitoring by a multi-disciplinary team of individuals. Examples of such components include daily observation of animals by trained animal care personnel and communication to the veterinary staff for follow-up, facility monitoring by facility maintenance personnel, post operative care by trained personnel, evaluation of outcomes of animal procedures by investigators and staff, hands-on training in animal procedures, and appropriate reporting of incidents involving occupational health and safety. All of these functions and responsibilities imply a level of monitoring. Ultimately the institution has flexibility in how it achieves compliance.

The institution may develop a PAM program with dedicated staff that physically monitors

procedures and practices associated with animal use protocols. This is one acceptable method that institutions may elect to adopt, but it is not a federally mandated requirement. Whatever methods an institution incorporate, it is important that the authority and responsibility of the IACUC not be contravened by a PAM program, institutional compliance officials, or other mechanism established to monitor animal care and use.”

[Return to top](#)

IACUC Spring 2007 Semi-Annual Inspection Report

The IACUC inspected the animal facilities on March 06 and 07, 2007 (Bldg 102), March 14, 2007 (EMS, Bldg. 110), March 21, 2007 (Bldg. 105) and March 28, 2007 (CBCC, Bldg. 112) using the *Guide*, and, as applicable, 9 CFR Chapter I, 2.31. The PI labs were inspected on April 03 and April 09, 2007.

A number of significant and repeat minor deficiencies were noted. The IACUC Inspection Sub-Committee, IACUC office and CMF staff will conduct periodic inspections and communicate with research staff about the need to correct deficiencies as soon as they are identified. Occasionally we have surprise inspections. Please contact the IACUC office for details of the listing in your area.

Two of the concerns listed on the report:

1. May investigators use expired pharmaceuticals, biologics, and supplies in animals?

“The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal. Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study. The veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals.”

Please write “Do Not Use” on expired drugs while waiting to dispose them. We will provide you the mechanism for disposing of expired drugs properly. Expired drugs need to be disposed properly by the PI and/or will be confiscated by the IACUC and CMF inspection team at subsequent inspections. Please contact us to remove your expired drugs if you are uncertain.

2. Certification of fume hood and vaporizer of anesthesia machine must be current, regularly maintained and serviced by authorized agent or personnel.

[Return to top](#)

IRB/IACUC Seminar

“Step by Step Approach on how to complete a successful IRB and IACUC application - Some common mistakes and how to avoid them” was presented on April 25, 2007. Please contact the IACUC office for details and copies of materials presented.

[Return to top](#)

IACUC ACORP Form

The revised Routing Form will allow PIs to submit ACORPs without approval from their Department Chair. The IACUC approval date of an ACORP, however, requires department chair approval to be entered in the Portal. Research cannot be started until the routing form is signed off by the chair.

The ORS IT team has informed the IACUC that the ACORP Form will undergo revision in the summer of 2007. More details to follow.

Grant Administrators were added to the IACUC notification e-mails (Approval, Annual review and Termination submissions) on April 17, 2007.

[Return to top](#)

IACUC Training Info

The VA – www.ResearchTraining.org website has transferred to the AALAS website – www.aalaslearninglibrary.org. Our institution no longer has access privileges for the VA's ResearchTraining.Org website. AALAS has kindly agreed to host the existing courses and registrations on this website at no cost until September 14, 2007.

“The AALAS Learning Library (ALL) provides training that is essential for technicians, veterinarians, managers, IACUC members, and investigators working with animals in a research or education setting.

Emphasizing the appropriate handling, care, and use of animals, the courses are designed to help you study for AALAS certification, meet training mandates of regulatory agencies, and improve your knowledge in technical areas.”

We are in the process of changing the IACUC training program to AALAS Learning Library (ALL). More details to follow.

[Return to top](#)

Upcoming Meetings

Meeting the Information Requirements of the Animal Welfare Act: A Workshop

The objectives of the workshop are to provide:

- An overview of the AWA and its information requirements;
- A review of the alternatives concept;
- A comprehensive introduction to NAL, AWIC and other organizations;
- Instruction on the use of existing information databases/networks; and
- On-line database searching experience.

October 24-25, 2007

National Agricultural Library
10301 Baltimore Avenue
Beltsville, MD 20705-2351
(301) 504-5755

Link:

http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=1&tax_subject=188

2007 AWEN-MSMR IACUC-IBC-IRB Conference Continues the Dialogue on Harmonization

In June 2006, partnering with the Massachusetts Society for Medical Research (MSMR), The AWEN Group presented a groundbreaking two-day international conference -- BRINGING THE "I's" TOGETHER: *Toward IACUC, IBC and IRB Harmonization* -- that opened a dialogue on common ground areas among these three vital institutional committees.

AWEN will continue the dialogue in Waltham, MA, on June 14-15, 2007 with its 2nd annual BRINGING THE "I's" TOGETHER conference. Details and registration are available at the [MSMR website](#).

[Return to top](#)

ALTBIB – Literature Searches

ALTBIB - Bibliography on Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing.

"The intent of this bibliography is to assist in identifying methods and procedures helpful in supporting the development, testing, application, and validation of alternatives to the use of vertebrates in biomedical research and toxicology testing.

This bibliography is produced from MEDLINE database searches, performed and analyzed by subject experts from the Toxicology and Environmental Health Information Program (TEHIP) of the Specialized Information Services Division (SIS) of the National Library of Medicine (NLM)."

The key words "Species" and "Alternatives" must be used as search terms as part of the Literature Search.

Link: <http://toxnet.nlm.nih.gov/altbib.html>

[Return to top](#)

OLAW

The Office of Laboratory Animal Welfare (OLAW) provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

We have instituted the use of the OLAW incident report form presented at the March 24, 2007 PRIM&R conference and conform under the Guidance of the OLAW Notice Number: NOT-OD-05-034; "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals.

Link: <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html34.html>

[Return to top](#)

USDA

“Protecting American agriculture” is the basic charge of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of animals and plants. The agency improves agricultural productivity and competitiveness and contributes to the national economy and the public health. Revised USDA APHIS Animal Care Policy.

Link: <http://www.aphis.usda.gov/ac/publications/policy/policy15.pdf>

[Return to top](#)

LAWTE

The Laboratory Animal Welfare Training Exchange (LAWTE) is an organization of people who train in and for the laboratory animal science field. By sharing ideas on methods and materials for training, our members can learn together how best to meet the training and qualification requirements of national regulations and guidelines.

Link: <http://www.lawte.org/index.htm>

[Return to top](#)

CMF News

An approved ACORP (LU#) is issued a P/D#. The IACUC office needs the Account# from the PI or Grant Administrator for the ACORP to be issued an IACUC#. The IACUC# is needed so the approved ACORP animal information can be entered and linked to the CMF website. Once linked, PI and research staff can order animals. Please contact the IACUC office if the funding becomes available to an approved ACORP.

[Return to top](#)

Do You Have Questions or Concerns?

Jawed Fareed, IACUC Chair and staff of the IACUC (Tony Valero and Cheryl Paulus) will be happy to answer any questions from our faculty or research staff on animal research-related issues and clarify IACUC procedures. Please send us your questions and we will promptly respond.

[Return to top](#)
