Spring 2013

Remember the tragic story of the UCLA research assistant who was killed from burns suffered while working in the laboratory? Although it was available, she wasn’t wearing a lab coat— something that might have saved her life.

The associate professor in whose lab the RA worked has been charged and faces up to nearly 5 years in prison. The prosecution has emphasized that the PI is responsible for the health and safety of those working in the lab, for providing adequate safety training, and for providing and mandating the use of appropriate personal protective equipment (PPE).

We get an influx of trainees and new researchers as we move into summer and it’s critical that they receive safety training and that you document the training. It’s also getting warm and that means we tend to have bare skin. Remember lab coats, gloves, and other protective apparel are there for a reason and could save your life.

If you have a suggestion that will help us to help you, please contact us at research.compliance@uc.edu.

Jane Strasser, PhD
Director, UC Office of Research Integrity
Research Compliance Officer
Research Integrity Officer

IN THIS ISSUE:
Spotlight On: Conflicts of Interest
IACUC News
IRB News/New or Updated HRP Policies and Procedures
Quality Improvement Tips for Investigators
Biosafety News
Radiation Safety News
Educational Opportunities

SPOTLIGHT ON: CONFLICTS OF INTEREST

Conflicts of Interest

Mandates for reporting and managing potential and/or perceived conflicts of interest are increasing. To comply with the federal mandates and to ensure high ethical standards and responsible research practices, UC is strengthening its disclosure review processes. As Conflicts of Interest Director, Holly Bante, PhD facilitates and oversees the review, disclosure and reporting of conflicts of interest in research. Bante supports the Conflict of Interest Committee and provides guidance to investigators who require a conflict management plan. She also works closely with the Office of Entrepreneurial Affairs and Technology Commercialization to create conflict management plans related to the investigator’s technology-based startup companies. If you have questions regarding how potential conflicts of interest are reviewed at UC or how your outside activities may relate to your UC research, please contact Bante at holly.bante@uc.edu or 513-556-5501.

- back to top -

IACUC NEWS

AAALAC Site Visit

We would like to thank everyone for their participation in the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) site visit. The site visitors were
impressed by the knowledge and skill of the researchers with whom they interacted. Your commitment to animal welfare is essential to UC's ongoing accreditation.

**Protocol Submission Process Reminders**

To ensure the timely processing of IACUC protocols, please keep the following items in mind when you submit your protocol.

- Protocol renewals must be submitted at least three months prior to expiration.
- Protocols should be emailed as a Microsoft Word document to iacuc@ucmail.uc.edu.
- Associated forms include:
  - Endorsement page (with PI and Chair signature)
  - Addition of personnel
  - Satellite location requests
  - Exception to IACUC policy requests
  - Addendum A & B
- Please ensure that all associated forms are included in the initial email.
  - Whenever possible forms should be sent as signed and scanned PDFs; if scanning is not possible, please ensure that the signed forms are promptly sent via campus mail.

**Limited Modification Submission Process Reminders**

To ensure the timely processing of limited modifications (e.g., changes in contact information, changes in animal age, changes in disinfection methods, etc.; for more details see IACUC Policy #023) to your approved protocol, please keep the following items in mind:

- Limited modifications must be signed by both the PI and a LAMS veterinarian prior to submission to the IACUC office.
  - Whenever possible forms should be sent as signed and scanned PDFs; if scanning is not possible, please ensure the signed forms are promptly sent via campus mail.
- The following are not allowable as limited modifications:
  - Changes resulting in an increase in the pain category
  - Additions to the numbers of animals used
  - Changes in the overall scientific justification or purpose of the protocol

**Implementation of the Updated AVMA Guidelines for the Euthanasia of Animals: 2013 Edition**

(OLAW Notification 3/1/13)

New euthanasia guidelines have been published (NOT-OD-13-048) and provide guidance to Public Health Service (PHS) awardee institutions on implementation. As an institution receiving PHS funds we must begin using the 2013 guidelines when reviewing research projects as soon as possible, with full implementation by September. Previously approved projects undergoing continuing review according to PHS Policy, IV.C.5., must be reviewed using the 2013 Guidelines before September, 2013. The NIH is seeking input from the public regarding the updated guidelines. Input can be submitted electronically at http://grants.nih.gov/grants/olaw/2013avmaguidelines_comments/add.cfm?ID=32. Comments must be received on or before May 31, 2013.

**#028 Transfer of Animals to LAMS Holding Protocol**

As a reminder, the following use limitations apply to animals held under the LAMS Holding Protocol:

- Animals may not be used for experimental procedures.
- Standard breeding and weaning may occur.
- Special feed and water, genotyping and identification may be used but must be done by LAMS or under LAMS direct supervision
- Other procedures may only be performed with IACUC approval.
- Animals may be euthanized by LAMS staff if the animals are no longer needed.
- Animals may not be euthanized for research purposes.
- No tissues may be utilized from animals euthanized without specific IACUC approval.
- Approved activities must be performed by LAMS staff or under their direct supervision.

- back to top -

**IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES**

**NCI Informed Consent**

The National Cancer Institute (NCI) recently completed a two-year initiative to revise the NCI informed consent template. Various working groups were asked to develop a consent template that fulfilled all
regulatory requirements while allowing investigators to draft a shorter, more concise and understandable consent form. The groups consisted of patient advocates, institutional review board (IRB) chairs, central IRB (CIRB) chairs and members, clinical research associates (CRAs), investigators, nurses and cooperative group regulatory and protocol development staff, and consulted with individuals from the U.S. Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP). While some aspects of the NCI consent form template are specific to oncology studies, much of the language and formatting is also applicable to any consent form. The revised NCI Consent Form Template and a description of the initiative are posted on the CTEP website at http://ctep.cancer.gov/protocolDevelopment/. Please take the time to review this information to see how you can apply it to improving consent forms used in your studies.

CITI Refresher Training and Expiration Dates
All CITI expiration dates fall on December 31 of the expiration year. Completion Reports may show a different date but that does not matter. Three CITI courses need to be renewed every three years:
- Academic and Regional Health Centers Core Curriculum
- Good Clinical Practice
- Human Subjects Research Core Curriculum
Other courses never expire.
CITI will send reminder emails to people whose training is due to expire starting at six months before expiration, then four months, two months, one month and one week before expiration; the reminders will continue until the refresher is completed or approval expires. The refresher modules will be available when the six-month reminder email goes out. They will not be accessible before that.
To ensure that you receive the reminders from CITI, remember to keep your email address current, add CITI to your safe senders list or monitor your spam/junk mail folder.

ePAS Tips
The following are some helpful reminders for IRB submissions using ePAS.
1. The final step for all submissions is the “Submit” button under My Activities. As you go through the forms, the final page has a “finish” button. This is just to indicate you have completed all the forms. The “Submit” button is the activity that sends it for review.
2. When providing additional information in response to follow up questions, please note:
   a) You have to make the requested follow-up changes to the form.
   b) Respond to each of the Reviewer Notes (it can be as simple as “Done”).
   c) Click “Submit Changes to IRB” under My Activities.
3. All consent documents should use the ePAS header templates (get templates)
4. All research staff must log in and “Agree to Participate” prior to submission of a study.
   a) The person completing the submission can send the Agree to Participate instructions under My Activities, this will send an email from the system to everyone listed.
   b) Additionally when you login, you can go into the study and under My Activities click the Agree to Participate button and follow the prompts.

ClinicalTrials.gov
Still have questions about ClinicalTrials.gov? Check out NIH's FAQ's for clinical trials registration: http://grants.nih.gov/clinicaltrials_fdaaa/faq.htm#836.

QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS
Tip 1: FDA does not consider a dietary supplement, including a nutraceutical, to be a drug. Dietary supplements therefore are not subject to the premarket approval requirements unless the intended use for which it is being studied or will be marketed is for a therapeutic purpose. In the event that a clinical investigation is intended to evaluate the dietary supplement’s ability to diagnose, cure, mitigate, treat or prevent a disease, then an IND application is required. This is the case even if there is no commercial intent. The regulatory basis for exemptions from the IND requirements on investigator-initiated studies needs to be documented within the study file. For more information see the FDA website (http://www.fda.gov/downloads/Drugs/Guidances/UCM229175.pdf).
Tip 2: When establishing the design and development plan for an investigational medical device, confirm the classification using the FDA classification database. Identify predicate devices already cleared for market by FDA using either the 510(k) Premarket Notification database or the Premarket Approval database.
Tip 3: Include institutional policies and procedures for research with humans as part of the training for key
personnel to ensure awareness and ongoing compliance.
http://ahc-sharepoint.uc.edu/hrp_policies/HRP%20Policies/Forms/Public.aspx

Tip 4: When outsourcing aspects of medical device development, a thorough evaluation of vendors can help prevent noncompliance with regulatory requirements. When developing a qualification process, include a site audit of the potential vendor’s facility. This may be performed on or off site depending on the nature of the services required. Once a vendor has been approved, ensure there is periodic monitoring in place to identify and address potential/actual deficiencies. For further assistance contact researchcompliance@uc.edu.

Tip 5: When making changes to the informed consent form, carefully consider the need to re-consent research participants. It is the investigator’s responsibility to provide research participants or their legally authorized representatives with new information that may influence a participant’s willingness to continue in the research throughout the course of the study. This is described in UC Institutional Review Board Policy II.01 and CFR 50.25(b)(5).

BIOSAFETY NEWS
Dual Use Research and Dual Use Research of Concern
Some scientific and technological advances that provide great benefits to society can also be used maliciously. For example, research on the origins of virulence, the development of vaccines, and the genetic manipulation of biological agents are simultaneously relevant to public health and to biological weapons. Research yielding new technologies or information with the potential for both benevolent and malevolent applications is referred to as "dual use research."
The small subset of life sciences research with the highest potential for yielding knowledge, products, or technology that could be directly misapplied to threaten public health or national security is referred to as "dual use research of concern (DURC)."
Managing dual-use science requires the involvement of the research community. It can be argued that scientists not only have a moral obligation to prevent the misapplication of research technologies or findings; they are also in the best position to understand the potential for misuse.
A short video discussing dual use research is posted on the NIH Office of Biotechnology Activities’ (OBA) website.

DURC Oversight
The Federal government has developed a policy for oversight of DURC including an institutional requirement to review research and research proposals to identify those that qualify as DURC and to ensure that acceptable risk-reducing mitigation plans are in place.

Disposal of Materials Containing Recombinant DNA
Although recombinant DNA by itself is not an infectious item, the NIH/OBA requires that materials containing recombinant DNA (including transgenic animal carcasses) be disposed of as hazardous biologic waste. For more information on disposal of these items, please go to http://www.ehs.uc.edu/Advisories/Advisory_10_2.PDF.

NEWS FOR RADIATION USERS
Learn about protecting vacuum lines from contamination, complete surveys, and answer audit questions in the April 2013 Radiation Safety Newsletter.

EDUCATIONAL OPPORTUNITIES
SAVE THE DATE! Human Subjects Protection Conference
The 15th annual regional Human Subjects Protection Conference is September 20, 2013, at the Northern Kentucky Convention Center. This conference will have great presentations on the role of engaged and empowered patients in medical research, protecting research participants in the digital age, improving communication between IRB and investigators, human subjects protection issues in translational research, and informed consent in behavioral research and more.