GETTING RID OF UNWANTED CHEMICALS
To promote their removal, the university has identified limited resources to fund an amnesty on chemical removal fees. To qualify for the amnesty you must submit an inventory of the chemicals that you would like removed no later than March 18, 2016. The template is available at http://researchcompliance.uc.edu/Libraries/Compliance_Matters/Unused_Chemicals.sflb.ashx Please submit your completed inventory spreadsheets to https://ehs.uc.edu/chem_upload/chem_upload.aspx. EH&S (556-4968) can answer any questions that you have about the inventory process. Sincere thanks to those who have already completed the inventory.

AAALAC SITE VISITORS HERE MARCH 7-9
Our animal care and use program will be inspected next week. Site Visitors will be reviewing all aspects of the program including walking through LAMS and satellite facilities. They are here to assess our entire program, to make us better, not to cite you. They may ask questions that don’t apply to you, it’s okay to not know everything; however, you should be able to answer questions about your protocol, training, etc. If you want to hear the Site Visitors’ assessment, they are scheduled to present a public “closeout” from 3:00-4:00PM on Wednesday March 9th in the Vontz Auditorium. For more information about AAALAC, please see the Animal Care and Use section of this newsletter.

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

Jane Strasser, PhD
Associate Vice President for Research
Director, UC Office of Research Integrity
Research Compliance Officer
Research Integrity Officer

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ANIMAL CARE AND USE PROGRAM UPDATE

AAALAC Site Visit (March 7-9, 2016)
The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) website has a list of resources with information about accreditation; ALN Magazine has additional information about site visits. PI’s are strongly encouraged to review their currently approved IACUC protocol(s) with all individuals working on the protocol.
Guidelines for Use of Drugs and Medical Supplies in Animals

The regulations state that expired drugs, materials, and devices cannot be used in animals. As described in IACUC policy #004, all drugs and medical materials/devices that are intended for use in live animals must be marked with an expiration date. For materials that don’t have a manufacturer’s expiration date (e.g., syringes, needles), it is assumed the material is sterile if the package is not opened or damaged. Remember, all dilutions and mixtures made from a drug must be discarded as specified by the manufacturer and documented in your IACUC protocol, as the chemical composition of a drug may change and could alter its shelf life. Expired drugs must be clearly labeled “For in vitro use only” and stored in a physically separate location from items used in vivo. If their use does not adversely affect the animal’s well-being or compromise the validity of the scientific study, the IACUC may approve an exception to IACUC policy #004 to use expired medical materials/devices. If approved, expired materials must be segregated from other supplies to avoid unapproved use; additionally expired materials and devices must be labeled with: (1) IACUC protocol number(s), (2) expiration date, and (3) “for non-survival use only”. Pharmaceutical grade compounds or drugs must always be used, even in acute procedures, unless that grade is unavailable. In the event that the use of non-pharmaceutical drugs is required, an exemption form (Addendum B) must be submitted to and approved by the IACUC.

If you have any questions about the use of drugs and medical materials/devices with your research animals, please contact LAMS or the IACUC office.

New Animal User Training

To streamline the addition of new personnel, we recommend registering for LAMS training when you register for IACUC Orientation. This will prevent delays in approving new personnel. For more details concerning registration and flow of events please visit: http://researchcompliance.uc.edu/IACUC/TrainingAndPersonnel/trainingschedule.aspx

BIOSAFETY NEWS

Incident Response and Reporting
Research involving biological hazardous materials carry intrinsic risk for an accidental exposure. Accidents happen so it’s important to have incident response procedures in place. To comply with institutional and federal reporting requirements, UC personnel are required to report any incident (e.g. inoculation, ingestion, skin and mucosa contact, inhalation, spills) involving a biohazard and/or recombinant or synthetic nucleic acid materials. Incident reporting is solely intended to help improve workplace safety. A new section on incident response and reporting has been added to the website and is available at http://researchcompliance.uc.edu/Biosafety/Incident.aspx.

EXPORT CONTROLS UPDATE

The Export Controls regulations are complex and confusing; these new regulations require that we rethink things that we have done for years. If you are travelling or shipping things internationally; or if you work with restricted and/or proprietary items or information there may be restrictions of which you are unaware. To protect both you and the university the Export Controls Office (ECO) monitors this changing regulatory landscape and can answer questions, provide guidance, help developing technology control plans, and apply for licenses. The ECO is here to help. For more information visit the Export Controls website or contact the ECO Director, Tara Wood, at 513-556-1426 or exportco@uc.edu.
Reducing Administrative Burden

Many events do not need to be reported to the IRB until continuing review. Per HRPP Policy Number: II.02, “Reporting to the IRB: Unanticipated Problems Involving Risk to Participants or Others, Adverse Events, and Other Problems” the following events do not require prompt reporting:

- Protocol deviations or violations not involving risks to participants or unlikely to recur
- DSMB reports, interim analyses, or other reports, findings, or new information not altering the risk/benefit profile
- Investigator Brochure updates not involving safety information

These events should be reported with the annual continuing review of the protocol. Reporting of these events as they occur increases the burden on the researcher and doesn’t impact participant safety. Effective April 1, 2016, these reports will be returned to the investigator to be withdrawn if they are submitted outside of continuing review. If you are unsure whether an event should be reported, please contact your HPA for assistance.

Emergency Use of a Drug or Device

If a drug or device is administered without prior IRB approval (which can only be done to prevent serious harm to a patient), then it must be reported to the IRB with a separate emergency use submission or a reportable event in ePAS. Following submission, send an email in Outlook to notify your HPA of the submission.

Tip #1
Reporting requirements for each research site may vary depending on the IRB, sponsor, departmental SOPs, and requirements of individual medical facilities. Research sites should discuss potential contradictions or conflicts during staff meetings. To prevent misunderstandings during quality assurance reviews, include documentation in the study file justifying reporting determinations for events such as unanticipated problems.

Tip #2
When conducting an inpatient research study, consider performing a practice or “dry run” before starting recruitment efforts in order to ensure that the details of study procedures are complete and accurate.

Tip #3
The principal investigator is responsible for the conduct of the clinical trial at the research site including the selection and training of qualified staff to perform trial related duties. To facilitate the process of selection and training study personnel, principal investigators should be knowledgeable in how to prepare and maintain accurate records, assess and report adverse events, and maintain compliance.

RADIATION SAFETY

Relocation of the Radiation Safety Office
The Radiation Safety Office is moving to the Medical Sciences Building (MSB). Their offices and labs will be in/near 5451, 5452, and 5351 MSB; phone numbers and mail location will remain the same.

Annual Occupational Dose Record
The RSOf provides an Occupational Exposure Report annually to individuals who wear dosimeters. The reports are received by the RSOf between March and April and are distributed with the April or May dosimeters. If you have questions about your report, please contact the RSOf at 558-4110.