Winter 2016

Happy New Year! This newsletter is for you. Let us know what you do/don’t find helpful; what you want to see/learn more about. Our goal is to provide you with the information and support that you need to perform your research successfully, safely and responsibly.

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**ANIMAL CARE AND USE PROGRAM UPDATE**

**NEW IACUC REQUIREMENT: Online Temporary Transfer Form / Revision to IACUC Policy 029**
The IACUC has approved a revision to Policy 29 “Transfer of Animals between UC Approved IACUC Protocols”. Researchers must submit the form at least 24h hours prior to initiating a temporary protocol transfer. Information for the submission process can be found at: [http://researchcompliance.uc.edu/IACUC/QuickForms/TempTransferInfo.aspx](http://researchcompliance.uc.edu/IACUC/QuickForms/TempTransferInfo.aspx)

**AAALAC Site Visit (March 7-9, 2016)**
The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) will be onsite March 7 - 9, 2016. The AAALAC website has a list of resources that provides information on the purpose and value of AAALAC accreditation. Click on the hyperlink for additional information on AAALAC Site Visit Preparation from ALN Magazine. PI’s are strongly encouraged to review their currently approved IACUC protocol(s) with all individuals working on the protocol.

**Handling rodent cages**

- Any cage that has held or housed a rodent for any length of time is considered dirty. Once a cage leaves clean side cage wash, it cannot return there without going through cage wash
- When returning a cage to the designated cage drop location (when removing a dirty cage), researchers must ensure that nothing remains in the cage except dirty bedding, nestlet material, enrichment objects, discarded diet and/or a water bottle. It is your responsibility to check, and double-check if necessary, for any other objects in the cage. Leave your empty, covered dirty cages on the designated cart(s) for your facility. Please contact LAMS if you have any questions
- All rodent cages (clean or dirty) must be kept covered with a filter/solid cage top (filter top must be used if animals will be in the cage >30 minutes) at all times. Under no circumstances are cages to be left without a cage top cover in the hallway, mouse barrier containment animal housing rooms, animal procedure rooms (including necropsy), satellite housing, and satellite procedures rooms
Storage and Location of Animal Diets
Improper storage of food is a hot topic for AAALAC. Common concerns include storing diet at temperatures above 21°C (70°F) and humidity >50%, not monitoring room temperature and humidity, or storing diet with biologicals, chemicals, or radioisotopes. If you are storing animal diets outside of LAMS please refer to IACUC Policy 033. Diets stored outside of LAMS must have an approved “Storage of Diets Outside of LAMS” form (Form #F-03). Diet storage areas are inspected by the IACUC at least once every six months. Please contact the IACUC Office if you have questions or concerns.

Custom Rodent Diets
Attention to any type of contamination that may be present in the diet is paramount to protecting the animals and your research. Diets are frequently contaminated with microbes and rodent pathogens. Since most diets do not withstand autoclaving without compromising the nutrient content or drug/chemical additives, the use of gamma-irradiated diets in rodent barrier facilities is strongly encouraged. Standard rodent diets provided by LAMS are irradiated. Irradiated diets minimize the risk of introducing infectious contaminants to our facilities; (2) extend diet shelf life by preventing microbial growth; (3) minimize nutrient or drug/chemical damage compared to autoclaving; and (4) do not alter diet palatability which results in less waste (and cost savings). When ordering custom diets, keep in mind that gamma-irradiated diets typically have a nominal additional cost and usually require an additional ten-day’s manufacturing time. If you are considering the use of a custom diet, ensure the diet is described in the IACUC approved protocol under question #9. Please contact LAMS if you have any questions or concerns.

Diet Shelf life and storage requirements
Diet may not be used after its expiration date. The shelf life of custom diets is typically 6 months; however, certain diet formulations and storage conditions or freezing can extend the shelf life. Unless specified differently by the manufacturer diets should be stored under conditions of <39ºF/4ºC and ≤ 50% relative humidity. In cases where the shelf life is greater than 6 months, the manufacturer must provide documentation describing the recommend storage conditions to support the extended shelf life. This documentation must be available for auditors. If you are considering the use of a custom diet, ensure the diet is described in the IACUC approved protocol under question #9.

BIOSAFETY NEWS

Biologic Toxins
Even in minute quantities, some biologic toxins can be extremely hazardous, requiring strict safeguards. The Biosafety Office has recently created a safety guide for the use of biologic toxins. PIs whose research projects involve the use of biological toxins must ensure that personnel are properly trained, that emergency procedures for spill and exposure are in place, and that they have an updated Chemical Hygiene Plan. Click HERE for a template of this plan.

Some biologic toxins are classified as Select Agents due to their potential to pose a severe threat to public health and safety. Possession, use, and transfer of these toxins is highly regulated. In small quantities, however, these toxins are exempt from the Select Agent registration. To ensure compliance the Biosafety Office created the Biologic Toxins Exempt Amounts – Assurance form to monitor the location of any potential select toxins.

EXPORT CONTROLS UPDATE

International Travel, Shipments, Collaborations, and/or Students
Export regulations carry the risk of personal fines and imprisonment. Regulations apply to conversations with people who are not US citizens or permanent residents. If you are involved in international travel, international collaborations, sponsoring of foreign visitors/scholars, and/or shipments, you need to be aware of the export control regulations and how they apply to your activities. Information is available on the Export Controls website for in person training or additional information please contact Export Controls Office.
New Addition to the Export Controls Office
Please welcome Tina Bosworth to the Export Controls Office. Tina comes to UC with vast international compliance experience and she is excited to apply her knowledge to the academic environment. She will be assisting Tara Wood’s efforts to facilitate export controls compliance.

HRPP NEWS

Extended IRB Approvals
To ensure protections of human research participants while reducing administrative burden effective February 1, 2016 some minimal risk protocols will no longer require annual review. These studies will instead be reviewed every 2 years (biannually). The time to review determination will be made during the initial and continuing review processes.

In order to qualify for the extended approval period, the study must meet all of the following:

- Will not involve more than minimal risk to participants (as defined by 45 CFR 46.102)
- Will not involve vulnerable populations (e.g., minors, prisoners, parolees, pregnant women, etc.)
- Will not involve medical interventions, including and not limited to FDA regulated investigational products
- Will not involve federal support, be initiated by federal agencies, or otherwise subject to federal oversight including any involvement with Veterans Administration facilities and/or personnel, any federal funding (awards/sub-awards, training grants, program project grants, no-cost extensions, etc.), and/or a certificate of confidentiality
- Will not contradict contractual obligations for approval periods
- Will not include studies where the site(s) apply the federal standards to all research regardless of the source of funding

When the UC IRB determines that a study is eligible for extended IRB approval, the approval period will be delineated in the approval letter. Please contact the HRPP Office with any questions or concerns.

Electronic Conflict of Interest Form Submission
In the next few weeks you will have a choice to either upload the paper version of your conflict of interest OR complete the conflict of interest questions electronically when submitting a new study, agreeing to participate or submitting a continuing review in ePAS. Please list all external key personnel as internal when completing the ePAS smart form. For instructions on how to register external key personnel and request an ePAS account please refer to http://researchcompliance.uc.edu/HRPP/IRB/ePAS.aspx. Please direct any requests for external key personnel ePAS accounts as well as any other questions and concerns to IRB@ucmail.uc.edu.

Helpful Hints for Speeding Up IRB Approval
Here are a few suggestions to facilitate IRB review:

- If a grant is involved, include a copy of the grant application; although not required for non-federally funded studies, that information can be very helpful.
- If your research is taking place at a location outside of the university that does not have its own IRB (i.e., a school, prison, nonprofit organization), remember to submit either a Site Support Letter or some other form of approval/permission letter from the site. Even if you were invited by the site to do the research, providing documentation upfront will spare you from answering unnecessary questions.
- An important—and often overlooked—aspect of the protocol document is the ‘Background’ section. This is of particular value when your current study is either based on—or is a continuation of—previous research. The key here is that you can never provide too much information in your Background section.
Remember communication is key throughout the review process. Each unit has HRPP personnel dedicated to supporting your protocols, you can identify your contacts on the website. We welcome and encourage phone calls, emails, and face-to-face visits. We are here to help; the only bad question is the one not asked!

**IRB Billing**
The infrastructure that supports the Institutional Review Board (IRB) is funded by the indirect (F&A) return on expenditures. That cost is not captured when the funding is run outside of UC (e.g., if the funding/contract runs through UC Health or CERV). The fees apply to any study (including investigator initiated) with funding that is run outside of UC; please ensure that you include the fees in your budgets. For additional information please refer to the website. Please contact Amy Bryant if you have any questions or concerns.

**Emergency Use Drug/Biologic/Device**
There are circumstances where it is in the best interest of a patient for an investigational drug or biologic to be used without IRB review and approval. As described in HRPP Policy III.05, emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening or severely debilitating situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. As described on the website, emergencies involving devices may arise where an unapproved device may offer the only possible life-saving alternative, but an Investigational Device Exemption (IDE) for the device does not exist, or the proposed use is not approved under an existing IDE, or the investigator or institution is not approved under the IDE. If an IDE for the use exists, the Sponsor must authorize use. If an IDE does not exist, the FDA must be notified with a written summary of the conditions constituting the emergency, subject protection measures, and results. The emergency use of an unapproved investigational drug or biologic is described on the website and requires an Investigational New Drug (IND) application. If the intended subject does not meet the criteria of an existing study protocol, or if an approved study protocol does not exist, the investigator should contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company’s IND. If this is not available through the manufacturer, the investigator should contact the FDA in order to obtain an emergency IND.

The investigator is required to obtain informed consent of the subject or the subject’s legally authorized representative. If the manufacturer has an existing consent form, that form may be used. If there is no existing consent form available from the manufacturer, a clinical consent form should be used.

If time permits, the Human Research Protection Program (HRPP) should be notified of the intended emergency use. Investigators can reach the HRPP via phone (513) 558-5259 or email (irb@uc.edu).

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**RADIATION SAFETY**

**No-Use Surveys**
All areas where unsealed radioactive material (RAM) is used must be surveyed for removable contamination at least monthly and results documented on an Authorized User Routine Survey Report (RS Form 12) or its equivalent. If no RAM use occurs during a month, “no use” may be documented in lieu of a survey being conducted. Minimum documentation for “no use” is date of last clean survey, date of last use, and date of documentation of “no use”. “No use” documentation may be recorded on an RS Form 12. **Storage is considered use**: “No use” documentation is not applicable in areas where radioactive material is stored. If the only “use” is storage, an abbreviated survey may be conducted. The abbreviated survey may be limited to the storage area and area immediately surrounding the storage area. For example, if a room has stock radioactive material vials stored in a refrigerator and radioactive waste stored in containers on the floor, wipe surveys must be performed of the refrigerator, floor in front of the refrigerator, the waste containers, and the floor surrounding the waste containers. Please contact the Radiation Safety Office if you have questions or concerns.

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