Integrity Matters Autumn 2022

The days are getting shorter and the temperatures are starting to drop that means it's time for annual disclosures. All colleges and units except College of Medicine/Hoxworth must complete their annual disclosure form (**Outside Activity Report, OAR**) describing any collateral employment and other outside activities between October 3 and November 4, 2022. Employees in the College of Medicine/Hoxworth were required to complete their OAR between August 8 and September 9, 2022. Please answer all questions honestly and completely, providing all necessary activity details. Remember that your disclosures are confidential and your supervisors need these details in order to review and approve your outside activities. Please contact oarquestions@uc.edu if you have any questions about the form, what requires disclosure or if you need assistance disclosing.

Would you like some pointers to learn How to Navigate Human Subject Research? Join a virtual conversation on Friday, October 14, 2022 from 10-11am. Register here. Attendees will gain additional knowledge on navigating human subject research and the process at the University of Cincinnati. The presenters will engage in discussion with investigators about protocol development, and provide promising practices when navigating human subject research. Presenters include: Angela Braggs-Brown, Director, Human Research Protection Program (HRPP), Office of Research and Mike Linke, PhD, Chair, University of Cincinnati Institutional Review Board (IRB) and StrokeNet Central IRB.

It should go without saying that diversity, equity, and inclusion are essential components of an ethical environment; they also promote creativity and enhance outcomes. To raise awareness and motivate change Sponsors are increasingly mandating that mechanisms to address and promote DEI be included in proposals. Most recently Department of Energy (DOE) announced that all funding solicitations will require applicants to submit a Promoting Inclusive and Equitable Research (PIER) Plan as an appendix to their proposal narrative. PIER Plans should describe the activities and strategies applicants will incorporate to promote diversity, equity, inclusion, and accessibility in their research projects. PIER Plans will be evaluated as part of the merit review process and will be used to inform funding decisions. You can learn more here https://science.osti.gov/grants/Applicant-and-Awardee-Resources/PIER-Plans

The CHIPS and Science Act of 2022 (https://www.commerce.senate.gov/services/files/1201E1CA-73CB-44BB-ADEB-E69634DA9BB9) states "Responsible conduct in research training. Expands the requirement for responsible conduct in research training to include faculty and other senior personnel on Foundation awards and expands the scope of such training to include mentoring training and training to raise awareness of research security risks as well as Federal export control, disclosure, and reporting requirements." NSF has not formally announced an implementation date but anticipates implantation for proposals submitted on or after July 31, 2023. Please reach out to integrity@uc.edu if you would like help developing an implementation strategy.

The Biden Administration published **research security** guidance for federal agencies to implement NSPM-33 including plans to develop consistent disclosure requirements for federally funded researchers and common disclosure forms for the Biographical Sketch and Current and Pending (Other) Support sections of applications for federal grants or cooperative agreements. The National Science Foundation (NSF) is soliciting public comment at 2022-18746.pdf (govinfo.gov) this includes an excel spreadsheet that summarizes all of the data elements that will be collected in both the Biographical Sketch and Current and Pending (Other) Support" NSF has posted all of the information and background on its website NSTC Research Security Subcommittee NSPM-33 Implementation Guidance Requirements & Standardization (nsf.gov). Public comments are due on October 31, 2022.

We are here to facilitate your research.
Feel free to reach out with suggestions, questions, or concerns.

Jane Strasser, PhD
Senior Associate Vice President for Research
Research Compliance Officer
Research Integrity Officer

ANIMAL CARE AND USE PROGRAM UPDATE

PI-Delegated Husbandry

When research staff assume husbandry duties, those duties must be documented on the PI-Delegated Room log (located on the backside of the LAMS Husbandry Log hanging outside each room). If research staff are providing special diet (PI Will Feed) or medicated water via bottles (PI Will Water), those cages must be assessed and PI-Delegated room log completed at least once every 3 days. Withholding food and/or water requires prior IACUC approval. All "PI Will Feed" diet bins must be sanitized in accordance with LAMS policies. Please contact lams-husbandry@uc.edu if you have questions or concerns.

Weaning Rodents

Researchers are responsible for weaning their animals. Standard rodent weaning is 21 days, if rodents are not weaned by day 24 then LAMS will wean and fees will apply. If the lab has obtained LAMS veterinary approval to extend weaning until 28 days (mice) LAMS will wean on or after day 31 and fees will apply. If the pups are too small to wean, submit an Animal Health Report to LAMS Veterinary Staff for prior to the wean date, extensions may be granted based on veterinary assessment. Breeding colonies should be checked at least three (3) times per week (e.g., Monday, Wednesday, and Friday).
When weaning animals ensure all new cages have food, a water bottle that is at least ½ full, and a cage card. Prior to placing cages on the ventilated rack, prime the drinker valve to ensure it is functioning properly and delivering water to the rodents. Before leaving LAMS, record your offspring on the Offspring reporting log (on animal room door) and turn in the

top portion of the cage card(s) for activation in cage card drop boxes (ensure the "On Census" box has been completed). Cage card drop boxes are located at the entrance to the facility, necropsy, and in MSB corridors.

AAALAC International Site Visit

The Animal Care and Use Program will be inspected by our accreditors (AAALAC) next spring. You are a key component of the program and accreditation is essential for funding. Issues that may arise include: (1) Expiration dates – all drugs/agents/compounds used in animals, materials used for survival surgery, and anesthesia machine inspections must be in date. (2) Controlled drugs and logs – ensure compliance with DEA and OBP regulations. (3) Satellite procedure locations – ensure they are clean, organized, and in good condition, including specialized equipment (e.g., behavioral testing apparati, anesthesia induction chambers). (4) IACUC protocols – ensure all staff have read and understand content outlined in approved IACUC protocols. (5) Safety practices – ensure staff follow safe practices (i.e., not recapping needles, using scavenging for waste anesthetic gases, proper use of PPE) and understand how to manage/report a work-injury. (6) Be familiar with the process for reporting concerns. If you would like additional information on how to prepare, please contact lams@ucmail.uc.edu or iacuc@ucmail.uc.edu.

The Guide for the Care and Use of Laboratory Animals 8th Edition states: *"Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies."* To ensure the wellbeing of all of our research animals and meet the Guide's expectations the **Post Approval Monitoring** (PAM) program will be reaching out to meet with researchers to observe and learn about your science and provide insight on IACUC policies and guidelines.

Fall Semiannual inspections were completed September 6-15. Top 5 deficiencies fall under two policies/guidance found on Research how 2:

ACUP Policy: 105 Expired Materials & Non-Pharmaceutical Substances

1. Expired items: drugs, agents, syringes, chemicals, diet.
2. Unlabeled or mislabeled jars, bottles, syringes; or labels that were faded/unable to read.

ACUP Guidance: Satellite Animal Use Areas and Diet Storage Locations

3. Diet stored in areas that were not approved on protocols.
4. Items in animal use areas that cannot be cleaned/sanitized-canvas, cloth, cardboard.
5. Dirty animal use areas and equipment
6.

Our next semiannual inspection will occur in March 2023 before the AAALAC site visit.

Procedure to transport cages to a containment (biological or chemical) room, return room, or last entry room

Prior to moving mice or rats: while still in their normal housing room, transfer animal(s) into a clean cage following standard procedures; provide sufficient food to last for 2 weeks; fill a clean water bottle ¾ full with fresh RO water; and place a filter top on the cage. Containment rooms with ventilated racks (chemical containment and return room) must have tops with flaps to dock properly onto the ventilated racks. These tops can be found in each containment room or with the submission of a husbandry service request. All other containment rooms are SMI (static microisolator) caging; a standard filter top without flaps can be used.

EXPORT CONTROLS, RESEARCH TRANSPARENCY, AND SECURITY

Are you now, or will you soon be working on a project with data restrictions [e.g., work with controlled unclassified information (CUI) or work that falls under the CUI or International Traffic in Arms Regulations (ITAR)]? Restricted data may not be sent through UC's standard email, we are moving to a new software system PREVAIL to facilitate storing and sharing restricted information. If you (will) need access, have questions or concerns, reach out to Laura Elkin or Tina Bosworth.

Cybersecurity Soundbytes

Removable media includes thumb drives, portable hard drives, USB Sticks, SD cards, mobile devices, and more. They provide portable and easy capabilities for moving data from one place to another; but they have risks including information loss and malware/ransomware spread. For example, a malicious actor could drop a USB drive in the library with some ransomware on it. When someone picks it up and plugs it in to see who it might belong to, the ransomware spreads to the computer and possibly the network. Secure your computer and removable devices when not in use. Whenever possible password protect devices. Do not use removable media that comes from an unknown source do not plug it into your computer; turn it in to the Office of Information Security or your local IT office. When using removable hardware that is given to you by vendors, marketing advisors, etc. If you were not expecting to receive it, discuss with your local IT office before using it. Restricted, controlled, and/or sensitive data may not be stored on removable hardware. Use a malware scanner to scan your computer and external drives regularly. Reach out to Laura Elkin with questions or concerns.

HUMAN RESEARCH PROTECTIONS PROGRAM

Adverse Event and Serious Adverse Event Reporting

Investigators must have written procedures to ensure prompt reporting of unanticipated problems involving risks to study participants and others as well as applicable adverse events. Reporting requirements to FDA, the IRB and funding sources (e.g., NIH), may differ.

Ensure the study team is aware of all applicable requirements to prevent noncompliance and protect participants.

Type of Event	When to Report to Sponsor
Unanticipated adverse device effects (device study)	As soon as possible but no later than 10 working days after becoming aware of the event.
Serious adverse events (whether or not considered drug related and including those listed in the investigator brochure or protocol	Immediately
Nonserious adverse events	According to the timetable for reporting described in the protocol

Updating Accounts for External Users

Call the UC IT Help Desk @ (513) 556-4357 to update your UC user information (they are separate from the UC RAP IT team). Let them know you are external to UC, but have a UC login to access some applications and that you need to update your UC account email address. Let HRPP know the result of that phone call (and how long they say it may take); we coordinate with the RAP IT team and verify that your email address is being saved.

Study Modifications

When submitting modifications involving revisions to or the addition of study documents and/or procedures, provide a summary of those changes as well as the rationale. The submission should also include whether or not the proposed changes are anticipated to require reconsent or sending new information to research participants. If it is anticipated, then describe if this will apply to all research participants or a subset (e.g., active, follow-up, completed participants).

Multi-Site Studies

Principal Investigators who intend to coordinate multi-site studies that include sites that are unaffiliated with UC must submit a new study application in RAP. Such projects will either use UC IRB or an external IRB for all participating sites. Please contact reliance@uc.edu to initiate the process.

BIOSAFETY

Human Clinical Studies

Many human clinical protocols require registration with the IBC, especially those that involve the transfer of gene(s) into human subjects. The submission of IBC clinical protocols is now electronic. Submit new applications through this system. As the Biosafety Office transfers data of IBC approved/active IBC protocols to the new system, PIs will be contacted to confirm accuracy of information. Contact the Biosafety Office for more information or if you are unsure if a clinical study needs IBC registration.

RADIATION SAFETY

The Radiation Safety Office (RSOf) continues to make updates to the its software. Some of the new end user features include: revision to the default display of an AU/CP's workers (Management -> Manage Worker Group). The default setting will now only display those who are currently active. To view past workers, select the check box "Display All (Active and Inactive)" once selected and the search button clicked, the system will display all current and former workers. An additional new feature to this module is the ability to download/export the work list into an Excel file. This is done by clicking the "Download" button. This is also the area where the AU/CP can deactivate a worker by selecting the "Terminate" button on the workers row within the table. This will trigger an email to RSOf to cancel any applicable dosimeter(s) and required training. You can now download your sealed/unsealed inventory data into an Excel spreadsheet. Under the "Inventory" section select either "Sealed Source Inventory Verification" or "Unsealed Source Inventory Verification"; click the "Download" button to open in an Excel spreadsheet.
The RSOf is searching for an entry level Radiation Safety Technician. If you or anyone you know may have an interest in the world of Radiation Safety, please visit the UC's careers page at https://jobs.uc.edu/ – search the key words "Radiation Safety" and review the "Staff Hlth Phys Tech 1-U" position.