Integrity Matters Winter 2022

Welcome to 2022, so far it feels a lot like 2021. Thank you for all that you do to help move us through and beyond the pandemic.

Changes to the Chemical Management System
UC is moving to a new, chemical management system called EHSA. EHSA will replace our CISPro Chemical Inventory System. **Please note that as of Monday, January 10th, the CISPro application will no longer be accessible.** To further assist in the transition, a 5 minute tutorial on the EHSA system is available at the following link: EHSA Overview Video. EH&S will be posting tips, short-cuts, and tutorials on its website and Bearcats Landing Page, updates will also be sent out via email. After January 13th, 2022, the EHSA system can be accessed in the same manner as the old CISPro application. Your standard UC password will work to access the EHSA chemical inventory system.
If you have any questions concerning the system operation, please contact University IT at 556-4357. For questions related to chemical management, hazardous waste, and related issues contact the EH&S Office 556-4968/ https://www.uc.edu/about/admin-finance/ehs.html.

NIH Update: Biosketch and Other Support Changes

NIH will require new Biographical Sketches and Other Support format pages for applications and Research Performance Progress Reports (RPPRs) due on or after January 25, 2022. Changes related to electronic signatures and the collection of supporting documentation, where applicable, also will take effect Jan. 25, 2022.

The UC Office of Research continues to provide guidance and training on the International Collaboration website and has created additional FAQs based on questions collected from researchers and administrators at UC, meant to supplement NIH's FAQs on the Biosketch and Other Support and Foreign Components. Failure to follow the appropriate formats may cause NIH to withdraw applications from consideration.

For more information sign up for the Office of Research Development & Support Series: NIH Update - Biosketch and Other Support Changes on Wednesday, January 12 from 2:00-3:30 PM. You can also ask questions and get assistance during the **OoR Virtual Office Hours** (Zoom link is here) which convenes the first Tuesday of the month from 1:00-4:00 PM and the third Friday of the month from 9:00 AM-12:00 PM.

Sign up for listening sessions to help NIH chart the path forward to a more **racially and ethnically diverse biomedical workplace**.

I hope 2022 is a good year for you, your loved ones, and your research.

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

Rodent Housing Capacity and Requirements

Researchers are responsible for preventing/correcting overcrowded cages. Capacity requirements are based on floor space, cage, and LAMS husbandry practices. Special exceptions, such as extended weaning or multiple litters, must be approved by either the LAMS Veterinary Staff (lams-veterinary@uc.edu) or the Institutional Animal Care and Use Committee (IACUC) for one-time and ongoing/recurring situations respectively. To request a copy of LAMS Overcrowding Guideline, please email LAMS@ucmail.uc.edu.

ACUP Policies and Guidelines

All approved ACUP policies and guidelines can be found on Research How2. There you can find: **IACUC RAP Manual** – a comprehensive, illustrated manual detailing basic use of UC's IACUC protocol management website, Research Administration Portal (RAP). **Accepting an Animal Transfer from Different PI**- a quick and easy guide on how to accept a transfer from another Principal Investigator (PI), **IACUC Semiannual Inspection Lab Self-Assessment Checklist**- a self-evaluation tool to help your laboratory plan for an IACUC inspection and to remain inspection-ready year-round, and more. If you have questions or need help please email IACUC@ucmail.uc.edu.

Environmental Enrichment

Environmental enrichment enhances the physical and psychological well-being and promotes species-typical behavior in all laboratory animals. Unless approved by the IACUC social animals (e.g., mice and rats) must be group housed. When single housing occurs, additional enrichment is needed. Please remember to provide your single-housed animals with a second, different form of enrichment. For example, mice use nestlets to build a nest, so LAMS recommends a hut as a second different form of enrichment as it encourages chewing, hiding, and climbing behaviors.

BIOSAFETY NEWS

Poliovirus Survey

To help with the WHO's Global Polio Eradication Initiative, investigators are being asked to complete a **very short** (1 minute) survey with questions intended to identify laboratories that possess any materials that could potentially contain poliovirus. It is important to note that potentially infectious materials are identified based on the location and timeline the samples were collected, not based on any test results. Start your POLIO SURVEY

EXPORT CONTROLS AND RESEARCH SECURITY

Export Compliance is focused on the regulations, laws, and policies that restrict the release of certain technologies, information, and/or services to foreign nationals, both within and outside of the U.S., along with foreign countries. It covers all activities of import and export of goods and/or services, tangible, and intangible assets. An Export can be more than a physical shipment. A verbal release to someone who is not permitted to receive the information is a Deemed Export. Our US government rules and regulations change often, for guidance or if you have any questions or concerns, please reach out to the Export Controls Office at exportco@ucmail.uc.edu to confirm if there are any compliance matters.

Cybersecurity Soundbyte

Did you know that all data that you work with in your research has a classification type? Data classification helps everyone involved in working with your research data and protecting your research data understand what protections are needed, who can and should access that data and if special controls are needed. UC has 4 different Classification and Data types – Export Controlled, Restricted, Controlled, and public.

It is important that you understand what type of data that you have to make sure you're protecting it appropriately. Data which is not properly classified may not have the protections needed and increase the risk to your research project and UC. Some examples of risks to data:

- Tampering or theft of intellectual property or government-sponsored research
- Alteration, damage or loss of sensitive research data
- Unauthorized access or use of sensitive research data
- Improper disposal of digital media containing sensitive research data.
- Unauthorized and/or inappropriate release of sensitive research data.

You can find the University of Cincinnati's Data Classification policy here: https://www.uc.edu/content/dam/uc/infosec/docs/policies/Data_Governance_and_Classification_Policy_9.1.1.pdf

If you have questions about what type of data you're working with or if you want to discuss the controls needed for your data, please reach out to elkinle@ucmail.uc.edu.

HRPP NEWS

IRB Approval of Planned Protocol Deviations

A planned protocol deviation that potentially impacts the risk or the scientific integrity of the study must be approved by the reviewing IRB before the change is implemented. A planned protocol deviation is generally a one-time change to the protocol that affects a single participant. Principal Investigators (PI) must not submit multiple requests for the same deviation. If multiple requests are submitted for the same deviation, the IRB may require that the PI modify the protocol to avoid the protocol deviation in the future.

The UC IRB will review requests for approval of planned deviations on protocols overseen by the UC IRB. Planned deviations on protocols overseen by outside IRBs must approved by that IRB.

For sponsored studies, the deviation must be approved by the study sponsor prior to submitting to the IRB.

For Investigator-Initiated studies, the deviation must be approved by a faculty member with appropriate expertise who is not associated with the study prior to submitting to the IRB. The faculty member must determine that the protocol deviation does not negatively affect the,

- participants' rights, safety, or welfare
- scientific integrity of the research data

Planned protocol deviations on studies conducted under an IND or IDE may also require approval by the FDA prior to submitting to the IRB.

Submit requests for approval of planned deviations on protocols reviewed by the UC IRB using a new information report (RNI) in RAP

- Provide a detailed description of the deviation and why it would not negatively affect the:
    - participants' rights, safety, or welfare;
    - scientific integrity of the research data.
- Include
    - sponsor approval for sponsored studies:
    - faculty member determination for IIT studies;
    - FDA approval (if applicable)
- To ensure rapid review notify the UC HRPP that you submitted a request for a planned protocol deviation

NIH is revising their **Genomic Data Sharing policy**. They are specifically seeking input regarding maximizing data sharing while preserving participant privacy and preferences, and the types of data covered. Deidentification, potentially identifiable information, data linkage, consent for data linkage are all things that could impact your work. If you want to respond the deadline is February 28, 2022. You can learn more and provide feedback at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-029.html

RADIATION SAFETY NEWS

The Radiation Safety Office is in the process of decommissioning and removing the gamma irradiators from campus. These devices are often used in research to irradiate lab samples. Completion of this project is anticipated to take place in early 2022 and as such, will no longer be an available option. Take this time to review your grants/research protocol(s) to ensure any refences, specifically to the use of a “gamma irradiator” or “gamma irradiation” are noted to be amended now or upon renewal to remove this reference. Any work requiring the specific use of “gamma irradiation” should now be terminated. The UC Pre-imaging Core (PIC) offers irradiation services utilizing the Xen-X closed cabinet “X-ray” irradiator technology. The Xen-X is designed for irradiation of in vivo and ex vivo samples.