Winter 2023

The **NIH Data Management and Sharing Policy** is now in effect. While there are resources to help you, don't wait till the last minute to develop your data management plan. UC Libraries can help with data management, storage, and sharing. You can find more information at: https://libraries.uc.edu/research-teaching-support/research-data-services/research-data-resources.html. They have also developed specific guidance for data sharing here: https://libapps.libraries.uc.edu/liblog/2023/02/uc-resources-to-help-you-navigate-the-new-nih-policy/. A recent presentation describing UC resources and the policy can be viewed here

If you work with **controlled substances** be aware that that all DEA and OBP registrations must align and room numbers must be provided. DEA has indicated that they will start verifying/following up with noncompliant registrants. Remember that the person named on the registration is responsible for ensuring the accuracy of the registration and must be able to provide sufficient oversight of the controlled substances on their registration. Registrants should not order drugs for other researchers. If you are the person named on the registration then you alone are responsible for the drugs, drug inventory, drug security, drug destruction, etc. and while you may delegate some of the actions associated you remain responsible. Visit our Bearcat's Landing Page for more information on UC's DEA policy and procedures.

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

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ANIMAL CARE AND USE PROGRAM UPDATE

AAALAC International Site Visit

The AAALAC site visit is scheduled for **March 14-16, 2023**. AAALAC representatives will be onsite reviewing all aspects of ACUP and may ask you questions. It is okay to not know everything; however, you should be able to answer questions about your protocol, training, and safety. PIs are strongly encouraged to review their currently approved IACUC protocol(s) with individuals working on the protocol(s).

The IACUC will be performing semi-annual inspections of all satellite locations prior to AAALAC's arrival. You can prepare using the Lab Self-Assessment Checklist, and review your drug inventory to ensure items are appropriately labeled, stored, and/or safely destroyed. Remember that expired materials should be segregated in storage from non-expired materials, controlled substances must be securely maintained with related records, and all non-pharmaceutical grade agents must be approved by IACUC.

Protocol Transfers

- Temporary Protocol Transfers (TPT): all procedures being conducted during the TPT must be referenced in the original PI's protocol. If procedure(s) is/are not referenced, an amendment to the original PI's protocol must be submitted and approved by the IACUC in advance of the TPT.

- Permanent Protocol Transfers: sending PI personnel must update the animal counts for barcodes in AOPS **prior** to submitting the transfer request in RAP, and label cages with red "Transfer" cards (available in the LAMS offices). Contact lams-husbandry@uc.edu with questions.

Automatic Watering System for Rodent Cages

You must activate the drinker valve in mouse cages to prevent dehydration and attract mice that may be slow to learn or find the valves challenging due to lack of vigor, weakness, or cognitive impairment. These valves are located within IVC cages (Reading Campus) or are mounted to the housing rack (MSB, Vontz). For studies that require "PI Will Water" – ask LAMS for alternative caging and **never** remove a drinker valve.

Compliance Reminders

Compliance with all regulations is critical to the success of our program; everyone must do their part. To avoid non-compliance:

1. Know what's in your IACUC-approved protocol. Your protocol is essentially a contract between you and UC regarding what animal care and use is permitted.
2. Verify you have completed all necessary training required by ACUP Training Policy 101. Not all required training needs to be completed prior to being added to an IACUC-approved protocol; contact animaltraining@uc.edu for assistance.
3. Be familiar with ACUP policies and guidelines, available on Research How 2.
4. Contact the IACUC office with questions regarding protocol contents or for help navigating RAP.

Reporting Concerns

You have a responsibility to report any suspected or observed animal abuse, mistreatment, neglect, or other non-compliance with federal, state, or local regulations or an approved protocol (see ACUP Policy 106).

Common ways to confidentially report concerns include:

1. IACUC office, 513-558-5103
2. Attending Veterinarian, 513-558-5518
3. Compliance Hotline: 1-800-889-1547 or UC Anonymous Reporting Hotline

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EXPORT CONTROLS, RESEARCH TRANSPARENCY, AND SECURITY

Our internal research accounts are expiring this month. We have a new software system "PREVEIL". This system will help you manage secure and restricted information quickly and efficiently and provides added capability of file sharing. Are you or will you be working on a controlled unclassified information (CUI) or International Traffic in Arms Regulations (ITAR) project soon? Reach out to Laura Elkin or Tina Bosworth for details on setting up your account in the PREVEIL system prior to starting a project.

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HUMAN RESEARCH PROTECTIONS PROGRAM

IRB Fees for Single IRB Review

There are fees for IRB review when UC is acting as the IRB of record for federally funded studies. These fees will not apply to the UC site submission but will apply to external sites. NIH funding proposals may include fees for single IRB review as direct costs.

- NIH FAQs for sIRB Costs
- NIH Scenarios of Direct and Indirect Costs for sIRB Review
- ClinicalTrials.gov Lunch &Learn January 19th, 2023

Clinicatltrials.gov

NIH mandates that all clinical trials with any NIH funding register on clinicaltrials.gov. Annual updates of records as well as posting study results are required. Letters of non-compliance are being issued when updates are not complete for each individual applicable study. Failure to comply jeopardizes funding to the PI and the institution. Please join us for a discussion of this important requirement and a "How To" walk through of the process.

Indemnification

IRB approvals from WIRB and Advarra on UC studies are no longer being held for proof of indemnification in an executed contract. Indemnification is being verified by UC Office of General Counsel and Sponsored Research Services.

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LAB SAFETY NEWS

Did you know that UC has a **Research Safety Council**? This committee is comprised of Faculty and students from across UC and is charged with promoting and facilitating research safety. If you have suggestions or concerns you can reach out to Council Chair Dr. Allan Pinhas.

BIOSAFETY

The U.S. government maintains policies overseeing dual-use research of concern (DURC). DURC involves research that may pose a substantial biosecurity threat, and the oversight of work involving enhanced potential pandemic pathogens (ePPPs). Earlier this year the National Science Advisory Board for Biosecurity (NSABB) released a draft with findings and recommendations for DURC. Among the recommendations is the proposal of the expansion of the current list of agents requiring review for potential DURC to include any human, animal, or plant pathogen, toxin, or agent that is reasonably anticipated to result in one or more of the seven experimental effects. Learn more about current UC DURC review procedures.

RADIATION SAFETY

When radiation workers leave the lab, it is important to notify the Radiation Safety Office (RSOf) so we can stop dosimeter services and cancel automatic training reminders. Remember there is a cost associated with each dosimeter. Authorized Users, Lab designees, Managers or Individuals Responsible for Radiation Generating Equipment can "terminate" a worker's status in Gamma 2 by navigating to the "Management" tab, then selecting the "Manage Worker Groups" option. Within the table of all active accounts tagged to your lab. you can edit the dosimetry fund account string, request an authorization deactivation, or select the "View Group" button to display all active group participants. To remove a worker, click the "Terminate" button for that individual – the RSOf will then cancel the dosimeter(s) and training requirement(s) for the individual.

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SAVE THE DATE & ONLINE RESOURCES

Research and Innovation Week March 20-24, 2023
To learn more about speakers and events go **to**: https://research.uc.edu/researchweek#speakers

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