Spring 2017

You’re Invited
UC is committed to excellence and diversity; both are essential to our mission and both are reflected in our research portfolio. To support and promote research excellence and scientific integrity at UC, the Graduate School and the Office of Research have partnered to develop a series of entertaining, informative, research-centric video shorts. The videos are produced by students in the CCM Electronic Media program, who are learning about the topics while they produce videos that resonate with their peers. This academic year these outstanding students have generated 8 videos (each under 4 minutes) that showcase our creativity, highlight the importance of performing research ethically and safely, and demonstrate our commitment to research excellence. These videos are designed to be conversation starters among aspirational, emerging, or established researchers. You are invited to the premier on April 26th from 2:30-3:30 in room 220 of Tangeman University Center (TUC).

Online Training
When systems communicate directly it eliminates human error and delays. As we move toward integrating online training with protocol management systems direct communication can only occur if you are using your UC email. While the integration is still on the horizon keep in mind that logging into CITI using a non-UC email may cause delays in approvals.

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

Coming Soon: “Research Activities Portal” (RAP)
This spring the new IACUC web based protocol management system (RAP) goes live. The new system uses building blocks to create a protocol. These building blocks consist of groups of procedures and drugs that you assemble to create a study. Common procedures have been preloaded and are available, you can also create new procedures as needed; more information is available online. Identifying the building blocks that comprise your studies will facilitate your transition into the new system.

If you are willing to beta test the system and provide suggestions for improvement, please let us know.

No Longer Working with Animals?
To protect the integrity of the animals and research being conducted at UC please submit a “Removal of Personnel” Form#P-02 to the IACUC Office to ensure that only people who need to be in the animal facility as part of an approved research activity have access. If someone in your laboratory no longer
works with animals, and whenever personnel leave the lab, please remove them promptly. Until that form is submitted the individual will continue to be listed as Authorized Personnel on your IACUC protocol and will have access to the vivarium and to your animals.

Service Request Submissions
Please remember that any request submitted after 12:00 p.m. will not be reviewed and processed until the next business day. LAMS cannot guarantee completion of service requests submitted less than 3 business days in advance. Under extraordinary circumstances please contact LAMS (558-5171) to discuss. Urgent animal welfare needs should always be communicated directly to LAMS staff, not through service requests.

Transporting Rodents
When preparing to transport rodent cages out of the vivarium, animals must be placed in a clean cage, with food and water, and each cage must have a filter top. Cages must be covered with a sheet or cover paper. Cover paper is located just inside the entrance door to MSB animal facility. For transport, use the service elevators only. Please refer to IACUC #003 Transportation Policy for additional information. If you have any questions, please contact LAMS staff at (513) 558-5171.

BIOSAFETY NEWS

Working with Lentiviral Vectors – Know Your Risks
HIV-1-based lentiviral vectors are widely used to produce viral particles for gene-delivery. Even modified vectors can cause harm; don’t assume that vectors are replication incompetent. A researcher was recently demonstrated to have been infected with HIV while working with what (s)he believed were replication incompetent samples. Additional risks include the potential harmful effects of the transgene, insertional mutagenesis, or the activation of neighboring genes from vector integration or generation of replication competent lentivirus (RCL).

Each PI should develop an emergency response plan in case of exposure to lentiviral vectors. Post-exposure prophylaxis (PEP) should begin as soon as possible and no later than 72 hours following exposure. It is the responsibility of the PI to provide risk assessment information if emergency providers have any questions regarding health hazards. To learn more about lentiviral and other viral vectors, go to: http://researchcompliance.uc.edu/Biosafety/Training/ViralVectorWebtraining.aspx

Laboratory Activities & Cell Phones
Cell phones and music headphones can become contaminated in the lab and they can be a distraction. To protect your cell phone, you can place it in a sealed plastic bag while in the lab. When leaving the lab, you should decontaminate the bag before removing your phone. This fun video from Cornell University talks about the use of phones in laboratories.

EXPORT CONTROLS NEWS

Purchasing or Receiving Items
You may not know it but every item has an export control classification number. Some classifications restrict access to, and use of, the item. The Export Control Office’s Product Classification form can assist you in requesting the export control classification from the vendor. For guidance, please visit the Export Controls Website or contact the Export Controls Office.

New regulations for Controlled Unclassified Information (CUI)
Even unclassified information may require restricted access and distribution. Controlled technical information is defined as “technical information with military or space application that is subject to controls on the access, use, reproduction, modification, performance, display, release, disclosure, or dissemination.” The law requires a minimum set of safeguards and reporting of cyber incidents related to controlled unclassified information; these safeguards must be implemented by December 2017 for each
contract that contains a CUI clause. The CUI Registry contains the current description of information considered to be CUI with links to training and additional information. For further information, contact the Export Controls Office.

HRPP NEWS

Title IX Reporting and Research
Title IX prohibits discrimination on the basis of sex including sexual harassment, violence, and retaliation. All UC employees, except those specifically designated as confidential resources (e.g., health services) are required to report any incidents of possible sexual harassment, sex discrimination, or retaliation on campus of which they are aware within 24 hours using the online reporting form or to the Title IX Coordinator or a Deputy. Title IX reporting applies to researchers. Questions/Concerns regarding Title IX reporting compliance may be sent to the Title IX Coordinator at titleix@ucmail.uc.edu or visit the UC Title IX webpage http://www.uc.edu/titleix.html

Documents may not be removed from ePAS
To ensure that the record of the IRB review remains intact, researchers cannot remove study documents from ePAS. Researchers should select “Upload Revisions” to provide the most current study document. If a study document was uploaded in error, HRPP personnel will need to assist you with removal. To identify the person dedicated to serving your department visit the HRPP website.

Closing Expired Protocols
In addition to researchers, department/division heads will be notified when studies expire. All associated research operations must stop once a study has expired. No new research participants may be enrolled. To move a study out of expired status one of the following must occur:

1. Open a Continuing Review to Reactivate the study and open a Reportable Event noting why the study expired. The reportable event MUST note a) what/if any research activities occurred after study expiration, b) confirm that all research activities have ceased until the study is in an approved state, and c) what actions will be taken to avoid study expiration in the future.
2. Open a Continuing Review – Request to Close the study. The report should include the information that caused the study to expire and not be closed in a timely manner
3. If there is a continuing review submission open, complete the process by choosing one of the options above and responding to the questions in the application.

Studies that have been expired for longer than 6 months with no response to inquiries will be administratively closed.

CITI Training for Human Subjects Research
In the summer of 2017, new CITI modules will become available. As we transition to the new modules, you will receive e-mails from the UC Human Research Protection Program (HRPP) office providing you with instructions directing you to the new modules prior to expiration of your current training. We will also begin to identify duplicate accounts and sync user information with the account information captured in ePAS (e.g., email addresses will need to match and UC users will need to utilize UC email addresses). Additional information will be provided as we approach the rollover.

Federal Education Rights and Privacy Act (FERPA)
FERPA regulates the disclosure of personally identifiable information from student education records. It specifies that a parent/guardian or eligible student must provide a signed and dated written consent for disclosure of personally identifiable information from education records. The Health Insurance Portability and Accountability Act (HIPAA) does not replace FERPA in the case of student health/medical information, and the IRB cannot grant a waiver of HIPAA authorization or a waiver of informed consent when FERPA applies. If you are denied access to information in an Education Record, the IRB cannot overrule the decision. Contact the UC Privacy Officer, Lorre Ratley to ensure compliance with FERPA and HIPAA.

Waiver of HIPAA in Research
To ensure efficient review, researchers are reminded to submit all required information on the following questions in the study submission:
1. Does the use or disclosure involve no more than minimal risk to the privacy of individuals?
2. What is the plan to protect health information identifiers from improper use or disclosure?
3. What is the plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them?
4. Provide a written assurance that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule.
5. Provide an explanation why the research could not practicably be conducted without the waiver or alteration.
6. Provide an explanation why the research could not practicably be conducted without access to and use of PHI.

UC Health Facilities in Research
Anyone using UC health facilities must register research activities with the designated UC Health representatives and have the appropriate approvals. Questions/Concerns should be sent to Research-Admin@UCHealth.com.

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RADIATION SAFETY NEWS

Radiation Safety - Dosimeters
Dosimeters monitor personnel and areas where radiation sources are used. If you are issued a dosimeter it must be worn anytime you are working with radioactive material or radiation generating equipment. Exemptions may be approved by the Radiation Safety Committee on a case-by-case basis.

To ensure that dosimeter reflects your exposure:
- Return your dosimeter to the RSOI promptly at the end of the monitoring period
- Wear only your assigned dosimeter; never wear another worker's dosimeter
- UC issued dosimeters are strictly for occupational use. Do not wear your dosimeter during personal medical or dental procedures (e.g., x-rays, tests, nuclear medicine, etc.)
- Do not store your dosimeter near radiation sources or heat sources
- Never intentionally expose your dosimeter to any radiation

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TRAINING OPPORTUNITIES

Save the date!
The 19th annual Human Subjects Protection Conference will be held in conjunction with an OHRP Research Community Forum September 6-7, 2017 for Representatives from Office of Human Research Protection (OHRP) and other federal agencies as well as research experts will provide perspectives and resources for interpreting and applying human subjects’ protections in an evolving regulatory landscape. Ethical research topics spanning social/behavioral, biomedical, community-engaged and innovative research will be presented. Registration will open in April.

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