Summer 2017

Reproducible Research
We have all heard the concerns voiced over the quality of research produced and the inability to reproduce much of it. Reproducible research is more than transparency and data sharing. You can find some useful tools to promote quality and transparency here and for replication here.

Single IRB Mandate
NIH has delayed implementation of the single IRB (sIRB) mandate to January 25, 2018. If you missed the CCTST Forum on sIRBs you can review the information here.

New Website
All units within the Office of Research are migrating to a new integrated web portal. You have the opportunity to provide input that will make the websites more useful to you. Please visit Research How2 and take the Application Tour.

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

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ANIMAL CARE AND USE PROGRAM UPDATE

We need your input
The new IACUC protocol submission application is nearing completion. The next step will involve thorough user testing to ensure that the system is functional and meets your needs. Volunteers are needed to submit their current IACUC protocols in the new system.

Transport and Disinfection of Supplies and Equipment
All supplies and materials within any LAMS facility must be in a closed, nonporous, leak proof container (styrofoam and cardboard are not acceptable) and items must be secured during transport. All carts and containers must be sprayed with Clidox when entering animal facilities. Items being placed in the laminar flow hood or biosafety cabinet must be sanitized.

Expand Your Skill Set
Did you know LAMS offers free training on surgical and non-surgical procedures? Topics include blood collection techniques, genotyping, perfusion methods, anesthesia administration and monitoring, aseptic technique, renal capsule implant and many more. To register for free LAMS training, please submit a Veterinary Service Request at:
http://researchcompliance.uc.edu/LAMS/ServiceRequests/ServiceRequestVet.aspx

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BIOSAFETY NEWS

Lab Hazard Awareness Training: Non-Lab Personnel
Online training is available to familiarize non-lab personnel with possible lab hazards (e.g. biological, chemical, radiological hazards), safety warning signs, and labels. This training also discusses the procedures for visiting a lab and how to respond to an accidental exposure.

Accidents Happen
Accident prevention is the most important part of our job, but we can't do it alone. If you are aware of a spill or potential exposure that involves recombinant nucleic acids, infectious or potentially infectious materials, please let us know. Were you involved in an accident? Click HERE to learn how to respond and report.

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EXPORT CONTROLS NEWS

International Travel Review
When traveling abroad export controls regulations apply to what you are taking, who you are visiting (institution/person), and where you are going. A license or exception/exemption may be necessary prior to your trip. When travelling internationally the Export Controls Office requests that travelers complete a brief form and submit it via email prior to travel, the form helps us protect you while you travel. Please let the Export Controls Office know if you have any questions or concerns.

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HRPP NEWS

CITI Training
As of July 1st we have new CITI training for human subjects’ researchers (“Core Human Subjects Research Curriculum” which is comprised of 9 required and 2 optional modules). You will start to see expiration notices if your training expires this year and new trainees will only see the new training. Remember, to facilitate cross-institutional research our training is under the “Greater Cincinnati Academic and Regional Health Centers” (not under UC). If you have previously completed training in CITI and you need to retrain click the “Add a Course” link inside of the My Learner Tools box. Guidance on answering the questions is on the website; if you have not previously completed CITI training information for registration is available here. Note that if your training does not expire this year you will not yet be able to access the training.

Collecting Pregnancy Information from or about Female Partners and Newborn Infants
In some research studies, investigators may be required to obtain information about the progress of a pregnancy if the partner of a research subject becomes pregnant. Collection of information about the pregnant partner and newborn infant constitutes human subjects research. In such cases, the IRB-approved protocol must include provisions for collecting information from the pregnant partner and newborn infant. The IRB must approve the study to include pregnant women and minors. Informed consent must be obtained from the partner prior to the collection of any data from her or the newborn infant. Written authorization for use and disclosure of protected health information must also be obtained.

Clinicaltrials.gov
There is increasing scrutiny of reporting in clinicaltrials.gov. Reports of noncompliance do not take into account the amount of time issues reside at PRS, or the number of times researchers send queries. Protect yourself and document your interactions.

EPIC Care Everywhere
UC Health does not permit the use the Epic Care Everywhere feature for research purposes. This includes screening for patients, validating inclusion and exclusion criteria, chart review, or follow ups.

SAE Reporting to UC Health
UC Health must be notified whenever there is an unexpected and related serious adverse event that occurs for a study patient while at a UC Health facility. Use the MIDAS system to report these events. For more details please review the SOP.
Agree to Participate in ePas for New Study Personnel
The notification to key personnel to agree to participate on amendments in ePas is still broken. Please direct new study personnel to log into ePas, search the study number and complete the ‘agree to participate’ form using the activity button to the left. If study personnel are not able to see the study after logging into the system contact your HPA for assistance.

Student, Fellow, and Resident Research
Per UC HRPP Policy IV.01, human subjects research conducted by a student, fellow, or resident must have a faculty member as the PI or Co-PI.

Billing changes
As of July 1st 2017, all invoices related to IRB review (including initial review) will go directly from UC’s Office of Research to the departments. If you have questions about fees for UC IRB services, please visit our website or contact Amy Bryant. For questions regarding the Office of Clinical Research and their billing process, please contact UCP-ClinicalTrials@UCHealth.com.

NIH e-Protocol Writing Tool and NIH-FDA Clinical Trial template
NIH has released the Final NIH-FDA Clinical Trial Template for Phase 2 and 3 IND/IDE Studies. The template aims to assist NIH-funded investigators in preparing clinical trial documents efficiently. NIH has also released a web-based platform where investigators can utilize the protocol template in an interactive fashion. The Electronic Protocol Writing Tool allows for a collaborative approach to writing and reviewing protocols. Investigators will be able to use the tool to form a “protocol writing team” and assign different individuals with writing and reviewing roles. All of the above resources can be found on the Office of Science Policy’s website.

RADIATION SAFETY NEWS
New Radiation Safety Officer
Please welcome our new Radiation Safety Officer, Terry Lindley, MRHP, CHP, CNMT. Terry has an impressive health physics background working with radiopharmaceuticals and most recently working for the Illinois Emergency Management Agency. Terry assumed leadership of our Radiation Control and Safety Program on May 30. Special thanks to Beth Boston for outstanding leadership as the interim Radiation Safety Officer while we completed the search.

TRAINING OPPORTUNITIES
Human Research Protection Forum
September 6-7, 2017 at the Northern Kentucky Convention Center
Space is limited--register today!
Representatives from the Office for Human Research Protection (OHRP) and other federal agencies as well as research experts will provide perspectives and resources for interpreting and applying human subject protections in an evolving regulatory landscape. Attend one or both days. OHRP presentations included both days. Visit the conference website to view the full conference schedule.