Winter 2014

IRB Delays

Several senior staff have left the IRB Office in recent months. We are in the final stages of hiring to fill the vacant positions, please be patient as the new people become familiar with our systems and processes. As always if something is urgent, or if you have concerns, please let us know.

Your safety matters

We all know that experiments cannot be confined to business hours, which means many of you are on campus at odd hours. NightRide is a free nighttime transportation service provided by Public Safety to offer safe and reliable transportation to and from locations within a one-mile radius of the UC campus. The service is available for students, faculty and staff. UC ID is required to use the service, and each UC user may take one non-UC person as a guest. Walking escort teams are available for those who want an escort to their own car in a garage on campus, or just from one building to another. Call 513-556-RIDE (7433) for service. For more information, including operating hours, visit uc.edu/publicsafety/nightride.

If you have a suggestion that will help us to help you, please contact us at research.compliance@uc.edu.

Jane Strasser, PhD
Director, UC Office of Research Integrity
Research Compliance Officer
Research Integrity Officer

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SPOTLIGHT ON: EXPORT CONTROL

Export Controls, New Director for UC

The U.S. export control regulations are intended to enhance U.S. security—including cyber and homeland security, foreign policy and economic objectives—and to strengthen the United States’ ability to counter threats. Importantly, failure to comply with these regulations can result in personal fines and jail time.

The University of Cincinnati is committed to compliance with all applicable export control regulations, particularly the Departments of Commerce, State, and the Treasury. These regulations are complex and difficult to interpret. UC’s newly hired Director of Export Controls, Tara Wood, has expertise in the interpretation of these regulations and the development and implementation of management plans.
The mission of the Export Controls office is to ensure compliance throughout the university by providing services to assist faculty, staff, and students with understanding and adhering to regulations, while facilitating research and international collaboration. The Export Controls office will partner with faculty, staff, and students to deliver efficient solutions that support the academic and research priorities of the university. If you have questions regarding Export Controls please contact Wood at woodt4@ucmail.uc.edu or 513-556-1426.

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**IACUC NEWS**

**Occupation Health and Safety for Personnel Working With Animals**

An updated checklist for visitors working with animals is now available. Also available are species-specific Data Sheets. These can be found at: [LAMS Information for Personnel with Animal Exposure](#).

**Grant, Contract Submission Requirements Regarding the AVMA Guidelines for the Euthanasia of Animals**

The 2013 Edition was published in the NIH Guide for Grants and Contracts on Aug. 7, 2013, NOT-OD-13-098. The Vertebrate Animal Section (VAS) of grants and contracts must be consistent with the 2013 Guidelines. In their submission to NIH, grant applicants and contract offerers are required to describe any method of euthanasia to be used and the reasons for its selection and to state whether the method proposed is consistent with the 2013 AVMA Guidelines. If the proposed method is not consistent with the AVMA Guidelines, a scientific justification must be included in the VAS.

**Observing the 48 Hour Animal Acclimation Period**

Animals received from outside of UC must be acclimated for 48 hours prior to use. Stress from shipping can alter hormone levels, hydration and nutrient intake, which could impact your research results. In some cases where animal welfare and the research results would not be impacted, the Institutional Animal Care and Use Committee (IACUC) has approved exceptions to the 48-hour acclimation period. Exceptions are noted in question 11 of your approved IACUC protocol. Not observing the 48-hour acclimation period is a significant deficiency that could result in corrective measures taken by the IACUC.

**Expired Drugs**

The use of expired medical materials such as drugs, fluids or sutures on regulated animals is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by animal welfare regulations. Research staff should check their inventory of drugs and supplies on a monthly basis and discard all items upon their expiration date. If an expired item can be used in experiments not involving animals, the item must be marked clearly "FOR IN-VITRO USE ONLY- NOT FOR USE IN ANIMALS" and stored in a separate location in the laboratory. If expired items are not clearly marked, the IACUC will assume they are being used in animals. More detail can be found in [IACUC Policy 4](#).

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**HUMAN RESEARCH PROTECTION PROGRAM NEWS**

**IRB/HRPP RE-ORG**

Our human subjects’ protection program includes the independent committee that oversees that research (the Institutional Review Board, or IRB). Historically the IRB has been supported by the IRB Office, with quality assurance from the Post-Approval Monitoring Program (PAMP), and FDA assistance from the IND/IDE Assistance Program (IAP). To minimize replication and streamline processes, all of these offices/programs have now been collapsed into a single Human Research Protection Program (HRPP) with Angela Braggs-Brown serving as its director.

**Helpful Hints for Expediting IRB Approval**

Here are a few suggestions for researchers that may help to improve the speed of your review and get you started on your research:

- If a grant is involved, always include a copy of the grant application. Although policies don’t require it for non-federally funded studies, that information can be very helpful for the board members reviewing your study.
- If your research is taking place at a location outside of the university at a location that does not have its own IRB (i.e., a school, prison, nonprofit organization), remember to submit either a Site Support Letter or some other form of approval/permission letter from the site. Even if you were invited by the site to do the research, providing documentation of such a situation will spare you from answering unnecessary questions.
- An important—and often overlooked—aspect of the protocol document is the ‘Background’ section. This is of particular value when your current study is either based on—or is a continuation of—previous research. The key here is that you can never provide too much information in your Background section.
- Finally, it cannot be stressed enough the importance of communication throughout the review process.
The IRB welcomes and encourages phone calls, emails and face-to-face visits. We are here to help; the only bad question is the one not asked!

**Research Note in EPIC**

To ensure a more comprehensive communication between research and clinical personnel when a research participant is also receiving medical care within UC Health, the Research Note in EPIC will be used. The Research Note may provide information that could impact clinical care or be an informational item for any UC Health employee providing service or care.

The inclusion of this information in EPIC must be disclosed in a new informed consent document for studies conducted at UC Health. The following language must be added to the confidentiality section of informed consent documents for studies conducted at UC Health:

> “Your research information will be saved in your UC Health medical record. UC Health employees providing service or care to you will be able to see it.”

Please add this information to your new informed consent documents as needed.

For ongoing studies in which participants are still being seen, please document with a note to file in the CRF that participants were told that information about their participation in the study will be added to their medical record at UC Health. This information is being added so that it is available to UC Health clinical providers who are involved in your clinical care so they can care for you appropriately.

Please contact the IRB office with any questions.

**Participant Recruitment**

Would you like to recruit more participants for your clinical trials? In the next couple of months the UC Health Clinical Trials Office is launching a new feature on the UC Health website that will advertise studies direct to the public and let patients search for studies they might be eligible for. The UC Health website gets nearly 140,000 hits each month, so this is a great opportunity to increase the visibility of your studies.

The Clinical Trials Office has worked with the IRB to make it quick and easy for your study to be included. If your study is approved by UC’s IRB, all you need to do is fill out a short form that is located in ePAS, the electronic IRB system. A step-by-step guide to completing the form can be found at [http://webcentral.uc.edu/gradresearch/cto/ePAS_Tip_Sheet.pdf](http://webcentral.uc.edu/gradresearch/cto/ePAS_Tip_Sheet.pdf). For further information, please contact Wendy Newman in the Clinical Trials Office at wendy.newman@uchealth.com.

**TIPS**

- If someone needs help entering results into ClinicalTrials.gov for parallel design, crossover design, diagnostic accuracy or bioequivalence studies, refer to the helpful hints document at the link below. It includes examples of how the tables will look in the subsections. [http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf](http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf)

- If you are required to submit results to ClinicalTrials.gov after a trial has been terminated without ever enrolling a participant, then set the Overall Recruitment Status to “Withdrawn,” and submit the completed record to your administrator.

- If you are required to submit results to ClinicalTrials.gov after a trial has been terminated after enrolling at least one participant, then specify zero for the number of participants analyzed in each arm/group and leave the data fields blank. This is performed under the Outcome Measures subsection.

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**BIOSAFETY NEWS**

**UC Energy Saving Project, BSC & Thimble Risk Assessments**

As part of the Energy Saving Project developed by the Planning, Design & Construction department, the Biosafety Office is performing a risk assessment to determine which biosafety cabinets (BSCs, tissue culture hoods) at the CVC, CARE/Crawley and Vontz buildings need connection to the building exhaust through a thimble. If considered unnecessary, thimbles will be disconnected from the exhaust vents. This will not only save much energy, but also obviate the unnecessary expense of thimble alarm installation and any other problems with BSC certification.
Question and Answer

Q: “My BSL2 lab works with viruses and bacteria. Can I use a BSC with no thimble?”

A: YES, a Class II type A2 BSC (the type of BSC most commonly found at UC) is manufactured without a thimble. In this equipment, part of the filtered air recirculates and part is exhausted/released into the room. The High Efficiency Particulate Air (HEPA) filter of a BSC is designed to capture particles of any size, such as microbiological agents (e.g., viruses, bacteria, fungi, protozoa), chemical/toxin powder, dust and animal dander. Environmental protection is one of the features that make this type of BSC recommended for BSL1, BSL2 and BSL3 experiments.

The only time a lab needs a BSC connected to the building exhaust by a thimble would be if volatile hazardous items (e.g., volatile toxic chemicals, toxic gases and/or volatile radionuclides) need to be handled within the sterile environment of this equipment. This way, hazardous materials which cannot be removed by the HEPA filter are not released into the room exposing its occupants.

For more information, please contact the Biosafety Office at 558-6182 or espinoma@ucmail.uc.edu

EDUCATIONAL OPPORTUNITIES

Clinical Research Forum
University of Cincinnati, Cincinnati Children’s Hospital Medical Center/Office for Clinical and Translational Research, Cincinnati Department of Veterans Affairs Medical Center and the Center for Clinical and Translational Science and Training (CCTST) are co-sponsoring the

2014 Office for Human Research Protection (OHRP) Regional Community Forum (RCF)
Clinical Research and All That Regulatory Jazz!

The one-day Forum will be presented on Wednesday, May 21, 2014, at the Kingsgate Marriott Conference Center, and will focus on ethical issues for protecting human subjects and some of the innovations on the research horizon. In addition to keynote speakers, curriculum tracks/breakout sessions include: regulatory, biobanking, technology and internet-based research, novel research, and network-based research. Clinical research presentations, updates and panel discussions will be delivered by representatives from OHRP, as well as regional academic researchers and experts from the four partnering institutions.

The early registration fee for Clinical Research and All That Regulatory Jazz! is $125 (before March 31, 2014) and $150 afterward. This activity has been approved for AMA PRA Category 1 Credit™. Additional program and registration information can be found at www.cincinnatichildrens.org/ohrp-rcf.

SAVE THE DATE! Human Subjects Protection Conference
The 15th annual regional Human Subjects Protection Conference, “Don’t Stop Believin’,” is Sept. 12, 2014, at the Northern Kentucky Convention Center. This conference will have great presentations on the role of engaged and empowered patients in medical research, protecting research participants in the digital age, improving communication between IRB and investigators, human subjects protection issues in translational research, and informed consent in behavioral research and more.

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