April 2012

This newsletter is for you. Let us know what you do/don’t find helpful and what you want to see/learn more about.

Our goal is to provide you with the information and support that you need to perform your research successfully, safely and responsibly.

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

Jane Strasser, PhD
Director, Office of Research Compliance and Regulatory Affairs (ORCRA)
Research Compliance Officer
Research Integrity Officer

IN THIS ISSUE:

Spotlight On: Research Resources
IACUC News
IRB News/New or Updated HRP Policies and Procedures
Quality Improvement Tips for Investigators
Biosafety News
Educational Opportunities

SPOTLIGHT ON: RESEARCH RESOURCES

Center for Clinical and Translational Science and Training (CCTST)
CCTST is a great resource; are you a member? Become a member at http://cctst.uc.edu. It’s fast and easy and gives you access to research expertise in methodology, regulatory knowledge, biostatistics, biomedical informatics, data management, grant writing and application assistance, inpatient and outpatient clinical research services for both adult and child studies, and support for community engagement activities. The CCTST also coordinates a number of institutional programs, including pilot grant programs, the master’s in clinical and translational research and certificate in clinical and translational research, training programs, the KL2 and two K12 programs, and novel technologies and affiliated cores.

ResearchMatch
Having trouble recruiting participants? Try ResearchMatch. It’s like speed dating for researchers and the community. This nonprofit, web-based tool was produced in conjunction with the National Institutes of Health’s Clinical and Translational Science Awards (CTSA) Consortium. It’s simple to get Institutional Review Board (IRB) approval and takes minutes to register your study. Study volunteers enter contact information, interests and a variety of health-related details that can then be used to
match them with an appropriate study. Electronic notifications are then used to alert volunteers to potential study opportunities, and only at that point do they make decisions authorizing the release of their contact information. Check out ResearchMatch at https://www.researchmatch.org/?route=ucincinnati. If you have questions contact the CCTST at 513-803-1041 or by completing the web form at http://cctst.uc.edu/contact.

Research at UC Health
The UC Health Research Committee has developed a series of SOPs to facilitate research at UC Health sites. These include SOPs for managing study funds; the Greenphire ClinCard system; research equipment; research documentation in the medical record; quality review; recruitment and retention; and continuing IND, IDE, or biologics for inpatients who are on a research protocol. While UC Health builds their research website, these policies are available on the UC IRB website at http://ahc-sharepoint.uc.edu/hrp_policies/UCHealth%20SOPs/Forms/AllItems.aspx.

HIPAA Policies
The Health Insurance Portability and Accountability Act (HIPAA) protects health information by requiring the use of safeguards to ensure that protected health information (PHI) remains private and secure. The HITECH Breach Notification Rule requires that we report impermissible use or disclosure of PHI. Fines for violating HIPAA and/or HITECH are in the millions of dollars. If you have questions or concerns about how to handle PHI, please contact Mary Lopez, JD, UC Health’s corporate director for privacy and HIPAA at mary.lopez@uchealth.com. Lopez has a dual reporting relationship to Gary Harris, UC Health vice president for risk management, and Santa Ono, PhD, UC senior vice president for academic affairs and provost.

IACUC NEWS

Nembutal is Available Again!
Butler Schein has announced that Nembutal is once again available from Butler Schein (http://www.butlerschein.com). It will require a PO to purchase (as well as Butler Schein’s triple 2 form) so if you do use it, please allow sufficient time for processing of the purchase order.

Implementing the New Edition of the “Guide” at UC
To maintain our AAALAC accreditation and maintain federal funding, we must be compliant with the revisions to the Guide for the Care and Use of Laboratory Animals (Guide). There are many changes including: new requirements for social housing (pages 50-51; 64), restrictions on non-pharmaceutical agents (page 31), increased scrutiny and oversight of food/water restriction (pages 30-31), restrictions on satellite surgical locations/housing (pages 41-74; 144), storage of food (page 141), review of humane endpoints (pages 27-28), hazards entering animal facilities (pages 18-19), changes to housing temperature (page 44), sanitization of specialized equipment/housing (page 73), pre-surgical planning (page 116), and intra-operative monitoring (page 119). In preparation for the second half of semi-annual inspections and our institution’s AAALAC accreditation evaluation, we encourage you to review the new version of the Guide as we must comply with it. If you have any questions or concerns, please contact the IACUC office at iacuc@uc.edu.

IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

ePAS Rollout
It really is coming! The UC Institutional Review Board (IRB) will be rolling out the new electronic database (ePAS) to early adopters into the system (College of Education, Criminal Justice and Human Services, psychology, infectious diseases and emergency medicine) by June 1. On that date, all new protocols from the early adopters must be submitted through ePAS.

On or around July 1, ePAS will be rolled out to all UC departments and affiliated sites. From that point
forward, all new IRB submissions must be through the ePAS system. Additionally, existing protocols
will need to be converted into ePAS on or before their annual continuing review (progress report)
date. To get started in the system, come to our outreach/office hours. They are: Thursdays from 1 to 4
p.m. in Room 439 of Teachers College and Fridays from 1 to 4 p.m. in Room 101 of the French East
building on UC’s medical campus. Hours are also held at the Cincinnati Department of Veterans Affairs
Medical Center on Friday mornings from 8 to 10 a.m. in room E425. Additional trainings and
demonstrations will be announced on the website and by email.

Questions should be directed to Anthony Gardner in the IRB office at 513-558-5105 or
anthony.gardner@uc.edu.

- back to top -

QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

Tip #1
When in need of a process for verifying scanned records, specifically when the intent is to replace the
original paper record, you need to validate the process being used to ensure readability, accessibility
and security for the length of time you are required to maintain the records.

Tip #2
When preparing to close a study it is important to ensure the following:
- Regulatory documents have been reviewed for completeness,
- Any questions about the accuracy and completeness of study data have been resolved,
- Corrections and/or notes-to-file have been added the study records,
- Arrangements have been made for the transfer and storage of study documents to a secured
  storage facility and they will be available according to the applicable record keeping and record
  retention requirements.

Tip #3
Maintain temperature logs for refrigerators and/or freezers being used for the storage of applicable
research study supplies and/or samples. Ensure the study files contain the appropriate explanations,
notifications and/or actions taken as a result of temperatures that are out of range.

Tip #4
Ensure that equipment used for research activities is maintained appropriately in order to ensure
reliable data collection. This may include maintaining a service log with the name of the equipment and
the date of service.

- back to top -

BIOSAFETY NEWS

Human Derived Materials & IBC
Research experiments involving human-derived materials, including established human cell lines,
require Institutional Biosafety Committee (IBC) approval and BSL2 practices must be followed while
working with them. This type of experiment is subject to the OSHA Bloodborne Pathogens (BBP)
Standard, which includes a mandatory annual training for all individuals who can reasonably anticipate
exposure to those materials. The Environmental Health and Safety (EHS) department offers an online
OSHA BBP training at http://www.ehs.uc.edu/itc/courses.asp#.

BSL2 Laboratories Door Signage
According to the Centers for Disease Control and Prevention and the National Institutes of Health
guidelines, BSL2 laboratories must have signs posted on their immediate access doors. Those signs
must contain: the biohazard level (i.e., 2) and symbol; name of the biohazard or potential biohazard
items (e.g., bacteria, viruses, fungi species, human cells, human blood and tissues), special
requirements for entering the area and the name and telephone number of the principal investigator
(PI) and other responsible person. Laboratory door signage must be kept to a minimum. “Over posting”
materials on the lab doors may camouflage important messages. If a BSL2 laboratory is shared with more than one PI, the information regarding agents and emergency contact should be combined in a single sign. Also, the BSL2 sign must be kept up-to-date regarding the agent(s) currently handled in the location, so appropriate hazard alerts are provided. The biosafety office has two different templates for BSL2 signs; one for laboratories working with microorganisms and another for laboratories working exclusively with human-derived materials. Signs can be obtained through the biosafety office website at http://researchcompliance.uc.edu/Biosafety/BiosafetyAndBiosecurity.aspx.

EDUCATIONAL OPPORTUNITIES

FBI Academic Biosecurity Workshop
June 13, 2012, from 8 a.m. to noon
UC is hosting a free biosecurity workshop to discuss and clarify concerns with the potential for ‘dual use’ in biological research. Registration is required and can be completed online at https://academicbiosecurityworkshop.org.

Save the Date: Human Subjects’ Protection Conference Oct. 5, 2012
This year’s conference, titled “Human Subject Protection: With A Little Help From Our Friends,” will once again take place at the Northern Kentucky Convention Center. This year’s keynote speaker is Seth Mnookin, author of the New York Times best seller, The Panic Virus: The Story Behind the Vaccine-Autism Controversy. Seth will discuss his book and strategies to combat the growing public health crisis resulting from infants not being vaccinated. The event will feature a diverse group of speakers discussing cutting-edge topics including: social media in research, ethical relativism and its impact on research, returning research results to subjects and FDA’s oversight of human subject protection. Continuing education credits and nursing credits are also available to attendees. Registration is $100 for UC and Academic Health Center affiliates (UC Health, VA, etc.) and includes breakfast and lunch. The registration site opens Friday, June 1, 2012.