Winter 2013

This year promises to be a big one for UC. We have our triennial Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation and the Medical Sciences Building Laboratory Animal Medical Services (LAMS) facility will reopen after extensive renovations. We are also expecting a biennial site visit for our radiation license and an audit from FDA. Hopefully the government will release a draft of proposed changes to the common rule that will streamline human subjects' research oversight.

With all of that going on we will continue to strive to facilitate the research community in growing excellent, ethical research. I hope you have success with funding, publications, mentoring and career development in 2013. Let us know how we can help.

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

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IACUC NEWS

AAALAC Site Visit (March 4-6, 2013)
The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) is coming to perform the three-year site visit from March 4 to 6, 2013. Below are some helpful resources for research staff. In addition, PI's are strongly encouraged to review their currently approved protocol with all individuals working on the protocol.

- **Food Storage in Laboratories**: Improper storage of food is a hot topic for AAALAC. Common concerns include storing food at temperatures above 21°C (70°F), not monitoring room temperature, or storing food with chemicals, biological, or radioisotopes. For more information please see Institutional Animal Care and Use Committee (IACUC) policy 33 (below), or contact the IACUC office for assistance.
“Since You Asked” ... Here’s the link to an article on AAALAC Site Visit Preparation from ALN Magazine summarizing what to expect during the AAALAC site visit.

The AAALAC website has a list of resources that addresses concerns and provides information on the purpose and value of AAALAC accreditation.

IACUC Policy Update
In case you missed the notice, there have been a number of recent changes to IACUC policies. Current policies and forms are always available on the IACUC website.

New Form Requirements

- Protocol Addendum A: Withholding Enrichment or Single Housing (Must be submitted to withhold enrichment or singly house animals.)
- Protocol Addendum B: Use of Non-Pharmaceutical Grade Compounds (Required to use non-pharmaceutical grade compounds.)
- Disclosure of Diet Storage Outside of LAMS (Must be submitted to store food outside of LAMS.)

Summary of Approved Policies

- Policy 019: Use of Pharmaceutical Grade Compounds in Vertebrate Animals
  - Protocol Addendum B: Use of Non-Pharmaceutical Grade Compounds
- Policy 030: Environmental Enrichment and Social Housing (approved 11/08/12)
  - Protocol Addendum A: Withholding Enrichment or Single Housing
- Policy 033: Storage and Location of Diets Outside of LAMS
  - IACUC Form #F-03: Storage of Diets Outside of LAMS
- Policy 034: Food and Fluid Regulation Requirements in Rodents (approved 12/13/12)

IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

Use of an External IRB (WIRB and SAIRB) and Changes to the Research Team
To remain in compliance with university policies on conflict of interest and human subjects’ research training, staff changes to all IRB protocols regardless of the reviewing IRB (e.g., SAIRB, WIRB, etc.) must be submitted to UC’s IRB in ePAS via an amendment in addition to submitting the change to the IRB of record. The UC IRB will review COI and CITI Training only, documentation of this review must be received by the site before incorporating these changes.

Billable Services Fees Changing
The University of Cincinnati charges fees to cover the costs associated with the review and oversight of protocols that are industry funded with the funding held external to UC.

Since July 2009, UC IRB has charged:

- $2,000 for new submissions
- $5,000 to fast track new submissions (going straight to board without any pre-review)
- $1,000 for continuing review (annual progress report)
- $250 for each non-administrative amendment (i.e., no charge to change research personnel, submit reportable events etc.)

Beginning July 2013, these fees will change:

- $2,500 for new submissions
- $5,000 to fast track new submissions (going straight to board without any pre-review)—unchanged
- $1,000 for continuing review—unchanged
$500 for every non-administrative modification after the first 2 (no charge for first 2, $500 each thereafter)

University Hospital Name Change
University Hospital’s name has changed to University of Cincinnati Medical Center. Make sure that you keep this information current in your research documentation (e.g., FDA forms 1571, 1572, and investigator agreements; HIPAA forms, advertisements, etc.).

Data Management
What could help your research more than a free, secure and reliable data capture system? REDCap is a user-friendly, web-based, electronic data capture program that is fully compliant with Good Clinical Practice (GCP) guidelines. You can use it as a case report form, or to do research surveys. It has automatic backup, user-level access control, and it has audit trails so you know who is entering, adding or changing data. Data can be exported into a fully labeled SAS, SPSS or STATA data set at the click of a button. It is provided free of charge through the Center for Clinical and Translational Science and Training (CCTST) and requires very little training to be up and running. If you are conducting human subjects’ research, we recommend using REDCap because it satisfies the minimum standards for protection of identifiable research data when most other free or easy systems do not. Learn more about REDCap.

Not Human Subject Research Determinations
Studies that require Institutional Review Board (IRB) review must meet the definitions of both “Research” and “Human Participants” or fall under FDA regulations. “Research” is a systematic investigation, including data collection, that is designed to develop or contribute to generalizable knowledge. “Human Participants” are involved when data are collected about living individuals or the data include genetic materials and an intervention or interaction takes place or the information obtained from human participants is private and individually identifiable.

The IRB is the body that must make the determination that a project does or does not require IRB review. If the researcher believes their study does NOT meet the definition of BOTH research and human participants, they will need to submit their study to the IRB through ePAS for a determination.

- Log in to ePAS and click “My Home” in the top right corner.
- Click on the “New Study Application” button located on the left side of the page.
- Complete the smart form application by answering the questions/entering the information and clicking the “continue” button in the top/bottom right of each page.
- On the third page, titled “Research Classification,” select the option “Not Human Subject Research Determination” and click “continue.”
- The next two pages in the smart form ask for the same information we requested in the old paper Not Human Subject Research determination form.
- Once the smart form application has been finished and all listed researchers have agreed to participate, the PI needs to click “Submit Study” under “My Activities.”
- The IRB will document in ePAS that the study does not require IRB review and the PI will be notified by email.

Accessing ePAS
From this 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) submission. Access ePAS at: https://epas.research.cchmc.org/ePAS_PRD

For UC and affiliated sites, login by clicking on the UC logo at the bottom of the page, You will then login using your UC credentials.

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 the Research Office Conference Room. These hours are intended for study specific questions and overviews of the system only.
Questions should be directed to Anthony Gardner in the IRB office at anthony.gardner@uc.edu. We have set up formal ePAS training on Mondays from 1:30 to 4 p.m. in room 454 of University Hall. This is scripted training and will generally take the full 2.5 hours to get through. Please RSVP for this training to Melanie Fulton at melanie.fulton@uc.edu. Get ePAS Submission Documents and Guidance.

ClinicalTrials.gov
Records on ClinicalTrials.gov for investigator-initiated studies need to be maintained by the PI consistent with the applicable federal and/or journal requirements. In the event that the PI plans to leave the institution before closing out the record, one of two steps needs to be taken: 1.) Transfer the ClinicalTrials.gov record to another investigator at the institution for management. This needs to be someone who has access to the study data and is familiar with the protocol. OR 2.) Transfer the study record to the new institution. Data ownership issues need to be addressed using any applicable legal agreements, department head and intellectual property office. To transfer a record, send an email to register@clinicaltrials.gov with the NCT number, the name of the new organizational account and the name of the new record owner (PI) requesting the record transfer. If you require assistance, then send an email to researchcompliance@uc.edu.

Protecting Privacy
Mobile devices are everywhere and they are convenient, but is your data secure? The Department of Health and Human Services has an initiative called “Mobile Devices: Know the RISKS, Take the STEPS, PROTECT and SECURE Health Information.” It is available at http://www.hhs.gov/news with initiative and guidance at www.HealthIT.gov/mobiledevices.

UC Health SOPs
Approved UC Health SOPs are available on the IRB website. If you have any questions or concerns please contact Jason Johnson at 513-245-3095 or jason.johnson2@ucphysicians.com.

QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

Tip 1: For those investigators using an external IRB, ensure that you have reviewed all policies for the IRB of record including reporting requirements for unanticipated problems as well as planned protocol deviations/violations.

Tip 2: Hold a practice run or rehearse study procedures (e.g., enrolling participants) prior to study startup to identify and resolve potential issues (e.g., unclear eligibility criteria, overly ambitious schedule of events). Ideas for solutions: http://www.firstclinical.com/journal/2012/1212_Rehearsing.pdf

Tip 3: For those investigators conducting research at the Cincinnati VA, remember to hold on the use of IRB approved documents until the R&D Committee approval has been obtained. Using a tracking log (may include the name of the document, version, IRB approval date, date of release from the IRB, date of R&D approval) may be useful for ensuring the use of the correct forms, such as the informed consent document.

Tip 4: Ensure that each research feasibility assessment is done in combination with the protocol and the draft budget to ensure the best fit between your site and the proposed trial.

Tip 5: Include memos or notes-to-file in the study file documenting that each participant or legally authorized representative (LAR) received a copy of the informed consent form or declined a copy (if applicable) in order to demonstrate regulatory compliance (45 CFR Part 46.117).

Tip 6: A mobile application that meets the definition of a device and either is used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device is subject to FDA regulations. FDA has issued draft guidance on mobile medical applications (link below). For those in the process of creating and eventually commercializing a mobile medical application, remember to contact UC’s Office of Research Integrity (UCORI) and Office of Entrepreneurial Affairs & Technology Commercialization (OEATC) in order to ensure you are aware of the applicable regulatory
requirements and best options for meeting commercial potential. Download the FDA regulations.

Tip 7: For sponsor-investigators with an active IND application, there is an updated FDA Form 1571 (10/12; expires 4/30/2015) available on the Agency’s webpage (link below). As noted in the previous version, there is a section for you to indicate whether or not any sponsor obligations will be transferred to a contract research organization. Indicating ‘yes’ on the form and providing FDA with written statements identifying the organization and obligations transferred does not negate the need for a robust contract specifying precisely which duties are being transferred and which ones are being retained. http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm083533.pdf

BIOSAFETY NEWS

BSC & Thimble Connection—Certification
Class II A2 Biosafety Cabinets (BSC) are the most common type of BSC in use at the University of Cincinnati and are appropriate for most biohazardous work applications. Class II BSCs provide personnel protection from biohazardous materials using HEPA filtered air prior to release into the room, in addition to providing product protection (to maintain sterility). Type A2 cabinets normally return their filtered exhaust air to the room, but may optionally be connected to the building exhaust system with a thimble connection.

Thimble connections (also called canopies) are sometimes connected to Class II type 2 cabinets as an alternative for experiments involving minute amounts of volatile toxic chemicals and/or radionuclides which need a sterile environment. This way, hazardous materials which cannot be filtered by the HEPA filters are not released inside the room.

BSC Certification
BSC certification should be performed by the certifier upon installation and relocation of cabinets, after major maintenance is conducted, changing of HEPA filters, and at regular intervals thereafter. For use at biosafety level 2 or above, certification must occur at least every 12 months. When selecting a service provider for certification, ensure that the technicians are accredited field certifiers.

BSC with Thimble & Alarm
To enhance the safety of the user, federal standards for certification now include the requirement for Class II cabinets with thimble connections to be fitted with an audible and visible exhaust alarm to indicate when air flow is being returned to the room rather than being exhausted out. Thimble-connected BSCs built from 2010 are required to have an alarm. If you are having problems getting your BSC certified please contact the Biosafety office (513-558-6182).

NEWS FOR RADIATION USERS

Animal users aren’t the only ones expecting site visitors. Ohio Board of Health is coming soon to inspect UC as part of our license renewal. Learn more about what to expect by clicking here.

EDUCATIONAL OPPORTUNITIES

Electronic Submissions for INDs and IDEs
CCTST is sponsoring RAPS Virtual Program "Electronic Submissions for INDs and IDEs." This series is an ideal avenue for learning the very latest regulatory electronic compliance information coming out of FDA. RAPS Electronic Submissions for INDs and IDEs Virtual Program Series will instruct us on the standards, groundwork, expertise and technology required to submit compliant electronic submissions to FDA. All webinars are from noon to 1 p.m.
Empirical Bioethics Conference Feb. 21-22
UC will host the conference "Empirical Bioethics: Emerging Trends for the 21st Century," Feb. 21-22 at the Kingsgate Marriott Conference Center. During this two-day conference, participants will learn about cutting-edge research that defines the ethical framework guiding clinical and translational studies. Speakers include internationally recognized experts in the application of bioethics to clinical research and medicine. Continuing education credits are available. Cost is $100. Online registration is required by Feb. 15 at www.cincinnatichildrens.org/cme. For more information, call 513-803-2610 or email bettie.durant@cchmc.org.

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