Summer 2012

The old expression is true, familiarity breeds contempt. Despite lots of experience, lab accidents happen. It has been an unusually hot summer but you still need to wear appropriate attire in the laboratory. If you wear sandals outside keep some closed-toed shoes in a drawer and wear them when you are working, and remember to cover exposed skin by wearing a lab coat.

It may not always feel that way, but the group that comprises the research compliance and regulatory affairs team exists to facilitate research. Our goal is to provide you with the information and support that you need to perform your research successfully, safely and responsibly.

Please note that to more accurately reflect the goals of the Office, we have renamed the Office of Research Compliance and Regulatory Affairs to the UC Office of Research Integrity. This name change is reflected on our website, which you can now also get to via http://researchintegrity.uc.edu.

Let us know what you do/don’t find helpful; what you want to see/learn more about. 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: STATEWIDE IRB/CHANGING NAMES

Statewide IRB Rolled Out
The UC Center for Clinical and Translational Science and Training (CCTST) has partnered with the two
other Clinical and Translational Science Award (CTSA) institutions in Ohio—Case Western Reserve University and The Ohio State University—and their affiliated institutions to establish a statewide collaborative agreement allowing a single organization’s Institutional Review Board (IRB) to assume IRB responsibilities on behalf of multiple institutions when conducting multicenter studies.

This collaborative effort will serve to accelerate research by streamlining human subject protection processes when participating institutions are partnering on research projects requiring IRB approvals.

This is the first reciprocity agreement among multiple CTSA organizations and encompasses eight legally separate institutions in Ohio. Read more about the new agreement.

**Changing Names and Conducting Research at UC Health**

There have been multiple changes to institutional names as well as street name changes that may impact your research. 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.). Taking steps to make these revisions soon after implementation will ensure that important communications—including those from FDA and the Sponsor—are received and responded to in a timely manner.

-IACUC NEWS-

**AAALAC Site Visit Preparation**

In anticipation of the Spring 2013 Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) site visit, the Institutional Animal Care and Use Committee (IACUC), IACUC office, and Laboratory Animal Medical Services (LAMS) personnel will be conducting walkthroughs of both LAMS facilities and satellite animal areas. The purpose of these walkthroughs is twofold. First, we want to identify any potential areas of weakness in our program so that they can be addressed and corrected prior to the site visit. Second, we want to familiarize research staff with the types of questions and potential concerns AAALAC may have during their visit. If you see individuals from any of the above-mentioned offices/committees in your area, please feel free to ask them any questions or concerns you have regarding the upcoming site visit or about your animal practices, procedures, or animal areas. The IACUC, IACUC office, and LAMS personnel are here to assist you and to help ensure a compliant, high-quality, animal research program.

**IACUC Policy Updates**

The following policies have been approved by the Institutional IACUC and are now in effect. It is recommended that you review these and other IACUC policies relevant to your animal use. Your continued cooperation to ensure compliance is greatly appreciated. All approved IACUC policies are on the IACUC website.

#003 Animal Transportation Policy

This Policy describes requirements when transporting animals outside of a building and has been modified to include the temperature ranges in Celsius. The animals must be transported in a climate-controlled vehicle when the outside temperature is below 50°F (10°C) or above 85°F (29.4°C). Use of a climate-controlled vehicle is not required if the transportation time is less than 7 minutes.

#012 Policy on Housing Animals in Laboratories

This policy has been revised to reflect the changes to environmental requirements in the new “Guide” (8th edition). It also requires that the primary door to the satellite housing area must be locked when personnel are not present. Additionally, it requires that LAMS track temperature changes.
#012A Requirements for Mammalian Satellite Housing
This policy has been revised to define satellite housing areas and to assist researchers in documenting the required monitoring and maintenance of these areas. In addition, changes were made to facilitate the communication between researchers, LAMS staff, and IACUC regarding the activities that are occurring in satellite housing areas. To find the log referenced in this policy please click [here](#) or go to the LAMS website and look under “Staff SOP & Forms; 600-699 Environmental” and click on form “FM601.1.”

#029 Transfer of Animals between UC Approved IACUC Protocols
This policy describes the requirements for transferring animals between UC approved IACUC protocols and has been modified to clarify who to contact when research is grant-supported and involves a collaborator. If research is grant supported, the collaborator’s protocol number must be submitted to Sponsored Research Services. For further assistance, please contact the grant administrator for your department.

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IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

**ePAS Rollout**
Finally! On Aug. 6 the UC Institutional Review Board (IRB) rolled out the new electronic database (ePAS), (or more affectionately, imPASSe) to early adopters into the system (College of Education, Criminal Justice and Human Services, and the departments of psychology, infectious diseases, and emergency medicine; as well as any protocols involving a reliance agreement between UC and Cincinnati Children’s Hospital Medical Center). As of the Aug. 6 rollout date, all new protocols from the early adopters must be submitted through ePAS.

Effective September 4, ePAS will be rolled out to all UC departments and affiliated sites. From that point forward, all new IRB submissions should be through the ePAS system; however, exceptions may be made on a case by case basis through the first of October. Effective Oct. 1, 2012, ALL new submissions must be in ePAS. Additionally, existing protocols will need to be converted into ePAS on or before their annual continuing review (progress report) date. Once your study is converted, all future submissions for that study (i.e., amendment, reportable event, continuing review/progress report) will be in ePAS as well. For help getting started in the system, we encourage you to come to our outreach/office hours.

- Thursdays from 1 to 4 p.m. in Room 439 of Teachers College
- 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 online and by email. If you would like to set up a training for a group of researchers we will try to coordinate a time.

Please refer any questions about ePAS to Anthony Gardner in the IRB office at 513-558-5105 or [anthony.gardner@uc.edu](mailto:anthony.gardner@uc.edu).

**Departmental Designation**
To better serve the research community we are changing from our current, process-delineated work flow to having specific staff members dedicated to specific research groups. The primary contact is...
delineated by college/institute (except for College of Medicine, which is broken down into smaller units). Get details on the new departmental designation.

**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, 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!

**ClinicalTrials.gov**

The Food and Drug Administration Amendments Act or FDAAA (Public Law 110-85, Title VIII, Section 801) and the International Committee of Medical Journal Editors (ICMJE) mandate the registration of clinical trials. FDAAA requires registration of all trials for drugs, devices and biologics excluding Phase I drugs studies and small device feasibility studies no later than 21 days after the first participant is enrolled. ICMJE requires registration of all human research projects that prospectively assign human participants to an intervention or comparison group to examine the relationship between a medical intervention and a health outcome before the first participant is enrolled. Penalties for responsible parties who do not register applicable trials may include notices of noncompliance, monetary sanctions (up to $10,000 per day), withholding or recovery of grant funds for federally funded trials as well as difficulties publishing. The University of Cincinnati maintains an institutional account and individual investigators should not attempt to set up their own account. Investigators should contact the Office of Research Integrity for access to an account (research.compliance@uc.edu). Guidance for initial posting, updating and reporting basic results are available online at http://researchcompliance.uc.edu/HSR/ClinicalTrials.gov.aspx.

**FDA Updates**

Effective May 30, the FDA issued a final rule allowing the agency to disqualify an investigator “from conducting any clinical investigations that support an application for a research or marketing application for a research or marketing permit for products regulated by FDA” once the individual has been disqualified regardless of whether the research involved drugs, biologics, devices or animal drugs. https://federalregister.gov/a/2012-10292

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**QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS**

**Research Tips**

- Introductory training modules for investigators conducting medical device research are
available on the FDA website: http://www.fda.gov/Training/CDRHLearn/ucm162015.htm

- Ensure that all key personnel assisting in the conduct of a given study are informed about their obligations to meet their commitments. This includes ensuring that those responsible for completing study documents do so fully and accurately.
- Initiate and verify the effectiveness of procedures for ensuring that all study related tasks are performed accurately and in a timely manner. This includes recording and reporting unanticipated problems involving risk to human participants or others.
- Ensure that your device research qualifies for exemption from pre-market approval and IDE requirements. For instance, custom devices are defined in 21 CFR 812.3(b). A custom device that does not meet the criteria established by the regulations is not a custom device and an IDE application must be submitted to FDA in addition to obtaining IRB approval for the investigation.
- The interstate shipment and importation of drugs, devices and biologics that have not been approved for use in the U.S. by FDA is prohibited by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 331). Please send your questions regarding importation of unapproved drugs, devices or biologics for the use of research or single patient (compassionate) to research.compliance@uc.edu.

BIOSAFETY NEWS

Risk Group & Biosafety Level: Related But Not Synonymous

Risk Groups (RG) are used as part of a comprehensive research biosafety risk assessment of infectious agents that have the potential to cause human disease. An agent may be classified as belonging to risk groups 1 to 4 depending on the virulence of the agent, its mode(s) of transmission, its host range, and the availability of effective treatment.

<table>
<thead>
<tr>
<th>Risk Group (RG)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RG1</td>
<td>Agents that are not associated with disease in healthy adult humans</td>
</tr>
<tr>
<td>RG2</td>
<td>Agents that are associated with human disease which are rarely serious and for which preventive or therapeutic interventions are often available</td>
</tr>
<tr>
<td>RG3</td>
<td>Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)</td>
</tr>
<tr>
<td>RG4</td>
<td>Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)</td>
</tr>
</tbody>
</table>

Biosafety Level (BSL) corresponds to the facilities, equipment, practices and procedures for safe conduct of work with an agent. Biosafety levels also range from 1 to 4. The biosafety level frequently, but not always, corresponds to the biosafety level and is based on professional judgment. The RG guides the assignment of the correct biosafety level for containment. For example, the use of certain RG2 agents in large quantities might require BSL3 conditions, while some RG3 agents (such as HIV)
may be safely manipulated at BSL2 under some conditions.

EDUCATIONAL OPPORTUNITIES

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 conference 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 subjects’ protections. Continuing education credits and nursing credits are also available to attendees. Registration is $100 for UC and Academic Health Center affiliates (UC Health, VA, Cincinnati Children’s) and includes breakfast and lunch. Click here to register.

Pfizer Investigator Training Program
The Pfizer Investigator Training Program (ITP) will take place at Cincinnati Children’s (S building) on Oct. 9 (all day) and Oct. 10 (half day). ITP provides a forum to share experiences and receive practical advice on clinical trial organization and execution; examining the entire trial process, from the planning stages to trial close-out activities; and providing practical recommendations for increasing the efficiency of clinical trial conduct at investigative sites. Modules include: planning and preparation; recruitment and enrollment; in-trial procedures; safety in clinical trials; monitoring; audits, inspections, and publication; drug development process; and additional regulations. Attendance is limited to full-time academic health center faculty based at UC, Cincinnati Children’s and the VA. Registration is limited and pre-registration is required. The training will be streamed via internet but will not be recorded. To register, email: mina.busch@cchmc.org. The ITP is designed and presented by Pfizer and sponsored by the Center for Clinical and Translational Science and Training (CCTST).