

July 2008

This summer brings some big changes to the Office of Research Compliance and Regulatory Affairs (ORCRA) that will improve our service to the academic community.

ORCRA will be adding several new staff members, including a new biological safety officer and Institutional Biosafety Office director, additional staff for the Institutional Review Board (IRB) office and a Food and Drug Administration (FDA) specialist within ORCRA. Plans to move the ORCRA offices to University Hall are scheduled for September. See each section for additional details.

But the summer—despite all of its excitement—is also a sad time for me. I will be leaving at the end of August to take a position as senior scientific administrator in the ethics division at the National Institutes of Health, working for the deputy director. There has been sufficient time to identify a new director and we will be working together for several months with final turnover Sept. 1. It has been my pleasure and privilege to work with everyone at UC and I will miss the excitement and challenges of a university environment. I wish you all success for the years to come.

As always, you can contact us with questions at research.compliance@uc.edu. Let us know how we can better serve you.

Melissa Colbert, PhD
Director, Office of Research Compliance and Regulatory Affairs (ORCRA)
Research Compliance Officer
Research Integrity Officer

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SPOTLIGHT ON: ORCRA'S NEW FDA SPECIALIST

Joanne Lindwall has been promoted to senior regulatory analyst in charge of FDA affairs. She will continue in her role as director of post-approval monitoring. Lindwall is currently revising policies and procedures that relate to sponsor-investigator held Investigational New Drug/Investigational Device Exemption (IND/IDE) and will be available for consultation and advice on all new applications. Lindwall has experience working for a consulting group specializing in the clinical development of pharmaceutical and biological products as well as specialized training in drug law and medical devices. As a reminder, the IRB requires pre-review of all IND/IDE protocols and regulatory documents, including protocols not having commercial sponsors. Watch for announcements and links to changes in FDA policy at <http://researchcompliance.uc.edu/FDA/default.html>.

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ORCRA NEWS

Strasser Named ORCRA Director

Jane Strasser, PhD, has been named the new director of ORCRA. In this role, she will also serve as research compliance officer and research integrity officer. Strasser, an assistant professor in the department of pediatrics at UC, has chaired the institutional biosafety committee at Cincinnati Children's Hospital Medical Center since 2006, is a member of the UC BSL3 users group, and is the interim biosafety officer at UC. She has also served as a member of Cincinnati Children's institutional animal care and use committee. A researcher herself within the division of infectious diseases at Cincinnati Children's, Strasser received her undergraduate and graduate degrees from UC—completing her PhD in molecular genetics in 1995. She was a research fellow at the MRC Laboratory of Molecular Biology at University College, London, before obtaining a postdoctoral fellowship position at Case Western Reserve University in 1997. She joined the research staff at Cincinnati Children's in 1998. Strasser assumed the compliance officer role on a part-time basis in June—and will transition to full time director Sept. 1.

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IACUC NEWS

Expired Drugs and Medical Materials: Tips for Avoiding a Compliance Issue

According to Robert Willems of United States Department of Agriculture (USDA), preliminary data from the USDA Animal and Plant Health Inspection Service program indicated that “expired drugs and medical materials was one of the top cited issues inspectors found.”¹

- Be sure you have a schedule or procedure for reviewing the expiration date of items in your animal housing/procedure area.
- Ensure someone in the lab is clearly assigned the responsibility for reviewing expiration dates.
- Do not store *in vitro* supplies in the designated animal housing/procedure area.
- Discard expired drugs or medical materials as soon as practical.
 - Contact [Environmental Health and Safety](#) for advice on proper disposal of chemicals.
 - If it is a controlled substance contact the Ohio Board of Pharmacy for permission to discard, or clearly label the material as “DO NOT USE” and segregate it in the your drug safe away from the non-expired material (Use a clearly labeled bag or box, or place it on a separate shelf.)

¹ Willems R. (May 21, 2008) *Non-Compliance*. Presentation at IACUC 201 Plus, Delray Beach, FL.

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IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

WIRB Negotiations

ORCRA and the IRB office have been working for several months on a contract with Western IRB for review of multi-site industry-sponsored trials (see [Compliance Matters, Jan. 2008](#) for details). The contract has now been signed by both parties and we are preparing the local language for informed consent documents and finishing details for electronic submissions. The IRB office will also add a dedicated IRB staff member to ensure rapid processing of protocols submitted for Western IRB review. Representatives from Western IRB will be visiting the campus this summer to meet with investigators and coordinators to go over their requirements and to answer any questions on process or procedures. Watch for further announcements.

University Hospital Required Consent Information

All consent forms for new protocol submissions, progress reports and modifications for research studies performed at University Hospital facilities must include patient name and date of birth on the first page of the consent. The current template on the IRB Web site has lines included for this additional information. Please be sure to use this format. <http://researchcompliance.uc.edu/irb/default.html>.

New Staff for the Front Desk

The IRB office has a new person, replacing Susan Groh, at the front desk. Justin Osborne joined the staff at the end of May. He came to us from Shulman Associates IRB and has quickly become a valued member of the staff. Justin will be assisting in many areas throughout the IRB as well as with external clients when they come into the office.

Policy Updates

UC Policies: III.05, V.03, V.06, VII.01

IRB Procedures: 303, 307, 308, 319 (removed), 320, 321

Access all updates under the policies and procedures heading at <http://researchcompliance.uc.edu/irb/default.html>.

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QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

REMINDER: Informed consents must be translated into the primary language of the participant. The use of an interpreter is in conjunction with the translated consent and is not to be used instead of a translated consent. See [University Policy II.01](#) for further clarification.

REMINDER: For all studies that enroll prisoners, a prisoner advocate must be involved in the review of your study. Do not forget to notify the IRB if a subject becomes incarcerated or if you intend to enroll prisoners as subjects.

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FDA ASSISTANCE

Are you an IND/IDE holder?

If you are the holder of an IND/IDE (also know as sponsor-investigator), you assume the responsibilities of both an investigator AND a sponsor.

The FDA assistance program can help ensure compliance with FDA regulations governing sponsor-investigators. The primary purpose of the program is to remind and assist sponsor-investigators of their reporting obligations to the FDA, track reports and communications with the FDA and assist sponsor-investigators to be compliant.

To fulfill this purpose the following services are offered:

- Offer explanation of IND and IDE regulations.
- Assist in understanding the obligations of a sponsor-investigator.
- Assist in determining applicability of an IND or IDE.
- Assist in determining contents of IND or IDE.
- Assist in submitting IND and IDE applications to FDA.
- Offer regulatory assistance during FDA inspections of investigator-sponsored clinical trials.

Prior to any submission of an IND/IDE, or to learn more about the FDA assistance program, contact

Joanne Lindwall, FDA specialist, by phone at (513) 558-3576 or by e-mail at joanne.lindwall@uc.edu.

Data Monitoring Service Offered

Beginning Aug. 1, 2008, ORCRA will offer monitoring of FDA IND/IDEs on a fee-for-service basis at significantly reduced rates. This service—offered at \$45 per hour—is available through our FDA assistance program. The fee is just half the price normally charged by most contract research organizations. For more information, contact Joanne Lindwall at (513) 558-3576 or e-mail joanne.lindwall@uc.edu.

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RADIATION SAFETY NEWS

Radiation Safety to Separate from ORCRA

The consolidation of the Office of Research in University Hall and the hiring of a new ORCRA director facilitated the move of radiation safety from under the auspices of ORCRA. Victoria Morris, radiation safety officer, will remain director of radiation safety. Please check the radiation safety Web site for news and future developments. <http://researchcompliance.uc.edu/radsafety/default.html>.

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BIOSAFETY NEWS

Espinola Named Biosafety Officer

Marcia Epsinola, DVM, will join UC in July as our new biological safety officer and director of the Institutional Biosafety Office. Espinola is coming to us from Washington University in St. Louis after completing a biosafety fellowship at the Midwest Regional Center of Excellence for Biodefense and Emerging Disease Research. A native of Brazil, Espinola is trained in veterinary medicine, holds a master's in microbiology, certification as a specialist microbiologist in biological safety and is a certified biological safety professional from the American Biological Safety Association. She completed five years of bench research experience on poxvirus while at St. Louis University and Barnes Jewish Hospital prior to entering her fellowship.

BSL3 Facility Transferred to Molecular Genetics

Administration of the BSL3 facility has been turned over to Malak Kotb, PhD, chair of molecular genetics. The biosafety officer will continue to serve as the alternate responsible official and perform inspections of the facility. It will function as a service center and its management will be assumed by molecular genetics, with Gary Dean, PhD, as facility director.

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RESEARCH COMPLIANCE EVENTS & TRAINING

Look for announcements in the fall quarter. Have a good summer!