

October 2008

Welcome to the fall 2008 edition of Compliance Matters. I'm pleased to join you as the new director of the Office of Research Compliance and Regulatory Affairs. It was a pleasure working with Melissa Colbert and we wish her well in her new role at the National Institutes of Health.

Our office continues to seek ways to facilitate research while protecting our research subjects, our employees, the community and the institution. 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

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SPOTLIGHT ON: SHIPPING

Shipping of chemicals, dry ice, diagnostic samples and/or infectious agents is regulated by a variety of agencies. In order to ship things that are considered dangerous and/or infectious, you must have certification. **Failure to ship appropriately carries personal fines.** Spot checks of individual shippers by the Federal Aviation Administration (FAA) are ongoing. Information on FAA shipping regulations is available at www.faa.gov/safety/security. UC's Environmental Health and Safety (EHS) Office can answer your chemical shipping questions. You can reach EHS at by calling (513) 556-4981. Questions about biological agent shipping can be directed to the Biosafety Office by calling (513) 558-5210.

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ORCRA NEWS

Relocation News

There are some changes within the Office of Research Compliance and Regulatory Affairs (ORCRA). Post-Approval Monitoring and the Institutional Animal Care and Use Committee (IACUC) have moved to University Hall, Room 238. The Institutional Review Board (IRB) and Biosafety Office will move to University Hall in the next several months.

Compliance Reporting

ORCRA has expanded its compliance reporting capabilities. You can still anonymously report compliance concerns using (800) 889-1547. Now you can also use the internet at <https://secure.ethicspoint.com/domain/media/en/gui/22314/index.html>. Both methods of reporting are anonymous and will provide the reporter with a mechanism to follow up.

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IACUC NEWS

New Location and Contact Info

The Institutional Animal Care and Use Committee (IACUC) invites you to visit them in their new location. The office has relocated to University Hall, Room 238. The mail location and phone numbers have not changed, but the zip code and PO Box have. No service delays are expected to result from the move.

Contact Information:

IACUC Office

University Hall, Room 238

51 Goodman Drive

PO Box 210572

Cincinnati, OH 45221-0572

Tel: (513) 558-5187

Fax: (513) 558-3539

E-mail: IACUC@ucmail.uc.edu

Web: www.researchcompliance.uc.edu/IACUC

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IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

New IRB Team Members

In order to better serve the needs of the research community the Institutional Review Board (IRB) is undergoing a major re-organization. Julie Gerlach, BSN, MPH, chairperson of the social and behavioral IRB, has assumed the additional responsibility of director of the IRB office. As IRB director, Gerlach will oversee the day-to-day operations of the IRB office and continue to optimize office function.

To facilitate protocol modifications, new submissions, and the transition to a paperless system, Tara Knipp has joined the IRB as a research compliance analyst. Knipp brings a diverse regulatory background to the office.

CITI Training

The University of Cincinnati Institutional Review Board (UC IRB) is strengthening its ties to the Greater Cincinnati research community. The UC IRB is working with Cincinnati Children's Hospital Medical Center, The Veteran's Affairs Medical Center, The University Hospital and The Christ Hospital to coordinate **CITI** training through the Greater Cincinnati Academic Health Center (GCAHC). Acceptance of the CITI Training Courses by the above-named institutions, allows a researcher/key personnel who has completed training through affiliation with GCAHC to have their CITI training accepted by other GCAHC institutions. This universal training will be available in October. Please be aware that the CPD opt-out for training will no longer be an option.

Western IRB

UC is pleased to announce the addition of Western IRB for submission of funded pharmaceutical

protocols. For additional information, visit http://researchcompliance.uc.edu/wirb_contents/WIRB.html, or e-mail Justin Osborne at eirb@uc.edu.

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QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

REMINDER: The University Human Subject Protection Program revised policy # VI.01 now requires that all researchers who act as sponsor-investigator of an IND/IDE adopt the applicable IND/IDE assistance program template SOPs for all aspects of the clinical trial(s) as indicated in 21 CFR §312 & 21 CFR §812. These templates can be found at:

http://ahc-sharepoint.uc.edu/hrp_policies/SponsorInvestigator%20SOPs/.

Please contact Joanne Lindwall at (513) 558-3576 or lindwaj@ucmail.uc.edu with questions.

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BIOSAFETY NEWS

Understanding the Steps for Getting an IBC Approval

The Biosafety Web site has been modified to help researchers obtain Institutional Biosafety Committee (IBC) approval. A flow chart outlining the critical steps in the submission and approval process has been added at http://researchcompliance.uc.edu/biosafety/Submit_Protocol.html.

Frequently asked questions (FAQs) have been added. View FAQs at <http://researchcompliance.uc.edu/biosafety/faq.html>.

Use of Human Tissues, Cells and Cell Lines

Research involving the use of human-derived substances (for example, blood or blood components, tissues, cells or secretions) is subject to the OSHA "Bloodborne Pathogens" (BBP) Standard. It is impossible to test human cells, including established cell lines, for all BBP/adventitious agents. Therefore, ALL human tissues and cell lines (including established lines) fall under the BBP standard. Research experiments involving human derived materials, including established human cell lines, must utilize BSL2 practices and procedures and require IBC review. BBP training is required for all employees who can reasonably anticipate exposure to human blood and other potentially infectious materials. This training is required both at the time of initial work assignment and at least every twelve months thereafter. Information about BBP training can be found at <http://www.ehs.uc.edu/itc/courses.asp#>.

Human Gene Transfer (HGT) IBC Protocols

A human gene transfer (HGT) protocol must be submitted and approved for research activities involving the deliberate transfer of recombinant DNA or RNA into human subjects. Researchers interested in performing HGT must contact the Biosafety Office (inbiocom@ucmail.uc.edu or (513) 558-5210) to obtain an HGT protocol application. The IBC cannot review HGT protocols until the NIH recombinant DNA Advisory Committee (RAC) has reviewed and approved the study and appendix M has been completed. IBC review/approval is in addition to Institutional Review Board (IRB) approval.

Upcoming Shipping Training

To comply with federal regulations, a training for infectious agents/biologicals is being developed with a targeted release date later this year. Training will be provided in two formats: live classes and online. Links to register for the classes or to take the online training will be added to the Web site. If you need help with shipping in the meantime, please contact the Biosafety Office at inbiocom@ucmail.uc.edu or (513) 558-5210.

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RESEARCH COMPLIANCE EVENTS & TRAINING

2008–09 New Researcher Orientation Program (two sessions offered)

Friday, Oct. 17, 2008

8 to 10 a.m.

University Hall, Room 450

Monday, Oct. 20, 2008

2 to 4 p.m.

University Hall, Room 450

New researchers are encouraged to attend this orientation program. This two-hour introduction will feature presentations by Sandra Degen, PhD, vice president for research, Dawn O'Neill, executive director for research programs, Carol Fabby, senior regulatory analyst, and Mary Ucci, director of grants management. There is no fee for this program but registration is required for planning purposes. Register online for the session of your choice at <http://webcentral.uc.edu/researchetc/>. For additional information, contact O'Neill at (513) 558-6565 or e-mail dawn.oneill@uc.edu.

Clinical Research Orientation

Oct. 23, 2008

8:30 a.m. to 5 p.m. (lunch provided)

Room 450, University Hall

Newly hired research coordinators and nurses are encouraged to attend this review of the fundamentals of clinical research (clinical development, ethical concerns, UC's IRB processes, funding, study management, regulatory documents and subject coordination). No continuing education credits are available for this program. All attendees will receive a certificate of completion. Registration is free, but must be completed by Oct. 16. For more information, contact Sharon Smith at (513) 558-1813 or e-mail sharon.smith@uc.edu. You can also access information online at [Researcher's Gateway](#).