

July 2007

Wait! ... Don't hit that delete button! This e-mail could contain information helpful to your research enterprise. The Office of Research Compliance and Regulatory Affairs (ORCRA)—comprised of the Institutional Review Board (IRB) & monitoring programs, Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC) and Radiation Safety—is launching a new quarterly newsletter, *Compliance Matters*. Each issue of *Compliance Matters* will keep you informed about upcoming research training programs and the latest news and regulatory updates from each ORCRA unit. We welcome any suggestions you may have on content or on improving our service. Contact ORCRA at research.compliance@uc.edu. For archived editions of *Compliance Matters*, additional information on ORCRA or to download related documents, visit researchcompliance.uc.edu.

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SPOTLIGHT ON: AAHRPP ACCREDITATION

Following a rigorous three-year process, the University of Cincinnati has received full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Compliance with AAHRPP standards ensures protections are built into every step of the research process—from study design and selection of research sites and investigators, to the actual conduct of research and collection and interpretation of data. Additionally, it signifies systems are in place to verify that these protections are, indeed, genuine and that they are backed by policies, procedures and practices that guarantee the highest standards at every turn.

In the July 2006 issue of *Regulatory Affairs Focus Magazine*, AAHRPP executive director Marjorie Speers, PhD, said the accreditation process is “extremely detailed and rigorous—and that is precisely what makes it valuable.”

The accreditation process often results in system-wide improvements that provide greater protection for research participants, ensuring the integrity of their research. But beyond that, AAHRPP accreditation offers additional assurance to study sponsors and participants that the university continues to observe the highest standards in human subject protection.

UC is among 16 organizations to achieve full AAHRPP accreditation this round. Research institutions already accredited by AAHRPP now include 68 organizations with 261 entities. AAHRPP is currently

working with nearly 400 other institutions in the accreditation process.

Cincinnati Children's Hospital Medical Center and the Cincinnati Department of Veterans Affairs Medical Center—two of the university's affiliates and partners in clinical and translational research—also received full AAHRPP accreditation this round.

Congratulations to everyone who worked so hard throughout the accreditation. For more information, contact Dawn O'Neill, interim executive director of UC's Human Research Protection Program, at (513) 558-6565 or dawn.oneill@uc.edu. Learn more at www.aahrpp.org.

IACUC NEWS

Online Protocol Submission

IACUC anticipates rolling out an online protocol submission process by fall 2007. This application will allow online submission and review of protocols and modifications, and will include an online ordering function and automated alerts when your protocol is expiring or when you are about to exceed your approved animal allotment.

IACUC Policy Update: Use of Secondary Containers

To meet Occupational Safety and Health Administration (OSHA) requirements as enforced by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), all secondary containers holding drugs, compounds or chemicals used in animal procedure or housing areas must be clearly and completely labeled with the following information:

- Name of the substance(s) exactly as written on primary container
- Concentration of the primary substance(s)
- Date of expiration (date made alone is not acceptable)

Label the container "*in vitro*" or "*in vivo*." *In vivo* includes all oral, injectable, inhalant or topical drugs and compounds used with live animals

Labeling of secondary containers is generally an issue in areas that are used for both animal and non-animal experiments. One common effective strategy is to clearly label the specific benches cabinets and drawers where animal research is completed or where supplies are stored. Specifying the sub-areas within a lab where animal-related activities occur will allow IACUC to better focus its inspection. Information about the IACUC and the animal care and use program can be found at <http://researchcompliance.uc.edu/iacuc/> or by calling (513) 558-5187.

IBC NEWS

Proposed Biosecurity Review of 'Dual Use' Research

The National Science Advisory Board for Biosecurity (NSABB) has issued preliminary guidelines on federal oversight of biological research. [Download the draft guidelines \(.pdf\)](#). The committee—working since the Fink Report in 2003—called for greater review of proposed "dual use agents," (biological studies with the potential to be subverted for use by bioterrorists). In April the NSABB released a draft report suggesting that the scientific community self-regulate and report potential for dual use on National Institutes of Health applications. Several institutions participating in regional biodefense centers are moving forward with establishing their own internal review process. Updates and additional information on final decisions will be provided in future issues of *Compliance Matters*. For additional comments see Vol. 316, April 27, 2007 at www.sciencemag.org.

Transgenic Registry

ORCRA will establish a Transgenic Registry for transgenic animals at UC. The registry will serve to ensure UC is in compliance with the National Institutes of Health *Guidelines for Research Involving Recombinant DNA*. But it will also be a resource for researchers, since it will be a searchable database for investigators interested in learning more about transgenic resources at the university. All animals should be registered. View and complete the registry forms at <http://researchcompliance.uc.edu/biosafety/transgenicreg.html>. Please note the form has two sections—one required and one optional. The optional section is important for providing information for the searchable database. Once completed, the database will be secure and password protected. If you have questions or problems, contact Erin Dunn in the biosafety office (513) 558-5210 or Rob Anderson, director of IACUC, at (513) 558-5171.

IRB NEWS

IRB Adds Staff, Continues Work on Electronic Form Submission

In an effort to improve service, the IRB and Post-Approval Monitoring Program have added several new staff members. For contact information, visit <http://researchcompliance.uc.edu/irb/IRBstaff.html>. Work is progressing on a move toward electronic submission of IRB forms. Look for more information in an upcoming edition of *Compliance Matters*.

New Guidance for Reporting Unanticipated Problems

Both the Office of Human Research Protections (OHRP) and the Food and Drug Administration recently issued new guidance documents for reviewing and reporting unanticipated problems. These guidance drafts recommend that there be “careful consideration of whether an adverse event is an unanticipated problem that must be reported to the IRB” and define specific categories of reportable problems. The information from OHRP is available by clicking “Adverse Events” or “Unanticipated Problems” at <http://www.hhs.gov/ohrp/policy/index.html>. The FDA information can be found by downloading the draft (.pdf) [Guidance for Clinical Investigators, Sponsors and IRBs](#).

QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

Avoid Common Errors on the Informed Consent Signature Page

- When a subject signs the consent document, verify that **all** signature lines are properly completed. The document should be signed and dated by both the subject and person obtaining consent. Both signatures should be added **on the same day**.
- The next of kin line is **only** completed if the study has been approved for cognitively impaired subjects and the subject is deemed to be unable to provide consent on their own behalf.
- The witness line should **only** be signed if the consent has to be read to the subject and a witness should be a third party (not the person obtaining consent).
- The investigator should note their role in the study (Principal Investigator, Co-Investigator, Study Coordinator, etc.),

This quality improvement tip has been provided by the Post-Approval Monitoring Program. For more information, contact Joanne Lindwall at (513) 558-3576 or joanne.lindwall@uc.edu.

RADIATION SAFETY NEWS

Unit Web Site Filled With Valuable Information

For researchers concerned with radiation safety issues, easy access to policy information, training programs, and safety manuals and forms is vital to daily operations. UC’s Radiation Safety Office Web site (www.uc.edu/radsafety) is a place where researchers can find all of these necessary resources and more. On the site, visitors will also find “Isotope Fact Sheets,”—documents similar to Material Safety

Data Sheets that provide general physical and regulatory information, along with specific safety information for radionuclides commonly used under the UC Radiation Control and Safety Program. The site also has a 10-minute radiation safety awareness training video, designed for individuals who will not be working with radiation sources, but who may need to know more about basic radiation safety techniques and general information about the types of radiation sources used under the UC Radiation Control and Safety Program. And, anyone desiring to supervise users of radioactive material can look to the radiation safety Web site to find the 22-minute video titled "Becoming an Authorized User."

Each quarter, the Radiation Safety Office issues a newsletter focusing on issues related to radiation safety and uses of radiation sources. The newsletter is distributed to all authorized users of radioactive material and is posted online.

If you have questions or concerns about radiation source use, radiation safety or possible exposure to radiation, contact the Radiation Safety Office at (513) 558-4100.

RESEARCH COMPLIANCE EVENTS AND TRAINING OPPORTUNITIES

Clinical/Human Subject Events

Human Subject Protection: The Long and Winding Road
Oct. 19, 2007, 9:00 a.m. to 4:30 p.m.
Northern Kentucky Convention Center

This event requires registration. Be on the lookout for registration information, which will be sent via e-mail. For more information, contact Carol Fabby at (513) 558-5620 or e-mail fabbyc@ucmail.uc.edu.

IACUC 101 Training Opportunity

Sept. 27, 2007
Kingsgate Marriott Conference Center

This is a full-day didactic and interactive training course for new and seasoned IACUC members, IACUC affiliates including IACUC administrators, trainers, veterinarians, animal care staff, researchers, regulatory personnel, individuals responsible for their institution's animal care program and others interested in IACUC roles and responsibilities. The program is delivered by faculty renowned for their expertise in institutional animal care and use issues and program development, and includes representatives from both private and academic biomedical research institutions as well as the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), the United States Department of Agriculture (USDA) and the Office of Laboratory Animal Welfare (OLAW). Registration is available online at www.cme.uc.edu/iacuc101. Previous attendees of IACUC orientation will receive a three-year training exemption if they attend IACUC 101.

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