

October 2007

We appreciate the enthusiastic response we received after the first *Compliance Matters* hit inboxes. The second issue of *Compliance Matters* is coming to you with an added section under IRB News. Our recent accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) reminded us of the importance of communicating updates to policies and procedures to the entire research community. Each issue will include a listing of any updates we've made, along with links to the full policy and procedure revisions.

Read on to learn more about exciting new initiatives and educational opportunities, and don't hesitate to let us know if we're missing anything. You can contact us 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: THE TRANSGENIC DATABASE

For years, investigators at the Academic Health Center have requested that a database be developed to keep track of all transgenic mice at UC. The database would be designed to facilitate collaboration, allow faster access to mice, and provide a general benefit based on unique local resources. For several months, the biosafety office and IACUC have been working with ORCRA to set up a searchable database for transgenic animals. Last month we met with representatives from Cincinnati Children's, and they have agreed to include resources from their institution. Imagine the possibilities!

But to create this valuable database, we need the help of individual investigators. Please complete a registration form and send it to ORCRA. Forms are available at <http://researchcompliance.uc.edu/biosafety/transgenicreg.html>.

For questions, contact Rob Anderson at (513) 558-5187, or Melissa Colbert at (513) 558-5034.

ORCRA NEWS

ORCRA recently began reviewing—prior to IRB approval—all Food and Drug Administration (FDA) documents for sponsor-investigator protocols. This review-process change was implemented in April and was added to IRB policy III.08. The policy can be reviewed at http://ahc-sharepoint.uc.edu/hrp_policies/hrp%20policies/forms/public.aspx.

The FDA defines a sponsor-investigator as a principal investigator who initiates and conducts an investigation and who must comply with all the obligations of both a sponsor and an investigator (21 CFR §312 Subpart D; 21 CFR §812 Subparts C & E).

A sponsor:

- must be an individual, not a university, practice corporation or federal agency.
- agrees to provide for independent data-monitoring of the research.
- does not mean an agency that provides support for the research.

The ORCRA Web site will be updated to provide additional guidance on FDA rules and regulations, requirements for monitoring and links to Web resources at other institutions. ORCRA has purchased a series of templates from the Morely Research Foundation to assist sponsor-investigators who are unfamiliar with the FDA's requirements for Standard Operating Procedures (SOPs). These templates have passed FDA review and include sections on good clinical practices (GCP) and monitoring of clinical studies. The templates are available for download and modification for each study at researchcompliance.uc.edu.

IACUC NEWS

IACUC Protocol Modification Process

In order to facilitate the protocol-modification process, researchers should submit a cover letter itemizing any modifications to the Animal Use Protocol Form. Please be sure to reference the number of the question you are modifying and explain the nature of the change. Several researchers have already itemized their modifications, which has expedited the process.

IACUC 101

IACUC 101, a day-long basic introductory seminar presented by UC and the Office of Laboratory Animal Welfare, boasted a near-capacity crowd of 160 registrants from across the country, representing both industry and academia. The program covered topics ranging from the key components of an animal care and use program to protocol and personnel qualifications and training. Registrants gained hands-on experience evaluating specific scenarios by participating on a mock animal care and use committee.

IBC NEWS

Biosafety Officer Rounds

Gary Dean, PhD, biological safety officer, along with the UC biosafety office, will be initiating a new program of general laboratory assessments. Dean will visit laboratory areas that are known to or may be conducting research using biohazardous materials and/or recombinant DNA molecules. The intent of this program is to assess the effectiveness of the overall biosafety program and to determine how the biosafety office can better serve the research community, while ensuring that the institution is fully compliant with all regulations and mandates. Dean will evaluate approved areas to ensure compliance with current standards and will also look for areas where biohazardous materials may be in use but not yet reported. The intent is to provide guidance to principal investigators and members of their laboratories who may be unaware of federal and institutional requirements.

This assessment is not intended to target specific laboratories or principal investigators and is separate from the annual inspections conducted as part of the post-approval process for approved IBC protocols.

IRB NEWS

Technology Update

The research office, the IRB and AIT&L are putting the finishing touches on two new Web-based systems: eMODs and Researcher's Gateway. eMODs will enable researchers to electronically submit study modifications to the IRB. Researcher's Gateway will be a portal for access to a wide range of information regarding research. In addition to providing access to eMODs, Researcher's Gateway will be the starting point to access other IRB submission forms, research compliance Web sites (IRB, IACUC, biosafety, radiation safety), RESEARCH, Etc. (education, training, and consulting), and online training and policies and procedures. You'll receive a notice when these new tools are live and ready for use.

IRB-S Comes to the West Campus

Beginning Tuesday, Oct. 9, and continuing twice each week, the social and behavioral sciences IRB (IRB-S) will visit West Campus to answer questions about IRB submissions. Claudia Norman or Carol Fabby will be in Van Wormer Hall, room 230-C, Tuesdays 2–4 p.m. and Fridays noon–2 p.m. All research involving human participants conducted at UC or its affiliates must be reviewed by one of UC's designated IRBs. If you aren't sure whether your research needs IRB review, or if you have questions about the review process, please take advantage of these West Campus visits or call the IRB at (513) 558-5259.

New/Updated Human Research Protection Policies or Procedures

Updates to the following policies, procedures or clinical SOPs occurred in July.

UC Policies: I.01, II.01, II.05, III.01, III.02, V.06

http://ahc-sharepoint.uc.edu/hrp_policies/hrp%20policies/forms/public.aspx

IRB Procedures: 201, 306, 308, 312, 313

http://ahc-sharepoint.uc.edu/hrp_policies/irb%20policies/forms/allitems.aspx

Please note: Changes to the clinical SOPs templates occurred throughout the AAHRPP submission process.

Clinical SOPs: 1-1, 1-2, 1-3, 1-4, 2-4, 3-1, 3-2, 3-3

http://ahc-sharepoint.uc.edu/hrp_policies/clinical%20site%20sop%20templates/forms/allitems.aspx

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

Set Parameters for Data Points So That You Won't Have a Protocol Violation

For example: Saying that you'll order a "24-hour CT scan" on every patient is too specific and does not give an acceptable and valid time frame. It's far better to write your protocol as: "A 24-hour CT Scan (+/-6 hours) will be ordered."

RADIATION SAFETY NEWS

Radiation Safety Committee

UC is required by federal and state regulations to have a radiation safety committee (RSC). The RSC reports to the university president, but works on a daily basis with the vice president for research. The committee is responsible for generating, defining, implementing and monitoring a radiation control and safety program (RCSP) that complies with all regulatory, license, permit and registration requirements.

Key tasks performed by the RSC include: acquiring and maintaining licenses, permits and registrations that authorize possession and use of radiation sources needed by individuals who work under the RCSP; reviewing and approving associated uses of radiation sources; ensuring the radiation safety office has the necessary funding and support to carry out duties delegated to the radiation safety officer by regulation and the RCSP; and performing an annual audit of the RCSP.

The RSC comprises the radiation safety officer (Vicki Morris (513) 558-4110), a member of senior management, (Jan Hawk (513) 558-2485), and authorized users and/or individuals who have technical knowledge regarding each of the uses of radiation sources under the RCSP. Currently, the chair of the radiation safety committee is Glenn Talaska, PhD, (513) 558-0519. More detailed information is available in the RCSP manual, which can be found online at www.uc.edu/radsafety.

RESEARCH COMPLIANCE EVENTS AND TRAINING OPPORTUNITIES

Human Subject Protection: *The Long and Winding Road*

Oct. 19, 8 a.m. to 4:30 p.m.

Northern Kentucky Convention Center

Annual event sponsored by UC, the University of Kentucky and Schulman Associates Institutional Review Board Call (513) 558-7399 to register (nominal fee, lunch provided)

Mini-Symposium: Investigator-Initiated Studies Involving Investigational New Drug/Investigational Device Exemption (IND/IDEs)—What You Must Do to Ensure FDA Compliance

Nov. 16, 8 a.m. to noon,

MSB 7051

Free symposium. Registration required by Nov. 9.

Featured Speakers:

Harvey Arbit, PhD, director, IND/IDE assistance program, University of Minnesota

Jane Green, PhD, CEO, Walter B. Morely Research Foundation.

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