

January 2008

Happy New Year! There are a lot of new and exciting things happening in the Office of Research Compliance and Regulatory Affairs (ORCRA) in 2008. The office has experienced some personnel changes and, this year, will relocate to University Hall.

Researcher's Gateway—a Web portal for researchers—is almost ready to roll, so watch for changes and improvements in access to protocol information. If you missed ORCRA's research orientation presentations on Dec. 7 and 14, a video will be accessible at www.research.uc.edu.

As always, don't hesitate to contact us with questions at research.compliance@uc.edu. Let us know how we can better serve you.

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IN THIS ISSUE:

[Spotlight On: The IRB Task Force](#)

[ORCRA News](#)

[IACUC News](#)

[IBC News](#)

[IRB News/New or Updated HRP Policies and Procedures](#)

[Quality Improvement Tips for Investigators](#)

[Radiation Safety News](#)

[Research Compliance Events and Training Opportunities](#)

SPOTLIGHT ON: THE IRB TASK FORCE

In September Sandra Degen, PhD, vice president for research, established a task force, chaired by Nelson Vincent, EdD, to review and recommend ways to improve Institutional Review Board (IRB) service to both east and west campuses.

"The charge to this group will be to fully explore the IRB review process and define member roles and responsibilities. The Task Force will look at the committee composition for the three IRBs and their responsibilities. My hope is that there will be recommendations on committee composition and additional research expertise that needs to be included, a review of IRB committee processes and recommendations for improvement in these as well as improvement in communication between the IRB office and the investigator."

The Task Force on IRB Roles and Responsibilities is 22 members strong, comprising researchers in clinical and social sciences, graduate and undergraduate students, IRB chairs from UC and Cincinnati Children's Hospital Medical Center, representatives from the Cincinnati Department of Veterans Affairs Medical Center (VA), as well as other interested parties. On Nov. 8, 2007, the task force issued a draft report on "first steps," which identified specific goals, strategies and action objectives. The first steps were approved at the Nov. 22, 2007, task force meeting. Subcommittees have been formed to work on specific issues, including the use of commercial IRBs for review of eligible studies. Read more on this in the ORCRA report below.

[-back to top-](#)

ORCRA NEWS

Commercial IRB Review

ORCRA is exploring use of a commercial IRB to review multi-site, industry-sponsored clinical trials. This process is a joint response to the IRB and Clinical Trials Task Force, and will be undertaken in collaboration with the new Office of Clinical Trials Support. In order for external review to be used, the study must meet all the following conditions:

- The project is a study that involves human subjects and is designed to evaluate prospectively the safety and/or effectiveness of new drugs or devices or behavioral interventions.
- The protocol for the project was designed and written by the sponsor.
- The sponsor holds all Investigational New Drug/Investigational Device Exemption (IND/IDE) for the protocol.
- The only sponsor of the research is a for-profit entity/company.
- The UC investigator has not previously submitted the study to a UC IRB. [Only new projects will be eligible for Western IRB (WIRB) review. No transfers of projects already submitted to a UC IRB will be allowed]
- The project does NOT involve any of the following:
 1. Xenotransplantation
 2. Embryonic stem cells
 3. Review and approval by UC's Institutional Biosafety Committee (e.g. studies that involve recombinant DNA)
 4. Any research funds from a federal or other nonprofit funding source.

Be aware that the VA does not accept commercial IRB review. Therefore, projects to be conducted at the VA must continue to be submitted and reviewed by the UC IRB. We will keep you updated as negotiations progress.

Research Compliance Handbook

The third version of *A Basic Research Compliance Handbook* is now available online at www.researchcompliance.uc.edu. The .pdf document can be downloaded and saved to your computer, or printed for quick reference.

New Staff!

Melanie Fulton has joined UC as executive staff assistant for ORCRA. Fulton—who relocated to Cincinnati from California to be with family—has a compliance background in the International Standards Organization (ISO) 9000 Quality Standards Series.

[-back to top-](#)

IACUC NEWS

Who Do I Call IACUC or LAMS?

Because of the close relationship between the Institutional Animal Care and Use Committee (IACUC) and Laboratory Animal Medical Services (LAMS), paperwork or requests actually intended for one office often end up in the other. For example, protocol submissions that should go directly to the IACUC office are often sent to LAMS veterinary staff, resulting in delays.

Contact IACUC to:

- submit new or modified protocols.
- ask questions about IACUC training.
- ask questions related to what is in an approved protocol.
- get information about a grant submission, such as approval dates, registration and assurance numbers.
- report performed procedures not listed in your protocol, or inappropriate activity by others.

IACUC can be reached at iacuc@ucmail.uc.edu.

Contact LAMS to:

- report an animal health issue.
- ask questions about species-specific training.
- ask questions related to the status of an order.
- request housing, surgery or procedure space.
- request special services or equipment.
- determine how many animals are available for you to order on your protocol.
- discuss issues regarding billing.

LAMS can be reached at (513) 558-5171.

IACUC Policy Highlight

In response to the increased availability of core research services, IACUC and LAMS recognize the need for an efficient mechanism of transferring animals between research protocols. Below are details from Policy 29: Transfer of Animal Between UC Approved IACUC Protocols:

- Multiple major survival surgeries may not be performed on the animal being transferred unless it has been explicitly described and justified in the original protocol.
- Pain category may not be increased from a less painful/distressful to a more painful/distressful category (e.g. from category C to D).
- The original bar coded cage card must be kept on the animal cage.
- The cage must be labeled by the principal investigator with a secondary card as described in the policy.
- The originating principal investigator must maintain records as described in the policy.
- Animal numbers are not counted against the recipient's protocol.

In addition to the requirements noted above and in the policy, it's worth mentioning that when a transfer is performed as described in the policy, the principal investigator of the recipient protocol assumes responsibility for any violations that occur while the animal/s are in his/her possession. This includes ensuring that the protocol is followed and the personnel performing procedures on the recipient's protocol are approved to perform the work on that protocol.

Laboratories using this policy need to pay close attention to which animals are being used under what protocol. Mistakes made while using the temporary transfer policy can lead to significant reportable deficiencies. Those deficiencies can have a detrimental effect with regards to funding.

[-back to top-](#)

IBC NEWS

Select Agent Use

What: Select biological agents or toxins are those deemed a threat to public health, animal or plant health, or animal or plant products. (See www.cdc.gov/od/sap/ for a complete listing)

Why: President Bush signed the “Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” The law’s purpose is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, and requires that all persons possessing select agents register with the appropriate federal agency.

How: Individuals who intend to use select agents in their research must be approved by the United States Department of Agriculture (USDA) as part of the University of Cincinnati’s registration under the conditions specified in accordance with several Federal laws. *Those individuals who have previously been approved for the use of select agents will be required to re-register in the near future, as our license is due to expire this year.*

All documents must be submitted to the appropriate agencies by the responsible official, Sandra Degen, vice president for research. To begin the process, contact Gary Dean, biosafety officer (BSO), at (513) 558-0065.

The individual investigator and all laboratory personnel who will have access to select agents **must:**

- Undergo a security risk assessment (SRA) by the United States Department of Justice, Federal Bureau of Investigation (FBI), Criminal Justice Information Services.
- Have fingerprints taken by an authorized officer in the University of Cincinnati Department of Public Safety and submitted to the FBI.
- Complete sections II and III of form [FD-961](http://www.fbi.gov/terrorinfo/fd-961.pdf) (<http://www.fbi.gov/terrorinfo/fd-961.pdf>).
- Submit a detailed protocol of the proposed research or activities involving the select agent or toxin for review by the Institutional Biosafety Committee (IBC).

In addition to obtaining approval from the USDA, the principal investigator will be required to complete required BSL3 training and gain approval to work in the BSL3 facility. **Individuals may not self register. Approval of individual registrations may take from three to six months.**

[-back to top-](#)

IRB NEWS

New Web Tools

The Office of Research, IRB, and Academic Information Technologies and Libraries (AIT&L) are putting the finishing touches on eMODs and Researcher’s Gateway. Both will be ready for roll-out in the coming weeks. eMODs will allow researchers to electronically submit study modifications to the IRB. Researcher’s Gateway will be a portal for access to all types of information regarding research. In addition to providing access to eMODs, the Gateway will be the starting point to access such things as other IRB submission forms, research compliance Web sites (IRB, IACUC, Biosafety, Radiation Safety), RESEARCH etc. (education, training, and consulting), online training, and policies and procedures. Look for future announcements directing you to both tools.

New IRB Office Staff

Anthony Gardner has joined the IRB as its new manager. Gardner has several years’ experience in the research field, including two years at Schulman Associates IRB in Blue Ash, Ohio. As IRB manager, Gardner is responsible for oversight of the day-to-day operations of the IRB office. Laura Goins joined the IRB staff in December. Goins, who has several years of IRB experience at Schulman Associates, is replacing a departing IRB office staff member. She will assume all responsibilities associated with continuing review of study protocols.

New/Updated Human Research Protection Policies or Procedures

Updates to the following policies, procedures or clinical standard operating procedures (SOPs) occurred in December:

UC Policies: III.08 Review of Sponsor-Investigator IND/IDE Research
http://ahc-sharepoint.uc.edu/hrp_policies/HRP%20Policies/Forms/Public.aspx

Update on Informed Consent.

The Office of Human Research Protection (OHRP) feels that the use of the first person (e.g. "I will view seven videos," "I give permission to...") can be interpreted "as suggestive ... and can constitute coercive influence over a subject." The second person pronoun (e.g., "you are being asked to participate in a study because....") is preferred because it is inherently more open and conversational with subjects. Use of first person may also be interpreted as presumption of subject consent, i.e. the subject has no choice. The second person writing style helps to communicate that there is a choice to be made by the prospective subject.

In all new protocols and those submitted for continuing review (progress reports), the informed consent document should be written in second person ("you will") as opposed to first person ("I will"). The IRB is now requesting that, if applicable, informed consents be revised when progress reports are reviewed. To speed re-approval time, remember to make this change.

[-back to top-](#)

QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

Improving Your Clinical Research Practices: Avoiding the 12 Most Common Problems

The following are 12 areas that are routinely examined during an on-site post-approval monitoring review. They are listed in order of occurrence of findings for each category:

- Deviations to informed consent process
- Lack of regulatory documentation
- Lack of reporting to the IRB
- Lack of source documents
- Protocol deviations
- Eligibility deviations
- Lack of SOP training for research staff
- Lack of clinical trial SOPs
- Lack of required UC online training
- Documentation errors
- Lack of meeting FDA requirements
- Incomplete data collection

In the past three years the post-approval monitoring program has conducted more than 42 on-site reviews. The following is a list of current IRB documentation findings:

| Deficiency Category | Percentage of Occurrence |
|---|---------------------------------|
| IRB Documentation | |
| Lack of reporting Protocol Deviation | 29% |
| Lack of reporting Key Personnel | 17% |
| CVs for PIs not submitted | 14% |
| Lack of COIs submitted for Key Personnel | 14% |
| Protocol Modification not reported | 10% |
| SAEs not submitted within timeframe | 6% |
| Updated IDB not submitted | 5% |
| Progress Report submitted late | 5% |
| Patient screening Documents not submitted | 5% |

[-back to top-](#)

RADIATION SAFETY NEWS

Radiation Safety Officer

UC is required by federal and state regulations to have a radiation safety officer (RSO). By regulation, the RSO must be an individual designated by the university who has the knowledge and responsibility for the overall radiation safety program, including implementation of daily radiation safety operations and compliance with regulations covering sources of ionizing radiation. The designation must be mutually agreed in writing and must include a list of the RSO's responsibilities.

By regulation, the RSO is expected to directly or indirectly report to the highest ranking official, e.g., the president of the university. At UC, the reporting is indirect. The president has delegated the day-to-day reporting to the vice president for research. To help ensure an exceptional radiation control and safety program is maintained, the RSO, Vicki Morris, (513) 558-4110, regularly meets and communicates with the Radiation Safety Committee (RSC) chair Glenn Talaska, PhD, (513) 558-0519, and RSC senior management representative, Jan Hawk, (513) 558-2112. 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 radiation control and safety program, reviewing and approving associated uses of the radiation sources, ensuring the Radiation Safety Office has the necessary funding and support to carry out duties delegated to the RSO, and performing annual audits of the radiation control and safety program.

[-back to top-](#)

RESEARCH COMPLIANCE EVENTS AND TRAINING OPPORTUNITIES

Clinical Research Orientation

Jan. 24, 2008
8:30 a.m. to 5 p.m.
450 University Hall
Lunch Provided
To register, contact Brenda Miller at (513) 558-7399

Clinical and Translational Research Ethics Conference

Feb. 20, 2008
Day-long conference at the Vernon Manor
Breakfast and lunch provided
Early registration: \$25 (\$40 after Feb. 1)
Contact Kathy Henderson at (513) 558-0890 or katherine.henderson@uc.edu, or Donna Wuest at (513) 636-7584 or donna.wuest@cchmc.org.

Cincinnati Children's Translational Research Trials Office Annual Educational Symposium, "The Challenges and Rewards of Investigator Initiated Trials"

Monday, March 17, 2008
Seating is limited, registration required
Contact Carol Johnson at (513) 636-7066 or carol.johnson@cchmc.org

[-back to top-](#)

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