

April 2009

Spring is here and we have some major changes coming up, with two compliance offices moving this month and substantial changes in Institutional Review Board fee structures for industry-sponsored research. Please take note and include these changes as you negotiate budgets.

We are here to facilitate research (while maintaining compliance) if we can help you, please contact us. If you have a suggestion that will help us to help you, please contact us at [research.compliance@uc.edu](mailto:research.compliance@uc.edu).

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

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#### SPOTLIGHT ON: ADVERSE EVENT REPORTING

Researchers are responsible for reporting unanticipated problems involving risks to subjects or others to the Institutional Review Board (IRB) within 10 days of learning of the event. Failure to report unanticipated problems within 10 days of learning of the event risks suspension or termination of IRB approval. Events resulting in temporary or permanent interruption of study activities (to avoid potential harm to participants) should be reported immediately (within 48 hours) whenever possible. A list of unanticipated problems involving risks to participants and others can be found in Human Research Protection Program Policy, Number II.02. "Reporting to the IRB: Unanticipated Problems in Human Subjects Research." Event report forms are being revised. The current version can be found at <http://researchcompliance.uc.edu/irb/>.

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#### ORCRA NEWS

##### **IRB and Biosafety Offices Relocated**

The offices of the Institutional Review Board (IRB) and Biosafety have moved to **University Hall, Suite**

**300** (room 310). Mail locations and phone numbers remain the same. The official mailing address for this location is:

51 Goodman Drive  
Cincinnati, OH 45221

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## **IACUC NEWS**

### **External Collaboration With Non-UC Investigators**

There are many circumstances involving partnerships between collaborating institutions. Federal agencies do not require duplicate review of the Institutional Animal Care and Use Committee (IACUC) protocol by both institutions.

In accordance with NOT-OD-01-017 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-017.html>), IACUC must be provided with the following information in order to recognize the approval of the collaborating institutions:

- Documentation of the review in the form of an IACUC approval notice
- A list of any significant questions or issues raised during the semiannual program review or facility inspection for the facility housing this research activity
- Documentation of Association for Assessment and Accreditation of Laboratory Animal Care accreditation (AAALAC)
- Documentation of Public Health Service (PHS) assurance (if federally funded)
- Documentation of United States Department of Agriculture (USDA) registration (if involving a USDA Species)

If collaboration involves a foreign institution, the following additional requirements must be met:

- Submission of a UC IACUC protocol form
- Approval of the UC IACUC protocol by UC IACUC
- Proof of a foreign assurance form that must be provided to PHS

If the collaboration involves a Department of Defense (DOD) agency, the following additional requirements may be imposed by the DOD:

- Submission of a UC IACUC protocol form
- Approval of the UC IACUC protocol by UC IACUC
- Assurance by the UC IACUC of congruency between the UC protocol and the ACURO protocol.

For more information, please contact the IACUC office at (513) 558-5187.

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## **IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES**

### **New Fee Structure for Industry-Sponsored IRB Review**

Effective July 1, 2009, the UC Institutional Review Board (IRB) office will use the following fee structure for protocols that are industry-sponsored with funding held external to the university and submitted on or after July 1. Studies approved prior to July 1, 2009 will not be subject to the new fees for the first two

years of the study (i.e. if/when the study submits its second progress report, it will incur all of the relevant new fees but not prior) and the charges will only apply to industry-sponsored research. We are sending out notification now so that people have time to modify their budgets moving forward. In short, these fees go into effect July 1 moving forward with a grace period of two years for those protocols that are already approved.

The UC IRB charges fees to cover the costs associated with the board's review and related administrative responsibilities. Fees do not influence the decisions made by the board.

The fee schedule for industry-sponsored protocols is as follows:

**Initial review of the research fee\*: \$2,000**

Initial review encompasses the review of the research protocol, qualifications of the investigator, associated consent forms, protocol-related advertisements, questionnaires, screening scripts and other submitted materials.

**Fast-track review of initial IRB protocol submission: \$5,000**

Fast-track review requires: a) evidence from the sponsor indicating deadline/closure date for enrollment; b) evidence that approval delay would cause inability to enroll appropriate subjects for special requirement of a clinical trial; c) evidence of competitive enrollment by the sponsor. Other requirements for fast-track review can be obtained by contacting the IRB office at (513) 558-5259. Fast track submissions will be reviewed by the board within two weeks of the IRB office receiving ALL of the required documents and signatures.

**Continuing review fee: \$1,000**

IRBs must review ongoing research at least annually and that review must be substantive and at least comparable to the initial review. The protocol is reviewed on an annual basis, or more frequently as directed by the board.

**Changes to research fee: \$250**

Fees are incurred for modifications to research, such as protocol amendments, revised protocols, updates to consent forms and new recruitment or retention materials, or change of principal investigator or co-principal investigator. The change in research fee applies each time board review and preparation of regulatory documentation is required for a research site. There is no charge for administrative modifications (i.e., study personnel changes, or site additions) or submission of reportable events (i.e., unanticipated problems, adverse event/serious adverse event, protocol deviation).

\*Review of an expired protocol will be reviewed as an initial protocol. These protocols can be submitted for fast-track review but will incur all associated fees.

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## **QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS**

### **Tips for Setting up a Regulatory Binder**

Before setting up a regulatory binder, check the sample binder and instructions found on the Institutional Review Board (IRB) Web site under the sponsor-investigator SOPs in the regulatory section. This will help keep study documents organized and audit-ready if necessary.

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## **BIOSAFETY NEWS**

### **Are You Shipping Infectious Substances?**

The International Air Transport Association (IATA) requires that you receive training every two years. The Class 6.2 Infectious Shipping Training (Category A and B substances) is now available in two formats—live classes and online. For more information, visit <http://researchcompliance.uc.edu/biosafety/Training.html>

### **Do You Know How to Properly Work in a Biosafety Cabinet ?**

We are offering the seminar “Proper Selection, Use and Maintenance of Biological Safety Cabinets” to interested departments and divisions. This lecture can be customized to fit your group’s needs. If your department/division has interest in participating in this program, please contact the Biosafety Office ([inbiocom@ucmail.uc.edu](mailto:inbiocom@ucmail.uc.edu) or (513) 558-6182 or (513) 558-5210).

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## **RADIATION SAFETY**

### **Newsletter and Other Information**

You can access the quarterly Radiation Safety Newsletter at: <http://researchcompliance.uc.edu/radsafety/newsletters/Jan2009.pdf>.

For useful information about sources of radiation and radiation risks visit the Health Physics Society at [www.radiationanswers.org](http://www.radiationanswers.org) or contact the Radiation Safety Office at (513) 558-4110 or by e-mail at [vicki.morris@uc.edu](mailto:vicki.morris@uc.edu)

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## **RESEARCH COMPLIANCE EVENTS & TRAINING**

### **Revised and Expanded Clinical Research Orientation Program**

We’ve revised and expanded the Clinical Research Orientation Program. We now offer three half-day sessions. Additionally, we are offering this program more frequently and you can now register online. Sessions are offered both in the morning (8 a.m. to noon) and afternoon (1 to 5 p.m.). The course descriptions and links for online registration can be accessed at [uc.edu/ucresearch/Research\\_Programs/Orientation\\_Program.html](http://uc.edu/ucresearch/Research_Programs/Orientation_Program.html)

### **Two New IRB Presentations**

Researchers now have access to two new presentations on working with the Institutional Review Board (IRB) in approving research that involves human participants. One covers the roles and responsibilities of both the IRB and the researcher in approving research involving human participants. The other specifies how to submit information to the UC IRB for review and approval. Both presentations are applicable to biomedical and social and behavioral research. These presentations will be offered periodically throughout the year. You may also arrange to have the presentations delivered at a departmental meeting or in the classroom. Links for online registration can be accessed at <http://webcentral.uc.edu/researchetc/irboverview.cfm>