

January 2009

Welcome to a new year of *Compliance Matters*.

This newsletter is for you. Let us know what you find helpful or what you want to see or learn more about. Our goal is to provide you with the information and support that you need to perform your research successfully, safely and responsibly.

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
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SPOTLIGHT ON: IRB NON-COMPLIANCE

Please remember that any individual obtaining an informed consent must have completed CITI training, be listed as study staff on the Institutional Review Board (IRB) protocol in question, provide information and explanation to the potential research subject regarding the study in question and be present at the time consent takes place. Failure to meet any of the above guidelines is in violation of research compliance and puts research studies in jeopardy. If you have questions about this policy, please contact the IRB office at (513) 558-5259.

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ORCRA NEWS

Two Approvals Required for HGT Work

By federal mandate, research involving human gene transfer (HGT; work with recombinant RNA or DNA as nucleic acid, plasmid, vector, and/or in cells being administered to humans) requires both Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC) approval. There are fees associated with IBC review and biosafety oversight. Please contact the biosafety office at inbiocom@ucmail.uc.edu so that you can include the fees in your contract.

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IACUC NEWS

Semiannual IACUC Inspections:

It's that time of year again! Semiannual Institutional Animal Care and Use Committee (IACUC) inspections began Jan. 6, 2009. Here is a list of things you can do to prepare for the visit.

1. Please review all UC IACUC policies pertaining to your lab. Several policies have been recently updated so make sure you are aware of the most recent changes. They can be found at <http://www.researchcompliance.uc.edu/iacuc/Policies1.html>.
2. Make sure secondary containers are labeled with what's in the container, the concentration of the substance and an expiration date. This is the most common non-compliance cited during the semiannual inspections.
3. Make sure areas where IACUC-regulated research is performed are clean. If you do IACUC research in your lab, give that area a thorough cleaning. Wipe down counters and clean up general clutter. If you have absorbent pads lining the countertops, now would be a good time to change them.
4. We also recommend having a member of the laboratory present during inspections. This will help with any questions that arise. If there are concerns found during the inspection, the lab representative can often take care of things on the spot, eliminating the need for further follow-up.

If you have any questions about the upcoming inspections, please contact Sandra Rebolz at (513) 558-5103 or sandra.rebolz@uc.edu.

Mills Named CPIA

Please congratulate Kareemah Mills for her hard work in becoming a Certified Professional IACUC Administrator (CPIA). Mills is the second member of the UC IACUC office to achieve this nationally recognized certification.

IACUC Orientation Training Sessions

The IACUC provides training sessions for IACUC Orientation on a semi-monthly basis, within the UC community. A schedule of the training dates for the first half of the 2009 calendar year and detailed instructions for how to register can be found at:

<http://researchcompliance.uc.edu/iacuc/trainingschedule.html>.

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IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

Update on Cancer Research Protocols

Effective Nov. 28, 2008, all cancer-related Institutional Review Board (IRB) protocols must first be reviewed by Dr. Frank Smith. Please submit protocols to Alison Kastl, director of cancer clinical trials at UC. Kastl can be reached at kastla@ucmail.uc.edu, (513) 584-0436 or mail location 0502. Cancer-related IRB protocols submitted without scientific review/approval by Dr. Smith will be returned without review by the IRB office.

Time-Saving Tip

Save time and avoid unnecessary paperwork! Please ensure that contact name and phone numbers on the informed consent document are accurate prior to submission.

1572 Forms Required

Beginning Feb. 1, 2009—and in effort to ensure continued compliance with FDA Regulations (21 CFR 312.23 (a)(6)(iii)(b))—the IRB will require submission of Form FDA-1572 with all FDA regulated protocols involving an Investigational New Drug (IND). Additionally, any updates to the 1572 during the course of the study will need to be submitted to the IRB office as well as to the sponsor.

- A 1572 must be revised for a new investigator (including a change in principal investigator or addition of new investigator) who will participate in an ongoing study.
- If there are changes to information contained on the 1572 (for example, an IRB change, the addition of new sub-investigators, discontinuing the use of a clinical lab, etc.) the investigator should document the changes and inform the sponsor, so that the sponsor can appropriately update the IND. A revised 1572 is not needed in these instances.

Are You Engaged In Research?

Persons actively engaged in research include those who have direct contact with participants (i.e., obtaining consent from the potential participant), contribute to the research in a substantive way, have contact with participants' identifiable data or biological samples, or use participants' personal information). All personnel that are actively "engaged in research" must be included on the Research Review Submission Form (RRSF).

- All IRB protocols with UC faculty as principal investigator must be reviewed by UC IRB or by an IRB with which UC has an agreement, regardless of where the work is performed.

New CITI Security Procedures

Rather than e-mail forgotten passwords, CITI will now ask you to generate a security question and provide an answer. When the correct password is not entered, CITI will ask the question. Correctly answering the question will prompt you to reset your password. Please contact the IRB office at (513) 558-5259 or e-mail irbadmin@uc.edu with any questions or concerns.

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QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

FDA IND/IDE Review Policy

Per University Policy III.08, all FDA IND/IDE applications for sponsor/investigators must be reviewed by Sandra Degen, PhD, vice president for research, for signature prior to submission. Please send these applications to Joanne Lindwall, FDA specialist, at (513) 558-3576 mail location 0629, or lindwai@ucmail.uc.edu. Applications will be returned to the sponsor/investigator once review/signature is obtained.

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BIOSAFETY NEWS

Respiratory Protection and Biological Aerosols

There are many documented cases worldwide of laboratory-acquired infections resulting from the production and inhalation of infectious aerosols created during routine laboratory activities (e.g. centrifugation, sonication, pipetting, syringe loading, etc). Engineering controls such as biosafety cabinets are specially designed to minimize exposure to aerosols. However, the use of Personal Protective Equipment (PPE), such as a respirator, is sometimes necessary.

Because certain disposable respirators are similar in appearance to many surgical/procedure masks, their differences are not always well understood. Surgical masks do not provide respiratory protection for the wearer. They are designed exclusively to protect against mucosal exposure. To provide respiratory protection, respirators must be considered.

One of the most common respirators used in health care and research facilities is the type N95 disposable respirator. Respirators, which are certified by the National Institute for Occupational Safety and Health (NIOSH), are designed to fit tightly to the face and create a seal between the face and the respirator. To determine proper fit, wearers must be fit-tested to make sure they have selected the appropriate model and size. The Occupational Safety and Health Administration (OSHA) requires that every employee who wears a respirator receive an initial fit-test prior to using that respirator (followed by annual tests), have a written program for the specific work location and be trained in the proper use of respirators. Additionally OSHA requires that, prior to the fit-test, employees must receive an initial medical evaluation, which consists of a medical questionnaire and a physician evaluation. For details on the UC Respiratory Protection Program, go to http://www.ehs.uc.edu/Advisories/Advisory_11_1.PDF. To discuss the need for respiratory protection when working with potential biological aerosols, please contact the biosafety office at (513) 558-6182 or (513) 558-5210.

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RESEARCH COMPLIANCE EVENTS & TRAINING

Intensive Clinical Research Orientation

Starting in February 2009, we will be discontinuing day-long orientation session on clinical research and instead will be offering three half-day training sessions. For those who are new to research and have not already completed our day-long training, session 1 is strongly recommended before taking sessions 2 and 3. For those who have already completed the day-long program, it will not be necessary to take session 1. Sessions 2 and 3 will provide additional, more in-depth training and will include such topics as data safety monitoring, budget preparation, HIPAA, informed consent process, appropriate subject interaction, and study inspections—what to expect. Session schedules will vary and will be offered both in the mornings and afternoons. A master schedule listing all of the 2009 orientation sessions will be available online soon. Interested participants will be able to register online for a half-day session. There is no fee for these sessions but registration is required for planning purposes. For more information, please contact Dana Raab at (513) 558-7821 or raabd@ucmail.uc.edu. Additional research and compliance education and training opportunities are listed under the “Education/Training” link on [Researcher's Gateway](#).