

April 2008

This issue marks our first full calendar year of *Compliance Matters*. We hope that you have found these publications to be informative and useful.

After much hard work and anticipation, the Researcher's Gateway is now open for business. See our Spotlight section for more details, including more a new Institutional Review board (IRB) service for electronically submitting protocols.

The Research Compliance Web site can be accessed directly from the Researcher's Gateway—under the "Quick Links" section. FDA assistance pages are also there for easier access. And, while you're there, don't forget to check out archived issues of *Compliance Matters*.

If your research involves animal work, the consequences of noncompliance with federal regulations will now cost you money. Don't miss the details from the Institutional Animal Care and Use Committee (IACUC) in the IACUC News section.

As always, you can contact us with questions at research.compliance@uc.edu. Let us know how we can better serve you.

Melissa Colbert, PhD
Director, Office of Research compliance and Regulatory Affairs (ORCRA)
Research Compliance Officer
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IN THIS ISSUE:

[Spotlight On: Researcher's Gateway and eMods](#)
[ORCRA News](#)
[IACUC News](#)
[IRB News/New or Updated HRP Policies and Procedures](#)
[Quality Improvement Tips for Investigators](#)
[Radiation Safety News](#)
[Biosafety](#)
[Research Compliance Events and Training Opportunities](#)

SPOTLIGHT ON: RESEARCHER'S GATEWAY AND eMODS

New Online Tools for Researchers

A new electronic submission process and resource-filled Web site will provide UC researchers with speedier service and convenient access to research information.

Researcher's Gateway (<http://researchgateway.uc.edu>) is a new portal designed as a single point of entry for accessing the myriad sources of research information. The site is password-protected and contains information on sources of funds, collaborators, facilities, resources, education and training, and regulatory support. It also features information specific to new researchers and a "Quick Links" section for experienced investigators. The Gateway will feature regular announcements about upcoming events, link you to newsletters and research news articles, and point you to information of particular note in a section called "Did You Know?" For additional information contact Dawn O'Neill, executive director for research programs, at dawn.oneill@uc.edu or (513) 558-6565.

In addition to Researcher's Gateway, investigators can now submit protocol modifications to UC's Institutional Review Board (IRB) electronically. The electronic modification submission (eMods) is just the first of many forms soon to be electronic. This process change will be adopted in phases. eMods is now available for use. The current hard copy form will be accepted through April 30, 2008. However, beginning May 1, 2008, the hard copy forms will no longer be accepted.

To access the eMods:

1. Log on to the Researcher's Gateway <http://researchgateway.uc.edu>
2. Click on "Protocol Manager" on the top tool bar.
3. Select "Modification" under IRB.
4. Follow the on-screen instructions.

For additional information, contact O'Neill at dawn.oneill@uc.edu or (513) 558-6565, or Andy Gardner, IRB manager, at anthony.gardner@uc.edu or (513) 558-5105.

[-back to top-](#)

ORCRA NEWS

Board Rule Change: Investigation of Research Misconduct

On February 15, the UC Board of Trustees approved several modifications to [Board Rule 10.17.05](#) to be consistent with the Public Health Service (PHS) policies on research misconduct (42 CFR §93) adopted in June 2005. Although the PHS regulations are specific for National Institutes of Health- and National Science Foundation-funded studies, UC's policy covers all research misconduct, irrespective of support.

Highlights include:

- a new and more restricted definition of research misconduct, "fabrication, falsification or plagiarism in proposing, performing or reviewing research results."
- the sequence of events to be followed when allegations are made—assessment, inquiry, investigation.
- details and timelines for the proceedings.
- protection of the complainant against retaliation.
- mechanisms for restoring the reputation of the accused if no misconduct is found.

An important new addition includes the position of the Research Integrity Officer (RIO), within ORCRA. The RIO facilitates the process by obtaining evidence, assisting the investigation panels, and maintaining confidentiality and contact with federal agencies, if required. The RIO is not a finder of fact and plays no role in deciding the outcome of investigations. If you have questions or concerns regarding research misconduct you can call the RIO directly at (513) 558-5034 for a confidential consultation.

[-back to top-](#)

IACUC NEWS

Not Complying With Animal Welfare Standards May Cost You Grant Money

The National Institutes of Health (NIH) is now increasing enforcement of terms and conditions of grants with animal components. As part of terms and conditions for receipt of grant money, UC has agreed through its IACUC to ensure compliance with appropriate federal animal welfare regulations.

[What does this mean for you?](#)

If you use animals and you fail to comply with federal animal welfare regulations, charges you have made against your grant during the period of noncompliance may have to be returned to the sponsor.

Is this really happening?

The University of Connecticut was forced to repay more than \$65,000 to its NIH sponsor for research conducted while it was not in compliance.

What sorts of issue can result in the return of funds?

Performing activities in the absence of IACUC approval*, such as:

- Breeding animals when not listed in the approved IACUC protocol.
- Performing surgeries not listed in the approved IACUC protocol (especially after a transfer of animals from one protocol to another).
- Having animals “in-house” on an expired protocol and not transferring the animals to the holding protocol.
- Gross animal neglect or negligence of the principal investigator, such as not providing animals access to food and water unless specifically stated in an approved IACUC protocol.
- Performing any procedures on animals not listed in an IACUC approved protocol.

*Absence of IACUC approval includes failure to obtain IACUC approval or expiration or suspension of IACUC approval.

Further reading:

- [IACUC Policy 18](#)
- NIH Notice [NOT-OD-07-044](#).
- [NIH Orders UConn to Return Grant Money](#), *Chronicle of Higher Education*, Jan. 28, 2008

[-back to top-](#)

IRB NEWS/NEW OR UPDATED HRP POLICIES AND PROCEDURES

eMods

It is with great pleasure that the IRB Office announces the unveiling of Researcher’s Gateway and electronic modification submission (eMods). With the release of these programs, division head and faculty advisor signatures will no longer be required with new submissions. Thanks to all involved in the development of these programs, with a special thanks to Dawn O’Neill and the information technology staff.

Safeguarding Research Participants

Cognitively impaired persons are a vulnerable population in research. Because of that, research involving participants who are cognitively impaired warrants additional safeguards. Researchers must include in their proposals sufficient justification for inclusion of participants who are cognitively impaired and a plan to protect them and their surrogates from coercion and undue influence. The IRB will determine whether the involvement of such individuals in research is justified and whether the proposed plan minimizes or eliminates the risks to vulnerable participants. In making such determinations, the IRB will consider the degree of risk, the ability of the subject to consent to the research and the likelihood of benefit to the subject. Please refer to the university’s [policy for enrolling cognitively impaired subjects via surrogate consents](#).

[-back to top-](#)

QUALITY IMPROVEMENT TIPS FOR INVESTIGATORS

Modifying Protocols

Information gleaned during the course of a study often results in changes to the study protocol. However, such changes need to be approved by the IRB prior to their implementation. Investigators should review their protocols periodically, note any changes made and submit protocol modifications to the IRB as deemed necessary. [See UC Policy # III.09, ICH Guideline 4.5.2.](#)

[-back to top-](#)

RADIATION SAFETY NEWS

The Authorized User and the Contact Person

The last two newsletters reviewed the responsibilities of the Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO). The RSC and RSO are the rule makers and overseers of the Radiation Control and Safety Program (RCSP). In addition, through the Radiation Safety Office staff, the RSO provides services to assist individuals in complying with regulations and maintaining radiation doses as low as is reasonably achievable (ALARA).

By regulation, radioactive material must be used under the supervision of an “authorized user” (AU). The AU must have at least 40 hours of training and experience in radiation safety, and must have the authority to ensure workers comply with regulations, use good radiation safety practices and keep doses ALARA. The AU must be a faculty member, a research associate or a research scientist, or have a pay grade of at least 16.

As a supervisor of radioactive material use, the AU has many responsibilities. The most significant responsibilities are ensuring all individuals who may handle radioactive material under their supervision are properly trained, maintaining an up-to-date list of areas where the radioactive material may be used or stored, maintaining an accurate radioactive material inventory, ensuring the radioactive material is secured from unauthorized access or use, ensuring the radioactive material is used only in accordance with authorized procedures and ensuring all radioactive waste is disposed of in accordance with RCSP procedures. As with all individuals under the RCSP, the AU is responsible for ensuring doses to persons working with and around radiation sources are ALARA.

An equivalent authority and responsibility is applied to radiation generating device, also called RGE, such as X-ray equipment and electron microscopes. Under the RCSP, all RGE must be operated under the supervision of a “contact person” (CP). A CP is similar to an AU in their responsibility and authority expectation; however, there are no specified job classifications for someone becoming a CP.

[-back to top-](#)

BIOSAFETY NEWS

Adhering to Biosafety Guidelines

In order to continue to receive NIH funding, and according to the [NIH guidelines](#), our institution is committed to:

- establishing an Institutional Biosafety Committee (IBC);
- establishing and implementing policies for the safe conduct of recombinant DNA research;
- assisting and ensuring compliance with the NIH Guidelines by all investigators;
- ensuring appropriate training for IBC members and staff, principal investigators and laboratory staff;
- determining necessity for health surveillance of personnel; and
- reporting any significant problems or violations to the Office of Biotechnology Activities (OBA) within 30 days.

The principal investigator shall, among other things:

- initiate or modify no recombinant DNA research which requires IBC approval until approval is granted;
- determine whether experiments are covered under III-E and notify the IBC as appropriate;
- be adequately trained in good microbiological techniques;
- adhere to IBC emergency plans for spills and personnel contamination; and
- report any significant problems or violations to the OBA within 30 days.

[-back to top-](#)

RESEARCH COMPLIANCE EVENTS AND TRAINING OPPORTUNITIES

Clinical Trials Orientation

April 24, 2008

8:30 a.m. to 5 p.m.

Room 450, University Hall

Lunch provided

To register, contact Brenda Miller at (513) 558-7399.

[-back to top-](#)

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