

ORC Newsletter for Researchers

SUMMER 2008

CLEMSON UNIVERSITY

ORC (Office of Research Compliance)

Special Points of Interest

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- ◆ Animal Welfare Training
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New IRB Staff

Ms. Rebecca Alley joined the ORC as IRB Coordinator on May 2, 2008 and she can be reached at 656-0636 or email at

ralley@clermson.edu.

Ms. Belinda Witko joined the ORC as IRB Assistant on May 30, 2008 and she can be contacted at 656-3918 or email at

bwitko@clermson.edu.

Please join us in welcoming Becca and Belinda to our office.

Research Integrity

A strong commitment to research integrity is at the very core of Clemson University's (CU) highly-regarded research program. The term research integrity includes not only the ideals of honesty and fairness, but also compliance with research guide-

lines and policies.

To ensure that Clemson is in compliance with current regulatory requirements, as well as to assist the research community with issues of research integrity, the University has developed a policy that addresses how it will respond to allegations of research misconduct. As defined by federal regulation, research misconduct comprises fabrication, falsification, or plagiarism in proposing, performing, or reviewing research results. The procedures outlined in the policy meet the federal regulatory standards established by both the National Science Foundation and the Public Health Service. CU's Research Misconduct policy can be found on the "What's New Page" of the ORC

website:

http://www.clemson.edu/research/ospSite/forms/research_misconduct.pdf.

Online education in the Responsible Conduct of Research (RCR), which includes research misconduct as well as other topics such as human research protections, laboratory animal welfare, publication practices, and mentor-trainee relationships, is available for faculty, staff and students via the ORC website. Resources for RCR instruction are also available in the ORC.

Tracy Arwood, ORC Director, serves as Research Integrity Officer for the University. Questions or concerns regarding research misconduct as well as other RCR issues should be directed to her at 656-1525 or email tarwood@clermson.edu.

IACUC (Institutional Animal Care and Use Committee)

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Animal Welfare Training and 5 Year Refresher Training Requirements.

In compliance with federal regulations, the CU IACUC requires that all faculty, staff and students involved in the use of animals in research and teaching programs at Clemson University complete appropriate training.

CU now requires refresher animal welfare training be completed every 5 years. To meet these training needs, web based, interactive animal welfare training modules have been developed for CU administrators, faculty, staff and students. The specific training areas mandated by the

Animal Welfare Act and the PHS Policy are described in the training modules. All individuals involved in vertebrate animal use at CU are required to complete the [online training modules](#) prior to working with animals. Instructions to access these web based training modules are located on the ORC website at: http://www.clemson.edu/research/orcSite/orcIRB_CITIHelpPage.htm.

Because the refresher training is a new requirement for Clemson personnel, a grace period for completion of the training was instituted. The grace period ended June 30, 2008. Training

for all personnel listed in an Animal Use Protocol will be verified prior to a protocol application moving forward for review and approval by the IACUC.

Please contact Kathy Bryant at kbrynt@clermson.edu or 656-4538 if you need assistance.

AAALAC Accreditation.

AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care) is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. CU is preparing for its triennial AAALAC

IACUC (continued)

accreditation visit which should be in early Spring of 2009. The ORC is working with the CU research community in preparing the documentation to be provided to AAALAC. The accreditation includes both our biomedical and agricultural research and teaching programs.

Having accreditation represents and provides an external validation of quality. Organizations look for ways to communicate their commitment to excellence. In the scientific community, AAALAC accreditation shows that an institution is serious about setting, achieving and maintaining high standards for animal care and use in science. Around the world, AAALAC accreditation is recognized as a symbol of quality. More than 750 companies, universities, hospitals, government agencies and other research institutions in 29 countries have voluntarily earned AAALAC accreditation demonstrating their commitment to responsible animal care and use. Within the aca-

demical community, Clemson is one of only 15 land grant universities that have achieved university wide (biomedical and agricultural) accreditation. CU has been accredited since 1994.

CU has chosen to meet these standards. Our program has been carefully evaluated by a council of highly respected, expert animal care and research professionals who determine that we qualify for AAALAC accreditation. AAALAC accreditation is recognized worldwide as the “gold standard for animal care” for animal research programs and we are pleased to be awarded this exceptional designation.

An IACUC Member's Guide to Animal Facility Inspections is a free, online course primarily intended for persons sitting on an IACUC who conduct mandated inspections of animal facilities for compliance with U.S. regulatory standards, but research investigators, facilities managers, and others (veterinarians, scien-

tists, public committee members, and administrators) may find this material helpful.

The course addresses the regulatory requirements for animal facilities, including housing, surgery, cleaning, and storage areas. Each area is presented in a 360-degree panoramic image containing some commonly inspected items. The module provides tips for inspecting items and links to relevant regulatory documentation. Users may test their understanding with questions provided for each inspection item and with a quiz after completing the virtual tours. The time needed to complete the session is approximately 90 minutes, but may be longer depending on links to additional resources that are accessed and reviewed. This introductory course is not intended to be comprehensive. It can be accessed at: <http://ori.dhhs.gov/education/products/IACUC/home.html>.



Morgan
Poultry Center

IBC (Institutional Biosafety Committee)

NIOSH Releases Nano-Workplace Brochure.

NIOSH recently published a new two-page brochure “Safe Nanotechnology in the Workplace: An Introduction for Employers, Managers, and Safety and Health Professionals”. This document addresses in summary format four issues.

- ◆ Whether nanoparticles are potentially hazardous to workers
- ◆ Possible exposure routes
- ◆ Measurement techniques
- ◆ Exposure control

The brochure can be accessed at: <http://www.cdc.gov/niosh/docs/2008-112/pdfs/2008-112.pdf>

Signs and Labels.

The current version of the EHS-CHP (9/11/2007) has a section in Appendix E on signs and labeling. **Biological Hazard.** The sign will be accompanied by the standard biological hazard symbol indicating that an agent which may prove infectious to human beings is present within the area. **Carcinogenic Hazard.** The Laboratory Standard requires that areas in which carcinogenic agents are in use be designated as such. This can be done with a sign such as: CARCINOGENIC AGENT or CANCER-SUSPECT AGENT-Authorized Personnel ONLY.

Where the agent might be unusually dangerous, the agent would be specified and any special protective measures needed

would be appended.

Personal Protective Equipment (PPE)-Glove Type.

The current version of the EHS-CHP (9/11/2007) has a section on hand protection and glove type selection for some specific chemicals. This section is on pp. 161-170 of the CHP and investigators might find it useful in addition to information on the MSDS.

Forms Update.

One of our investigators has asked for the Section C spreadsheet to be available in Excel so that information could be cut and pasted from the EHS Hazardous Agent Inventory to our Section C of the IBC application. The Excel version is now available on our

IBC forms page. For the use of hazardous chemicals either a WORD or Excel version needs to be completed. We will also be working on changing the Section B for biological agents to an Excel format.

Student and Minors Supervision.

Each summer and sometimes during the other school semesters, students (who may not be enrolled at Clemson) and who may also be minors come to CU and work in our laboratories on approved IBC protocols. All of us are responsible for providing these young people a safe and scientifically rewarding experience. The following principles are important to assure the safety of the trainees.

- ◆ Students must be directly supervised when working with any actual or potential hazardous materials.
- ◆ Students over the age of 18 review the IBC protocol and any related materials such as MSDS and sign the Hazard Acknowledgement Form.
- ◆ Minor students assent to their participation in an IBC approved research (via an assent form) and must have the written permission of their parent or guardian. The minor registration form must list any potentially hazardous materials the student may encounter or work with. They also review the IBC protocol and sign the Hazard Acknowledgement

Form. The CU-policy can be accessed at: http://www.clemson.edu/research/orcSite/orcIBC_Reg.htm

- ◆ All students must receive safety training relevant to the laboratory procedures that they are performing.
- ◆ PIs/Supervisors must document specific training related to the work.
- ◆ Students are added to the IBC approved protocol via an amendment form.

Information on what qualifies as exempt recombinant DNA research. Investigators conducting recombinant DNA research will find the following addition to the IBC application helpful. In section A.1.B. of the CU application, PIs are asked to justify why the recombinant DNA research may qualify as 'exempt' under the *NIH Guidelines*. The application now has a hyperlink to the [NIH Guidelines](#) and [Appendix A \(Exemptions under Section III-F-5-Sublists of Natural Exchangers\)](#) and [Appendix C \(Exemptions under Section III-F-6\)](#) which contain details on certain experiments that may be exempt or are exceptions to

the *NIH Guidelines*.

Articles of Interest.

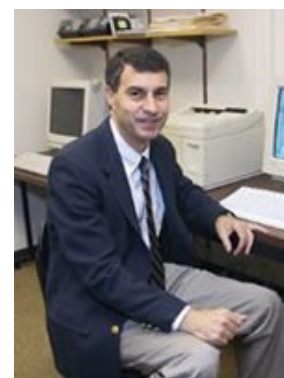
Poland et al.

"Carbon Nanotubes Introduced into the Abdominal Cavity of Mice show Asbestos-like Pathogenicity in a Pilot Study". Published online: 20 May 2008;doi:10.1038/nnano.208.111 Nature Publishing Group: Nature Nanotechnology (Advance Online Publishing) www.nature.com/naturenanotechnology.

Best Practices.

- ◆ After using sodium hypochlorite, wiping the Biosafety Safety Cabinet surface with 70% ethanol, will reduce the corrosive action of the bleach but will not affect the disinfectant properties of the bleach. This idea has been discussed on the ABSA biosafety forum (March 25, 2008) and in Biological Safety Principles and Practices.
- ◆ Even though some chemicals are used in small quantities, all toxic chemicals, even those that do not list a specific requirement for a hood, should be used in a hood whenever possible.
- ◆ When placing human body fluids in a -80C freezer, the freezer will need BBP signage on the outside, plus double bagging and identification of the material as BBP.
- ◆ Under BBP standards, manipulation of human bodily

An
Appreciation Reception
honoring the
Clemson University
Compliance Committee
Members
will be held
Monday,
September 29, 2008
3:00 p.m. – 4:30 p.m.
Clemson University
Alumni Association Lobby



Dr. Joel Greenstein will be leaving the IRB as Chair in August and has served on the IRB for 20 years. Thank you for your valuable service.

IRB (Institutional Review Board)

Principal Investigator Responsibilities Regarding IRB -Required Continuing Education and Updates to the Research Team.

The ORC would like to remind PIs (Principal Investigators) of important responsibilities related to continuing education in the protection of human subjects and

updates to research team membership. PIs are reminded that, in order to meet federal regulations, the CU IRB requires PIs and all research team members to complete appropriate training, with continuing education every two years.

The required training is offered online through the Collaborative

IRB Training Initiative (CITI) program (www.citiprogram.org) and it is anticipated that most individuals from CU will need the Basic CITI Course for Investigators Conducting Social and Behavioral Science Research. Additionally, every two years, researchers must complete a Refresher Course available

IRB (continued)

through the same website.

PIs are responsible for ensuring that all members of their research team are up-to-date on their training at all times. Beginning this summer, IRB staff will be verifying the training of all research team members before studies undergoing continuing review or amendment are sent on for review. Thus, it is important that PIs monitor the training of research team members so reviews of their studies are not delayed.

Additionally, PIs are responsible for informing the ORC/IRB when research team membership changes, including both departing and new members. Because failing to remove inactive team members from a research protocol may delay continuing review or amendment of the protocol,

the ORC encourages PIs to regularly review their team membership and submit amendments to remove any individuals who are no longer on the research team. To request a list of research team members and CITI training expiration dates for a given protocol, please email IRB Coordinator, Becca Alley, at ralley@clemsn.edu.

HSSC IRBs and Electronic Submissions.

IRBs for the Health Sciences South Carolina (HSSC) institutions other than CU have recently moved to electronic submission (eIRB) or have plans to do so in the near future. PIs conducting research at or in collaboration with these institutions may wish to familiarize themselves with the new eIRB system,

which has a core application shared across the 5 institutions, with additional institution-specific requirements.

If you will be the PI on a collaborative project to be reviewed by one of these IRBs, you'll need an eIRB username and password in order to be able to submit an application electronically. This username and a temporary password will be supplied to you by the IRB staff of the site to which you're applying, and each IRB office is handling this process differently. It is important to consult with the relevant IRB to determine institution-specific requirements.

These are the IRBs which have adopted or will soon be adopting this eIRB system, and their online submission start dates:

- ◆ **Greenville Hospital System:** already online. Contact: Jean Winter, 864-455-3145, jwinter@ghs.org.
 - ◆ **Spartanburg Regional Healthcare System:** already online. eIRB Technical Contact: 864-560-4226, eIRB@srhs.com.
 - ◆ **Palmetto Health Alliance:** beginning within two months.
 - ◆ **USC:** beginning within two months. Contact: Arlene McWhorter, 803-777-7095, arlenem@mailbox.sc.edu.
 - ◆ **MUSC:** beginning soon after Palmetto and USC.
- For more information, please contact Laura Moll, IRB Administrator, at 864-656-6460 or lmoll@clemsn.edu.

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The ORC (Office of Research Compliance) provides support and training for faculty, staff, and students in regulatory requirements for research and teaching activities involving vertebrate animals, research involving the use of human subjects, and research involving the use of hazardous agents. The ORC is responsible for the development and implementation of University policies and for coordinating institutional compliance with federal and state law/regulations. The ORC supports the University community in promoting the responsible conduct of research.

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Promoting ethical and responsible research involving vertebrate animals, hazardous materials, and human subjects.

[http://www.clemsn.edu/
research/orcSite/
indexComply.htm](http://www.clemsn.edu/research/orcSite/indexComply.htm)

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