

ORC Newsletter for Researchers

CLEMSON UNIVERSITY

SPRING 2009

ORC (Office of Research Compliance)

Special Points of Interest

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- ◆ Launch of New Email Addresses for IBC & IRB
- ◆ iThenticate Pilot Program
- ◆ Protocol Submission Online Pilot Testing
- ◆ New SOP Template Available
- ◆ IACUC Bylaws and Policies Updated
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New Website

We are pleased to announce that the ORC has recently gone live with our new website at <http://www.clemson.edu/research/compliance/>. This site was developed and implemented in accordance with CU's update to all web-based content. The new website format is an improvement over the previous version, with easier navigation and better organization of the information presented within. Researchers will now have easier access to forms and information on the various compliance issues that may apply to their work. We strive to make our website a helpful tool for researchers and a valuable source of information related to research compliance. In line with this, we encourage you to provide feedback regarding the website. Feedback regarding content of compliance related information should be directed to the appropriate compliance administrator (IACUC, IBC, IRB). General or technical feedback, such as broken links or text errors, should be directed to the IT Coordinator, [Daniel Harris](#) (656-1450). Any bookmarks or favorites listings you may

have from our previous website should redirect to the new site's main page.

Launch of New Email Addresses

The ORC announces the launch of the ibc@clemson.edu and irb@clemson.edu email addresses. Researchers are encouraged to submit new applications, amendment requests, annual and continuing reviews, and other IBC/IRB related inquiries to these central addresses. It is our hope that the use of central addresses will streamline IBC and IRB processing of research submissions and ensure that questions are answered in a timely manner. We welcome your feedback on the use of these new addresses, as we are always looking for ways to improve our processes.

iThenticate Pilot Program

In January 2009, the Office of Sponsored Programs began a pilot program using *iThenticate* software to evaluate the originality of randomly selected proposals. This program is intended to detect instances in which passages included within a PI proposal are found to be similar or identical with

published material. The use of this screening tool is meant largely to assure funding agencies that due diligence is being exercised within the Office of Sponsored Programs to avoid possible cases of plagiarism that might intentionally or accidentally be committed in submitted proposals. The decision to use this screening device at CU is a response to the increased number of examples of plagiarism in research proposals submitted by US universities that have been found in recent years. Any detection suggesting a possible issue of plagiarism in any proposal examined with this program would be reviewed carefully to ensure that the program execution was accurate in finding proposal passages that duplicate published material. An example of a "false detection" that might occur would be a case in which the PI cites material from one of his/her research papers without sufficient documentation as to the source. In any such instance, the PI would be requested to provide an explanation. Should the explanation be found lacking credibility, an inquiry involving the Research Integrity Offi-

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cer may be launched. Thus, the use of the *iThenticate* computer program provides an important safeguard that enhances the research integrity of research proposals

submitted by CU. If you have questions about this program, please contact [Nalinee Patin](#), iThenticate's system administrator in the Office of Sponsored Pro-

grams or [Tracy Arwood](#), Research Integrity Officer and Director of the Office of Research Compliance.

IACUC (Institutional Animal Care and Use Committee)

We have begun pilot testing the InfoEd online animal use protocol submission process.

Protocol Submission Online Pilot Testing

We have begun pilot testing the InfoEd online animal use protocol submission process. If you are interested in participating by submitting your animal use protocols online please contact [Kathy Bryant](#) or [Daniel Harris](#) to set up a time for instruction. Because this is a new process, please allow a bit more time for approval than you have experienced in the past. Thank you to those of you who have taken part in this pilot program. We

appreciate your patience as we work our way through this new process.

New Template Available

A Standard Operating Procedure (SOP) template has been added in the forms section on the IACUC website. Drafting SOPs can be challenging. We hope this template will make creating an SOP more understandable. Please feel free to download this template and the guidelines for creating an SOP.

Bylaws and Policies Updated

The IACUC Bylaws and Policies have been reviewed and updated. They are available on the IACUC website.

AAALAC Site Visit

Clemson's triennial AAALAC site visit will take place in late March. Detailed information will be forthcoming to principal investigators and facility managers as we solidify the agenda.

Effective January 1, 2009, the IBC at CU will no longer oversee the review of chemical hazards except....

IBC (Institutional Biosafety Committee)

Change in IBC Oversight

Effective January 1, 2009, the IBC will no longer oversee the review of chemical hazards used in research **EXCEPT** where the research involves select agents/toxins or the use of hazardous chemicals in research with vertebrate animals.

As federally mandated, the IBC will continue to review

and oversee the use of recombinant DNA in research. Additionally, the IBC will continue to review and oversee the use of infectious (or potentially) infectious agents in research. For more information or questions regarding the status of specific research projects, please contact [Marlene Ventura](#) (656-0118).

Select Agent Update

On November 17, 2008 both HHS and USDA updated the list of Select Agents and Toxins. **Added to the APHIS Select Agent List**
Xanthomonas spp. (oryzae)
Peronosclerospora sacchari
Phoma glycinicola
Rathayibacter toxicus
Removed from the APHIS Select Agent list

Candidatus Liberobacter spp. Additionally, APHIS made some very small changes to the definition of "virulent Newcastle Disease." Any faculty working with Newcastle or any of the new agents listed above should contact EHS for assistance. The updated list can be found on our website under IBC/regulations and policies.

Articles of Interest

1) A new publication is available on the second literature review on the

health risks of nanoparticles (NP). The review reveals the scope of current research in the field and points out that the toxic effects of NP on humans and animals are only partially understood. Claude Ostiguy, the chemist heading up the literature review, believes that "the documented toxic effects on animals, as well as the physico-chemical characteristics of NP, now justify taking all necessary steps to limit exposure and protect the health of individuals potentially exposed to them". For

more details or to download the report: <http://www.irsst.qc.ca/files/documents/PubIRSST/R-589.pdf>.
2) The Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 has been posted at http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf.
While this document is aimed at healthcare settings, the elements can translate to work in laboratory facilities.

Any faculty working with Newcastle or any of the new agents listed above should contact EHS for assistance.

IRB (Institutional Review Board)

New IRB Forms

Preparations for several new IRB Forms, including Exempt and Expedited/Full Application Forms, are currently underway. The ORC anticipates the release of these new forms sometime in the Spring of 2009. We hope these new forms will be more user-friendly and welcome feedback as we are always looking for ways to improve the IRB review process.

PIs should get the latest forms from the website for each submission. PLEASE NOTE: Protocols submitted using older (out-of-date) forms will not be accepted following a one-month transitional period.

Collaboration with Researchers Not Affiliated with CU

The Clemson IRB has re-

quirements regarding collaboration with researchers not otherwise affiliated with CU. These requirements vary depending on the institution(s) involved and the level of review needed for the research protocol:

1. Team members not affiliated with any institution, or affiliated with an institution that does not have its own IRB.

a. **Research eligible for Exempt review** – The Clemson IRB recommends, but does not require, the completion of human subjects protections training for these research team members. The non-affiliated team members are welcome to access the CITI training by declaring an affilia-

tion with CU during the CITI registration process.

b. **Research requiring Expedited/Full Board review** – The non-affiliated research team members must be brought under the purview of an IRB. Most commonly, these individuals will sign an Individual Investigator Agreement (IIA) in order to be covered by CU's IRB and will complete Clemson's human subjects protections training or an alternative training session approved by the CU IRB. Please contact [Laura Moll](#), IRB Administrator, if you need to have a research team member sign an IIA. In

The Clemson IRB has requirements regarding collaboration with researchers not otherwise affiliated with CU.

IRB (continued)

rare instances, the institution which the team member is affiliated with may need to obtain a Federalwide Assurance (FWA) and establish its own IRB. (For more information on FWAs, please contact [Laura Moll](#), IRB Administrator (656-6460).

2. Team members affiliated with an institution that has its own IRB.

a. **Research eligible for Exempt review** – To conduct exempt research in collaboration

with researchers from an institution having its own IRB, researchers should obtain IRB approval from both Clemson and the other institution. Team members not affiliated with CU will not be required to take Clemson's human subjects protections training but instead should meet any training requirements set by their own institution's IRB.

b. **Research requiring Expedited/Full Board review** – Before con-

ducting an expedited/full study in collaboration with researchers from an institution that has its own IRB, researchers should contact [Laura Moll](#), the IRB Administrator (656-6460) to determine whether both IRBs will need to conduct reviews of the research protocol or whether it will be possible for one of the IRBs to defer to the other so that only one IRB review will be required for the study. If one IRB will defer to

the other, the IRBs must agree which IRB will conduct the primary review. Additionally, an IRB Authorization Agreement (IAA) must be negotiated between Clemson and the other institution. Generally, researchers from the other institution will not be required to take Clemson's human subjects protections training but instead will be required to meet the training requirements set by their own institution's IRB.

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The Office of Research Compliance (ORC) 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.

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

[http://
www.clemson.edu
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compliance/](http://www.clemson.edu/research/compliance/)

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