

ORC Newsletter for Researchers

FALL 2008

CLEMSON UNIVERSITY

ORC (Office of Research Compliance)

Special Points of Interest

- ◆ Whistleblower Policy
- ◆ AAALAC visit
- ◆ IACUC training
- ◆ Addition or deletion of research personnel on IBC protocols
- ◆ Resource documents posted to the IBC website
- ◆ Verification of the identity of attenuated pathogens
- ◆ New policy regarding addition and removal of IRB research team members
- ◆ Differentiating sensitive participants from sensitive research

Whistleblower Policy

Administrative Council has approved a Whistleblower Policy which is now accessible via our website.

<http://www.clemson.edu/research/ospSite/policies/whistleblower.pdf>.

The policy defines how whistleblower protections defined

in South Carolina state law and federal regulations function within Clemson University.

IACUC (Institutional Animal Care and Use Committee)

AAALAC

Clemson University is preparing for its triennial AAALAC accreditation visit in early Spring of 2009. The Office of Research Compliance is working with the Clemson University research community in preparing the documentation that must be provided to AAALAC prior to the visit. Clemson University biomedical and agricultural research and teaching programs have both been AAALAC-accredited since 1994.

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 academic community, Clemson is one of only 15 land grant universities that have achieved university-wide (biomedical and agricultural) accreditation.

Our program will be 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.

Training

Effective July 1, 2008, animal welfare continuing education is required every 5 years. All

individuals who have not completed the online modules in the past 5 years will be required to do so before their protocol submission can be approved. If you experience problems or have questions, please contact Kathy Bryant at kbrynt@clemson.edu or 864-656-4538.

In compliance with federal regulations, the Clemson University Institutional Animal Care and Use Committee (IACUC) requires that all faculty, staff and students involved in the use of animals in research and teaching programs at Clemson University successfully complete appropriate training. To meet some of these training needs, web-based, interactive animal welfare training modules have been developed for Clemson University. All individuals involved in animal use at Clemson University are required to complete the online training modules prior to working with animals.

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IACUC (continued)

Updates to forms & policies

The protocol application form is being updated, so be sure to download current forms from the IACUC website when completing your protocol submissions.

IACUC policies are also being reviewed and updated. Policy #02: *Food and Water Restriction* and Policy #03: *Physical Restraint of Animals* have recently been revised. Policy #01: *Institutional Animal Care and Use Committee (IACUC) Policy and Procedures for the Use of Vertebrates in Teaching*, Policy #11: *IACUC Policy on Training for Students in Teaching Activities Using Vertebrate Animals*, and

Policy 15: *Institutional Animal Care and Use Committee Policy and Procedures for Reporting and Investigating Animal Concerns* were revised earlier this year.

All of the Clemson University Institutional Animal Care and Use Policies may be found on the Research Compliance website at http://www.clemson.edu/research/orcSite/orcARC_Regs.htm.

There is also a link to the CU Research Division Policies addressing veterinary authority and adequate veterinary care, and personnel categories for the assignment of Principal Investigator/Project Director.

Continuing Education

The Office of Research Compliance and the IACUC will

offer *Navigating the IACUC Seminars* as well as Brown Bag Seminars, and welcomes your input for subject matter of interest to you.

Article of Interest

The Wildlife Conservation Society sounds the alarm on wildlife-human disease threats in the age of climate changes for the following 12 pathogens: Avian Influenza, Babesia, Cholera, Ebola, Intestinal and External Parasites, Plague, Lyme Disease, Red Tides, Rift Valley Fever, Sleeping Sickness, Tuberculosis, and Yellow Fever. For more information access: http://www.wcs.org/media/file/DEADLYdozen_screen.pdf

“The protocol application form is being updated, so be sure to download current forms...”

“...the ORC has adopted a new policy regarding the addition and deletion of individuals...”

Addition or deletion of research personnel

In an effort to reduce paperwork for the PIs and to shorten review time, the ORC has adopted a new policy regarding the addition and deletion of individuals from IBC-approved protocols. The IBC office will now accept an e-mail from the PI in lieu of submission of an amendment form. In the e-mail, please identify the individuals to be added or deleted and the appropriate IBC protocol number. The e-mail should be sent to ventura@clemson.edu.

A Hazard Acknowledgement Form (HAF) should still be sent to the IBC office with the names and signatures of individuals added. If you are deleting research personnel, no

revised HAF is necessary. The HAF form can be accessed at: http://www.clemson.edu/research/orcSite/orcIBC_Forms.htm.

This e-mail option only applies to adding or deleting research personnel. All other types of amendments should still be submitted on the IBC amendment form.

Resource documents

Links to the following documents have been posted to the IBC website under “Regulations and Policies”.

They include:

1. “Working with Viral Vectors”. Stanford University has shared with the list-serve of the American Biological Safety Association (ABSAA)

a document that may be helpful to researchers working with viral vectors.

2. “Applied Biosafety” (Vol. 13, No. 1, 2008, pp. 6-15) had an article on “Comparative Analysis of the Fourth and Fifth Editions of Biosafety in Microbiological and Biomedical Laboratories” Section IV (BSL 2-4) that highlighted a change matrix that presents a systematic and streamlined methodology for identifying changes between the 4th and 5th editions of the BMBL.
3. The American Biological Safety Association has announced training videos for Working at Animal Biosafety Levels 1-3. They include:
 - ♦ “Working at Animal Biosafety Level 1” (10:24 min-

utes)

- ◆ “Working at Animal Biosafety Level 2” (19:35 minutes)
 - ◆ “Working at Animal Biosafety Level 3” (22:23 minutes)
 - ◆ “Overview of Risk Assessment and Risk Management in Laboratory Animal Biosafety” (7:54 minutes)
4. CU has developed a guidance document on Working with Human Bodily Fluids, Blood, Tissue, Cells and Other Potentially Infectious Material for PIs which presents, in checklist form, some tips on preparing the IBC application.

Verification of the Identity of Attenuated Pathogens

The Boston Public Health Commission reported in March of 2005 that three cases of pneumonic tularemia (1 confirmed, 2 probable) were reported in November of 2004. All three cases occurred in laboratory researchers at a BSL 2 laboratory in the Northeast who believed that they were working with the Live Vaccine Strain (LVS) of *Francisella tularensis*, the organism that causes tularemia. The LVS strain is an attenuated form of the bacterium not previously associated with human illness.

Laboratory testing by CDC showed that the LVS stock used by the researchers was contaminated with Type A

tularemia, a wild-type, virulent form of the organism. Because of the potential for use as bioterrorism agents, Type A and B tularemia are classified as Category A agents by the CDC and their use is restricted to CDC approved select agent programs.

Investigators should be aware of the possibility of contamination of microbial cultures obtained from other institutions, and the issue of verifying the identity of attenuated forms of any pathogens, which require only BSL 2 level containment (contrasted with contaminating virulent forms of the pathogen that require BSL 3 or 4 biosafety containment).

“Investigators should be aware of the possibility of contamination of microbial cultures obtained from other institutions, ...”

IRB (Institutional Review Board)

New Policy Regarding Addition and Removal of IRB Research Team Members

In an effort to reduce paperwork and shorten review time, the ORC has adopted a new policy regarding the addition and removal of individuals from IRB research teams. Under this new policy, Principal Investigators are no longer required to fill out an amendment form to add or remove team members. Instead, PIs may simply send a list of individuals to be added or removed, along with the appropriate IRB protocol number, to Becca Alley, IRB Coordinator, at ralley@clemson.edu.

Requests to remove individuals will be effective upon receipt and the listed individuals will be administratively removed from the protocol. Requests to add individuals will be effective upon IRB

approval. These requests for additions will be processed within one to three business days and PIs will receive email confirmation once the new team members have been added. Questions or comments regarding this new policy may be directed to Becca Alley, IRB Coordinator, at 656-0636 or ralley@clemson.edu.

Abstract below is reprinted with permission.

Differentiating Sensitive Participants from Sensitive Research

Research on the nature and healing of emotional harm typically requires asking questions that may produce strong emotions. Are these emotions harmful or beneficial? Do participants regret participating and experience lasting upset, or appreciate the experience, gain insight and closure, and want to participate in further research? Investigators who do sensitive research, such as trauma researchers, find that few report lasting upset while many report gaining lasting benefit.

There is growing evidence that a small percent of research participants in any

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IRB (continued)

research report negative reactions; this response may be more related to underlying psychopathology than the nature of the research in which they participate. Are subject selection and informed consent more important than seeking to protect all subjects from participating in research that evokes lasting negative reactions from a few and positive reactions from many? The

Reactions to Research Participation Questionnaire (RRPQ) is a measure of subjects' experience of research participation that may shed light on these challenging questions.

The RRPQ directly assesses research participants' appraisal of the benefits and drawbacks of participation, faith in the research team's professionalism, and emotional response to the protocol. The RRPQ

and related background may be found at <http://www.personal.utulsa.edu/~elana-newman/>

JERHRE Notes accessed on October 3, 2008: <http://www.csueastbay.edu/JERHRE/notes/ReactionstoSensitiveResearch.pdf>

Newman, E., Risch, E., Kassam-Adams, N. (2006). Ethical Issues in Trauma-Related Research: A Review. *Journal of Empirical Research on Human Research Ethics*, 1(3), 29-46.

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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/research/orcSite/indexComply.htm>

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