

# RESEARCH COMPLIANCE NEWSLETTER FOR RESEARCHERS

Clemson University, Office of Research Compliance, 321 Calhoun Street, 223 Brackett Hall, Clemson, SC 29634-5704  
TEL: 864-656-1525 FAX: 864-656-4425

## ORC

### Flu Readiness

The ORC has been diligently working to develop alternate plans for review of research protocols should the H1N1 flu disrupt normal business operations. If a disruption should occur, we will conduct business remotely as staffing levels allow, giving priority to funding deadlines, contractual obligations and changes in existing projects. Should these alternate plans become necessary, we will communicate this to PIs and grant coordinators. If you have concerns or questions, please contact [Tracy Arwood](#), Director, or the relevant compliance committee administrator.

### New NSF (National Science Foundation) Requirements – America COMPETES Act (Sections 7008 and 7009)

The NSF now requires PIs to submit a **mentoring plan** (Section 7008) with any proposal that will support postdocs. This plan must be written into the proposal or the NSF will return your proposal without review. While our office cannot author this individualized plan for each PI, we do have resources available that may help in writing and carrying out such a plan. The PI's mentoring activities must be reported on annual and final reports to NSF.

More information about mentoring plan requirements can be found at:

### INSIDE THIS ISSUE

ORC (Office of Research Compliance)	1
IACUC (Institutional Animal Care and Use Committee)	1-2
IBC (Institutional Biosafety Committee)	2-3
IRB (Institutional Review Board)	3
Research Integrity	4

[http://www.nsf.gov/pubs/policydocs/pappguide/nsf0929/gpg\\_2.jsp#IIC2j](http://www.nsf.gov/pubs/policydocs/pappguide/nsf0929/gpg_2.jsp#IIC2j).

Effective January 2010, Clemson University must have an institutional plan (Section 7009) in place to provide **training in the responsible conduct of research (RCR)** to any student (undergraduate or graduate) or postdoc supported under an NSF award. Clemson's plan for RCR instruction will include 2 components: (1) online education to provide a basic understanding of RCR concepts and (2) PI-determined discussion-based RCR instruction. Our draft institutional plan is being finalized and will be communicated to PIs and colleges in late fall/early winter.

More information about these requirements can be found on the NSF website at:

<http://www.nsf.gov/pubs/policydocs/newsletter/may09/>

Questions regarding these NSF requirements should be directed to your grant coordinator or to [Tracy Arwood](#), Research Integrity Officer.

## IACUC

### Clemson University Veterinarian Named as AAALAC Ad Hoc Consultant

Dr. W. Gregory Queen was recently selected by the Association for Assessment and Accreditation of Laboratory Animal Care, International, (AAALAC), to serve as an Ad Hoc Consultant. In this capacity, Dr. Queen will assist in evaluating biomedical and agricultural research facilities for accreditation by AAALAC.

Greg has a wealth of experience that will be extremely beneficial to serving in the position of Ad Hoc

Consultant. He worked for many years as a private practitioner and academician/educator in the specialty of food animal practice. He earned board certification in that specialty and has twice served as a Food Animal Regent for the American Board of Veterinary Practitioners. Additionally, he is an active participant in many food animal oriented professional groups. He has served Clemson University for seven years as the University (Attending) Veterinarian, as a member of the IACUC and as Interim Director of the Office of Research Compliance. During his time at Clemson, he has also

Please see **IACUC** on page 2

## IACUC continued

directed the daily operations of our laboratory animal facility, where biomedical research and teaching are performed, and overseen the health and welfare of livestock at University teaching and research farms.

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. More than 770 companies, universities, hospitals, government agencies and other research institutions in 29 countries have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use. These institutions *volunteer* to participate in AAALAC's program, in addition to complying with the local, state and federal laws that regulate animal research.

#### New from the National Academies: *Recognizing and Alleviating Pain in Animals*

Experts convened by the National Academy of Sciences recently concluded that “all vertebrates should be considered capable of experiencing the aversive state of



*Dr. Queen was recently selected by the AAALAC, International, to serve as an Ad Hoc Consultant.*

pain.” Minimizing animal pain, wherever possible, is important both ethically and legally. The National Academies have developed a free online resource to help those who care for and use laboratory animals, farm animals, and pets to prevent, recognize, and alleviate pain in different types of animals, from non-human primates to fish. Visit this online resource at [http://dels.nas.edu/animal\\_pain/](http://dels.nas.edu/animal_pain/).

## IBC

#### What are the *NIH Guidelines*?

The *NIH Guidelines (NIH Guidelines for Research Involving Recombinant DNA Molecules)* detail safety practices and containment procedures for basic and clinical research involving recombinant DNA, including the creation and use of organisms and viruses containing recombinant DNA. The *NIH Guidelines* are a “living” document that was first drafted in 1976 as an outcome of a meeting of scientists concerned about addressing the potential public health and environmental risks associated with this developing technology. Since that time, the *NIH Guidelines* have been frequently amended to reflect evolving scientific understanding of recombinant DNA

and its applications and may be amended again in the near future.

#### When Must Institutions Follow the *NIH Guidelines*?

An institution must follow the *NIH Guidelines* if it receives any funding from the NIH for recombinant DNA research. Even if only one project of recombinant DNA research benefits from NIH support, all such projects conducted at or sponsored by that institution must comply with the *NIH Guidelines*.

Also, adherence to the *NIH Guidelines* may be a condition of support from other federal agencies or even private funders of research. Finally, regardless of NIH funding, institutions may be subject to local ordinances, federal or state regulations, or agency guidelines that require compliance with the *NIH Guidelines*.

“An institution must follow the *NIH Guidelines* if it receives any funding from the NIH for recombinant DNA research.”

#### Why Must Institutions Comply with the *NIH Guidelines*?

Compliance with the *NIH Guidelines* is important because it promotes the safe conduct of research

**IBC** continued

involving recombinant DNA. Also, compliance with the *NIH Guidelines* is mandatory as a condition of receiving NIH funding. Institutions that fail to comply: (1) risk suspension, limitation or termination of financial assistance [for non-compliant NIH projects or for other recombinant DNA research with NIH funding] or (2) risk having to obtain prior NIH approval for any recombinant DNA projects.

Many institutions that do not receive any NIH funding for recombinant DNA research nonetheless

choose voluntarily to comply. These institutions recognize that following the *NIH Guidelines* promotes the safe and responsible practice of this research and gives the public confidence that the institution is attending to important safety matters.

From the OBA (Office of Biotechnology Activities) website:

[http://oba.od.nih.gov/oba/ibc/FAQs/IBC\\_Frequently\\_Asked\\_Questions7.24.09.pdf](http://oba.od.nih.gov/oba/ibc/FAQs/IBC_Frequently_Asked_Questions7.24.09.pdf)

---

**IRB****Conducting Research on Disease Outbreaks or Natural Disasters**

If you're interested in conducting research on disease outbreaks or natural disasters, you know that time is of the essence when a researchable event occurs. The CU IRB is committed to helping researchers get IRB approvals for such research as quickly as possible so they can get into the field and begin collecting data.

We offer two tools that can be especially helpful when you need to begin conducting research before an ephemeral research opportunity evaporates.

(1) **Umbrella Protocols**: Although each event that develops will have its own specific logistical challenges and research issues, it's likely that the broad strokes of the research protocols for all such situations will be very similar. Therefore, if you would like to conduct research on disease outbreaks or natural disasters, we encourage you to take the time now, before any specific research opportunity appears, to formulate and submit an umbrella protocol. This protocol can be based on your likeliest research methods and should include drafts of each document you might want to use (e.g., informed consent document, interview protocol, survey).

When a particular situation arises that fits your research agenda, you will only need to submit an amendment to your existing, approved protocol. This revision will allow you to make sure the approved research plan, data collection tools, and informed consent documents are appropriate to the details of the

**Reminder:**

*Starting October 1, 2009, researchers must submit IRB applications on the new forms. As before, researchers are encouraged to submit their applications electronically to our staff IRB account at [irb@clemson.edu](mailto:irb@clemson.edu).*

situation at hand. In this way, approval for a specific project should be obtainable within a matter of days.

(2) **Collaborative Agreements**: The CU IRB also has blanket agreements with IRBs at other South Carolina institutions to facilitate cooperative research or research by CU investigators at these other institutions. Since these agreements are already in place, arrangements for IRB review don't have to be negotiated anew with each new research study proposed.

The largest of the existing agreements is among the members of the Health Sciences South Carolina collaborative (Clemson University, Greenville Hospital System (GHS), Medical University of South Carolina, Palmetto Health, Spartanburg Regional Healthcare

System, and University of South Carolina). The IRBs of each of these organizations have agreed to accept each others' IRB reviews, with details about funding, participants, and research locations being used to determine which IRB will take the lead on any particular study.

The CU IRB also has an agreement with the Oconee Medical Center (OMC). When CU researchers conduct social / behavioral / educational research at OMC, the CU IRB will be the designated IRB-of-record for these protocols. All biomedical research conducted at OMC is reviewed by the IRBs at GHS.

AnMed Health is another local healthcare system that

the CU IRB has an agreement with. When CU-affiliated investigators conduct research at AnMed Health, the CU IRB will accept the review conducted by the AnMed IRB.

Please note that the CU IRB does require that protocols being reviewed by other IRBs be submitted to the CU IRB as well. The CU IRB conducts very brief administrative reviews of these protocols and keeps them on file in case of questions about research being conducted by CU personnel.

If you would like assistance in creating an umbrella protocol or if you have any further questions, please contact the IRB Administrator, [Laura Moll](#), at 656-6460.

---

## Research Integrity

### Discussion-based RCR Training Opportunities

The Brown Bag Seminar Series is an opportunity for the CU community to better understand research integrity and research compliance related topics. Please make plans to bring your lunch and join us on the first Thursday of each month.

**October 1, 2009**

*Scientific Misconduct*

Presenter: Dr. Julia Frugoli, Associate Professor  
Department of Genetics and Biochemistry

**November 5, 2009**

*Authorship and Collaboration*

Presenter: Dr. Julia Frugoli, Associate Professor  
Department of Genetics and Biochemistry

**January 14, 2010**

*The Care and Feeding of Your IRB Application*  
Presenters: Dr. Hugh Spitler and Ms. Laura Moll

**February 4, 2010**

Topic - TBA

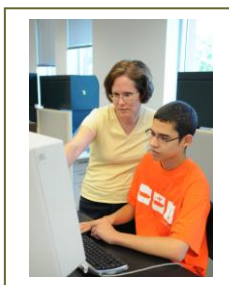
**March 4, 2010**

Topic - TBA

**April 1, 2010**

Topic - TBA

These sessions will be held at noon  
in the Student Senate Chambers.



---

The Office of Research Compliance (ORC) promotes a culture of compliance, research integrity, and high quality research within the University community. This is accomplished through consultation and educational programs for all researchers. The ORC facilitates University research, teaching, and public service programs by providing oversight and coordination of research compliance areas involving human subjects, vertebrate animals, recombinant DNA, hazardous agents and research misconduct.

---

<http://www.clemson.edu/research/compliance/>

---

---

## CONTACTS

Tracy Arwood  
Director  
Research Integrity Officer  
(864) 656-1525  
[tarwood@clemson.edu](mailto:tarwood@clemson.edu)

Bridget Owens  
IACUC Program Assistant  
(864) 656-1526  
[bridgeo@clemson.edu](mailto:bridgeo@clemson.edu)

Belinda G. Witko  
IRB Assistant  
(864) 656-3918  
[bwitko@clemson.edu](mailto:bwitko@clemson.edu)

Marlene Ventura  
Assistant Director/  
IBC Administrator  
(864) 656-0118  
[ventura@clemson.edu](mailto:ventura@clemson.edu)

Laura Moll  
IRB Administrator  
(864) 656-6460  
[lmoll@clemson.edu](mailto:lmoll@clemson.edu)

Daniel Harris  
IT Coordinator  
(864) 656-1450  
[dharr2@clemson.edu](mailto:dharr2@clemson.edu)

Kathy Bryant  
IACUC Administrator  
(864) 656-4538  
[kbrynt@clemson.edu](mailto:kbrynt@clemson.edu)

Rebecca Alley  
IRB Coordinator  
(864) 656-0636  
[ralley@clemson.edu](mailto:ralley@clemson.edu)

Cathy Welton  
Admin. Coordinator  
(864) 656-1525  
[jwelton@clemson.edu](mailto:jwelton@clemson.edu)