**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**

**Changes in Personnel**
Rebecca Alley has accepted a position with General Counsel’s office and is currently working in the Office of the Vice President for Research and Economic Development. Best wishes to Rebecca in her new position.

We are happy to welcome the newest member of our IRB team, Nalinee Patin.

**What’s in a Name??**
When a protocol is submitted to the IACUC, IBC or IRB, a part of the review process is checking required training for all research personnel. The name listed on the protocol for a research team member is the name used to check the training. If the name on the protocol does not match the name used when the training was completed, the ORC staff cannot verify training. The Principal Investigator (PI) is then notified that the application cannot be approved until this research team member has completed training.

To avoid preventable delays, please give as much information about research team member names as possible, so we will be able to check under different names. For example, Elizabeth Brown is a research team member but her training may have been completed under her maiden name of Elizabeth Doe, or she may go by the nickname, Beth, or her middle name, Jane. Please list her as Elizabeth (Beth) Jane Brown (Doe). That will alert us that her training may be listed under Elizabeth Doe, Beth Doe, Jane Doe, E. Jane Doe, or any of these name combinations with the surname Brown.

Please remember that required training expires after a period set by the corresponding compliance committee and all research team members are required to keep their training current.

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**Brown Bag Seminar Series Continues**
The ORC continues the Brown Bag Series this semester. The Brown Bag Seminars are an opportunity for the CU community to better understand research integrity and research compliance related topics. All members of the university community are invited to bring a lunch and join these sessions, held at noon in the Student Senate Chambers, 5th level of the Edgar Brown University Union.

**February 4**  
*Intellectual Property Rights and Responsibilities*, presenters  
Dr. Caron St. John and Ms. Vincie Albritton

**March 4**  
*The Importance of Mentoring*, presenter  
Dr. Sangeeta Panicker, Director of Research Ethics, APA

**April 1**  
*Identifying and Managing Conflicts of Interest*, presenter  
Dr. Gautam Bhattacharyya

If you have any questions, contact Tracy Arwood, 864-656-1525. For more information, visit the web at:  
http://www.clemson.edu/research/compliance/integrity/
Clemson University Biomedical Institute (CUBI)
In October of 2009, the Greenville Hospital System’s (GHS) Oncology Institute was renamed the Clemson University’s Biomedical Institute (CUBI) in the Biological Sciences Department. Thomas Wagner, Ph.D. is the Director and Xianzhong Yu, Ph.D., Yanzhang Wei, Ph.D. and Wen Chen, Ph.D. are Clemson faculty members and research investigators. The animal facility located at GHS remains at GHS, but transitioned to oversight by the animal care and use program at CU and is now known as the CU Transgenic Facility (CUTF).

New Edition of Guide for the Care and Use of Agricultural Animals Used in Teaching and Research
The third edition of the Guide for the Care and Use of Agricultural Animals Used in Teaching and Research was released in January. It is also known as the Ag Guide or FASS Ag Guide.

The new guide can be downloaded at no cost from: http://www.fass.org/page.asp?pageID=216. This publication will be used as a guide for evaluation of the agricultural facilities during their site visits. This edition expands on information on some topics that were covered incompletely in past editions due in large part to a developing literature. With more information now available on environment enrichment and handling and transport, these topics now have dedicated chapters. In addition, new information is included on biosecurity and genetically engineered and cloned farm animals. The US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training are endorsed in this guide as a basis for professional judgments about the appropriate treatment and use of agricultural animals in research and teaching activities. These judgments can be validated by third-party peer review, such as that provided by accreditation through the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Clarification of Signature Requirements
When a Principal Investigator (PI) is also the Department Chair/Head the IACUC requires that the PI obtain the signature of their direct supervisor in place of the Department Head/Chair’s signature on the cover page of the protocol. The animal use form is being revised to indicate the signature should be that of the direct supervisor.

Office of Biotechnology Assessment (OBA) Updates NIH Guidelines for Research Involving Recombinant DNA Molecules
National Level

The revised guidelines are preceded by a summary of the amendments/corrections/updates made since 2001. The amendments to Section III-D-7, Appendix B, and Appendix G-II-C, which were published in the Federal Register on September 22, 2009 (74 FR 48275) and became effective on that date, clarify and augment the current biosafety guidance for research with potentially pandemic influenza viruses, and harmonize with the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (5th edition) and other regulatory policies.

Section III-D-7 provides guidance regarding the biosafety level containment for research with influenza viruses generated by recombinant methods. In Appendix B, the potentially pandemic influenza viruses human H2N2 (1957-1968), 1918 H1N1, and HPAI H5N1 are classified as Risk Group 3 agents. Appendix G-II-C-5 provides additional biosafety guidance for research with these influenza viruses including Biosafety Level 3 enhanced containment, practices and training, animal containment and occupational health.

Local Level
The NIH Guidelines outline the procedures for reviewing recombinant DNA research. This review at the local level determines if the research work is considered to be “exempt from the NIH Guidelines”. If it does not meet exempt criteria as outlined by NIH-OBA then the project is reviewed at “Full Committee”. The IBC meets monthly and the 2010 calendar for meeting dates is now on the IBC website. Even if an
application appears to meet the exempt criteria as outlined in the NIH Guidelines, an IBC application needs to be submitted to the CU IBC so that the research work can be registered and the exempt status as noted by the PI can be confirmed by the IBC Chair or designee. Any protocol that qualifies as exempt is reported to the convened IBC at the next regularly scheduled meeting. So that there is not any interruption in approval of recombinant DNA research or lack of approval prior to external funding, an application should be submitted as far in advance as possible because it may be necessary to have the Full Committee review it.

**OSHA Mandate for Annual BBP Training**

OSHA mandates that individuals working with human material and other potentially infectious material take Bloodborne Pathogens (BBP) training annually. This includes work with human body fluids, any unfixed tissue or organ (other than intact skin) from a human (living and dead), cell lines and HIV containing cell or tissue culture or other tissues from experimental animals infected with HIV or HBV. Online BBP training is available on the EHS website. For IBC protocols that have work with material that comes under the BBP Standard, at the time of continuing review, EHS is contacted to verify that members of the research team have taken BBP training within the last 12 months.

**Form Changes**

The IBC is in the process of updating its IBC application. It is anticipated that it should be available on the website by early February. Changes are being made to Section A and a minor change to Section B.

**Updated EHS Chemical Hygiene Plan**

EHS has updated their Chemical Hygiene Plan. Copies can be obtained from the EHS website and should be in the laboratory areas and referenced in the IBC application when submitting new applications.

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**IRB**

**When Are Human Subjects No Longer Human Subjects?**

Do you have an IRB protocol that has been active for years and years simply because you are still analyzing data or might still wish to analyze them in the future? If yes, it may not be necessary to keep this protocol open.

The federal regulations governing research with human subjects apply to the collection of data from humans through interaction or intervention or to the use of identifiable private information. Therefore, once you have collected your data, if there is no way to identify the participants from whom the data were collected, you are no longer conducting research involving human subjects.

How does this work on the ground? Say you conducted an anonymous survey, collecting data from individuals through interaction. This was clearly human subjects research when the data were collected, but once data collection is complete, this study no longer falls under the purview of the IRB. This is because there is no further interaction with participants and you have no identifiable private information about those participants.

But what if you collected your data with personal identifiers because you needed to follow up with your participants? A good way to protect the confidentiality of participants when you are collecting names or other identifiers is to code your data, maintaining only one master list that gives the links between individual identities and the data collected about each participant. Once all data have been collected, you may wish to destroy your master list, since you may not need to know the identities of the individuals from whom you collected data. Destroying the master list provides much better protection of your participants, and means you are no longer working with data involving human subjects, because you no longer have identifiable private information.

In cases like these and many others, you may be eligible to close your active IRB protocols. If you would like to get more information about this or would like to discuss the specifics of your research data, please do not hesitate to contact Laura Moll, IRB Administrator, at 864-656-6460.
Clemson University RCR Training Program

Beginning with proposals submitted on or after January 4, 2010, in accordance with NSF requirements, all undergraduate students, graduate students, and postdoctoral researchers "who will be supported by National Science Foundation (NSF) to conduct research" must receive training in the Responsible Conduct of Research (RCR).

RCR is comprised of nine topic areas:
- Acquisition, Management, Sharing and Ownership of Data
- Animal Welfare
- Authorship/Plagiarism
- Collaboration
- Conflict of Interest
- Human Subject Protections
- Mentoring
- Peer Review
- Research Misconduct

The CU RCR training program includes both interdisciplinary general and program-specific RCR content. The phased program is intended to provide quality training experiences while offering flexibility for the learner.

1. Basic training: Undergraduate and Graduate Students and Postdoctoral Researchers supported by NSF awards will be required to complete an online RCR training program provided by the Collaborative Institutional Training Initiative (CITI). The CU Office for Research Compliance (ORC) will provide the conduit to this training via the ORC website (http://www.clemson.edu/research/compliance/integrity.html).

   This requirement must be completed within the first 12 months of employment/support on the award (or earlier, at the discretion of the PI).

   All students and postdoctoral researchers employed on an NSF award must complete basic training even if employed less than 12 months.

   Documentation of completion of basic training will be maintained by the ORC. Additionally, a completion certificate is available for printing via CITI. The student/postdoctoral researcher and the PI should maintain a copy of this certificate. The PI should attach this documentation to the RCR training documentation form he/she keeps on each student/postdoctoral researcher.

2. Advanced training: Undergraduate and Graduate Students and Postdoctoral Researchers supported by NSF awards will also be required to engage in an additional five contact hours of discussion-based RCR training. These discussions will encompass both general and discipline-specific material. The five contact hours may include a variety of activities determined by the PI to be effective and engaging. The 5 hours must include more than one topic area. Custom-designed workshops, forums, and classes, or existing classes and seminars offered by the college or department, and/or participation in external offerings may all be included. Plans may include encouragement to attend some of the RCR programs offered through the ORC, such as Research Integrity Brownbag discussions, RCR Workshops, Survival Skills and Ethics Workshops, and IRB or IACUC Training Programs. For an existing course or program to be suitable for fulfilling one of the training requirements, the PI must document that relevant topics from the above list are covered in the course/program.

   This requirement must be completed in the first 24 months of support/employment on the award.

   Documentation of completion of advanced training must be maintained by the student/postdoctoral researcher and the PI (on the RCR training documentation form) and provided to the University and/or the funding agency upon request. This component will be implemented by PIs with the assistance of their college and department in a way that meets the particular needs of each unit.

Resources

The Office of Research Compliance will provide the following resources to support the program and its implementation by the PI.
- Training opportunities for faculty involved in teaching RCR
- ORC-sponsored RCR workshops to complement college and departmental offerings
- Individualized consultation and advice
- Online resources:
  - Access to the CITI program and a list of upcoming RCR offerings available on campus http://www.clemson.edu/research/compliance/integrity/training.html
  - Teaching resources, such as slide shows and case studies, for RCR education http://www.clemson.edu/research/compliance/integrity/resources.html
Frequently Asked Questions:
1. Q: If a student works on my grant for less than 12 months, does he/she need to complete the basic RCR training? A: Yes. All NSF-supported students and postdocs must complete basic RCR training.
2. Q: Does this plan need to be included with my proposal? A: No. The institutional RCR plan (section 7009) is part of the institutional assurance and does not need to be included in the text of your proposal. However, a mentoring plan (section 7008) is required if you request support for a postdoc.
3. Q: Is this the same training required for IACUC, IRB or IBC applications? A: No. While animal welfare and human subjects protections are RCR topics, the online IRB and IACUC training modules do not meet the requirement for discussion-based contact hours.
4. Q: Can training sessions/courses taken last year be applied to these requirements? A: This decision will be left to the discretion of the PI. If the PI believes the session is recent enough and relevant enough to meet the requirement, they should simply document it on the RCR training documentation form. CU will not define a training expiration period at this time. Again, this will be a decision left to the discretion of the PI.
5. Q: Are my summer REU students required to complete the RCR training? A: Based on the most recent REU information, NSF considers these students "supported" by NSF to conduct research. Therefore, they must complete the relevant phase(s) of the training program.

NIH Update on the Requirement for Instruction in the RCR
The NIH has issued an update on the requirement for instruction in the responsible conduct of research. To access this update go to: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html.

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/

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