Greetings from the Office of Research Compliance and Assurance. We hope that your year has kicked off to a good start. As the University is charged with the responsibility of ensuring that all its employees and students comply with research compliance rules, a set of FAQs were developed by staff members in Research Compliance to aide in facilitating protocol submissions, training, and compliance with University and federal regulations germane to human subjects, animal care and use, biological hazards, export controls, conflicts of interest and conflicts of commitment, research misconduct, and the responsible conduct of research. It is hoped that use of these FAQs will help you pave your way in the right direction. This document is posted on the main homepage located on the Research Compliance website at: http://www.southalabama.edu/researchcompliance/index.html

Research compliance is vastly integrated into teaching, research, and health care components through combined efforts of administrative offices, regulatory review committees, and institutional leadership. The Office of Research Compliance and Assurance is available to assist you with training, policies, procedures or problem-solving to support you in your research activities.

**Navigating the IRB Process**

Want to learn more about human subject’s protection or need help navigating the IRB application process? The Office of Research Compliance and Assurance is available upon request to present an overview for students or staff.

Forward requests or questions to Dusty Layton at dlayton@usouthal.edu or 460-6625.
Animal Research Involving Domestic and Foreign Subcontracts

When submitting a new grant application involving animal work you should be cognizant of certain regulations that apply to activities performed at another domestic or foreign institution.

OLAW states: “When the grantee is a domestic institution (i.e., domestic grant with a foreign component), PHS animal welfare requirements are applicable. Accordingly, the grantee remains responsible for animal activity conducted at a foreign site and must provide verification of IACUC approval. That approval certifies that the activity, as conducted at the foreign performance site, is acceptable to the grantee. The grantee IACUC may accept, as its own, the approval of a foreign entity’s IACUC; however, the grantee IACUC remains responsible for the review. Additionally, the foreign entity must complete the Animal Welfare Assurance for Foreign Institutions available from OLAW.”

Domestic and foreign institutions with assurances on file are listed on the OLAW website.

In order to facilitate compliance, the Institutional Animal Care and Use Committee (IACUC) has adopted a new policy entitled, “Domestic and Foreign Subcontracts/Subawards” that provides instructions to investigators initiating a subcontract/subaward. The policy outlines the relevant documentation needed to comply with federal and University requirements. The IACUC will review and verify the submitted documents (administratively for domestic subcontracts and by full committee for foreign subcontracts). Post-review, the IACUC will provide the USA PI with a letter certifying review and acceptance of the subcontracted animal work.

Contact Shaun Kaulfers at skaulfers@usouthal.edu if you have any additional questions about these processes.

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Just-in-Time (JIT) procedures

As many of you are aware, NIH utilizes JIT procedures for certain programs and award mechanisms. Thus, this procedure allows certain components of a grant application to be submitted later in the application process once the review is complete and the application is under the consideration for funding. JIT procedures have been developed to aide faculty and staff during this process. The procedures and forms can be found on the Office of Health Systems and Grants Administration’s web site, go to: www.southalabama.edu/hsgrants/jit.html

Furthermore, when JIT information is requested by NIH and the application includes a domestic or foreign performance site for work involving animals, the Investigator will need to follow the new Domestic and Foreign Subcontract/Subaward Policy adopted by the IACUC and obtain the appropriate documentation to facilitate review.
First Successful Prosecution of University Related Export Control Violation Upheld

On January 5, 2011 the United States Department of Justice released that the U.S. Court of Appeals Sixth Circuit upheld the conviction of Dr. John Reece Roth of Knoxville, Tennessee. Dr. Roth was formerly an emeritus professor of electrical engineering at the University of Tennessee at Knoxville. He had been awarded a sub-contract working with technologies on un-manned drones for the U.S. Air Force. The contract prohibited the release of information associated with the work and the hiring of any foreign national. According to the DOJ, “During the course of that contract he allowed two foreign national students to access export controlled data and equipment, and exported some of the data from the contract on a trip to China. The Arms Export Control Act prohibits the export of defense-related materials, including the technical data, to a foreign national or a foreign nation.”

The crux of this case, and therefore the reason for the successful prosecution, was how doggedly Dr. Roth refused to accept that what he was doing was wrong. Innately he felt that the regulations were not justified and did not enable him to do what he wished to do. There is an inherent culture of free discourse in academia that can come in to conflict with federal law once international parties come in to play. Simply thinking that the laws are burdensome does not mean they do not apply to you. Dr. Roth was told multiple times that what he was doing was wrong, but refused to modify his behavior. The University ended up informing the FBI of Dr. Roth’s actions and escaped the consequences that might normally have been levied on the institution had the authorities discovered the issue on their own.

It just re-iterates the importance of education AND compliance when it comes to Federal Export Control laws. They are complicated, difficult to work with, and frustrating to researchers. However, they are the law of the land and there is no excuse for ignoring them.

Dr. Roth was sentenced to 48 months in prison and a host of fines. The DOJ announcement can be found here: http://www.justice.gov/usao/tne/news/2011/January/010511%20Roth%20Appeal%20Upheld.html

Interested to learn more? The Office of Research Compliance is holding a seminar on the “Basics of Export Controls” on April 28 from 10-11:30 am in the College of Medicine Conference Room. You can register for the event here: https://jagmail.usouthal.edu/cgi-bin/CA/seminar/semrca.cgi
Pathogenic Pfun with PATRIC

For those of you that teach or conduct research with pathogenic bacteria, there is a tool available called PATRIC (Pathosystems Resource Integration System). Developed with funds from the National Institute of Allergy and Infectious Diseases, it is supported by the Virginia Bioinformatics Institute out of Blacksburg, VA.

The site has a wealth of information on various pathogenic bacteria in a searchable and easy to use format. Basic information is provided along with diseases associated with infection and excellent graphic images. There is a watch list of organisms, as well as, a collection of the most searched for items. You can even “like” it on Facebook. What’s not to love?

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Training for New Biohazardous Waste Disposal Procedures

Beginning in March the Office of Research Compliance and Assurance will be implementing new procedures for all those who generate biohazardous waste on USA campus. New sharps containers will be arriving to replace the current "bucket" system. Representatives from Stericycle, our medical waste provider, will be on campus March 3 and 4 to provide in-service training on the sharps management program. Your attendance at one of the sessions listed below is MANDATORY if you are a PI or key personnel on a protocol approved by the Institutional Biosafety Committee.

Registration is not necessary; however, a sign-in sheet will be used to document training.

**Thursday, March 3, 2011**
College of Medicine Conference Room:
Three sessions offered -
1:15 pm
2:15 pm
3:15 pm

**Friday, March 4, 2011**
Main Campus Library, Room 181:
Three sessions offered -
9:00 am
10:00 am
11:00 am

Please direct questions to Alison Henry
460-6509 or ahenry@usouthal.edu.
IRB Review and Federally Funded Research

Be aware that granting agencies require IRB review of parts of the grant application applicable to the use of human subjects to ensure consistency between the activities approved by the IRB and activities described within the proposed application. Some agencies may further require additional tasks of the IRB before funds can be accepted by the University. The requirements are different between granting agencies, thus specific information as to what the IRB may need should be provided for within the sponsor guidelines. It is important that the investigator inform the IRB early in the process of possible funding and to facilitate submission of an IRB application for prior review and approval of receiving the notice of grant award.

IRB Submission Tips:

- Missing data: Forms must be complete and have all appropriate signatures. Applications are reviewed by the IRB administrative staff to determine the appropriate level of review and to confirm the required supplemental documents (i.e., consent, recruitment material, survey instruments, letter of support, etc.) is attached.

- Informed consent deficiencies: Consent documents must be sufficiently detailed to allow potential subjects to make informed, voluntary decisions about study participation, provided in a language that is non-technical and considering readability by targeting an 8th grade reading level. In particular, for exempt studies where there is no risk involved and the IRB grants waiving signed consent an information sheet may be used as provided by the IRB in template format.

- Training documentation: With the exception of secondary data collection and analysis, all researchers must complete the required human subjects training. Additionally, HIPAA in research training may be required if the researcher is collecting protected health information from a USA covered entity such as USA hospitals and clinics and the Mitchell Cancer Institute.

- Investigator-initiated studies: For clinical research activities, it is imperative that the IRB be provided with a comprehensive protocol, including data collection form(s) and statistical analysis plan.

RCR Resource:

Online Learning Tool for Research Integrity and Image Processing
by University of Alabama Birmingham

This site explains what is appropriate in image processing in science and what isn’t. Additionally, this tool shows how best practices in handling images intersect with other best practices. This online tool is tailored for students and faculty to help use and encourage best practices for promoting research integrity in their work groups. For access go to: http://ori.dhhs.gov/education/products/RiandImages/default.html
* * * **Noteworthy News** * * *

**Feature: Thinking responsibly: The ethics of global health research, The Wellcome Trust, Feb 1, 2011**

"The growth of international scientific research, including global collaborations, raises important new ethical issues. How can you ensure that the people taking part in studies aren’t exploited? Should data be shared? How can the interests of all groups involved be represented? Chrissie Giles meets two ethicists - newly qualified PhD Lainumbi Mbaabu from Kenya and his UK supervisor Professor Michael Parker - who have been working together to explore these issues..."

**The Lab: Avoiding Research Misconduct, Interactive Movie on Research Misconduct, US Office of Research Integrity (ORI), Feb 2011**

"In "The Lab: Avoiding Research Misconduct," you become the lead characters in an interactive movie and make decisions about integrity in research that can have long-term consequences. The simulation addresses Responsible Conduct of Research topics such as avoiding research misconduct, mentorship responsibilities, handling of data, responsible authorship, and questionable research practices..."

**Returning the Blessings of an Immortal Life, New York Times, Feb 4, 2011 (free one time registration required)**

"If there was one thing Rebecca Skloot was certain of when writing “The Immortal Life of Henrietta Lacks,” it was that she did not want to profit from the Lacks family without giving something in return..."

**2010 Year in Review: Stem cell research, CNN Health, Dec 30, 2010**

"From the start, 2010 was a fascinating year for stem cell research..."


Newsletter archives are posted on the Office of Research Compliance website at: [http://www.southalabama.edu/com/research/](http://www.southalabama.edu/com/research/)