Research Compliance Functions and Customer Survey

The Office of Research Compliance and Assurance is committed to helping faculty, staff, and students facilitate compliance with all applicable federal, state and institutional requirements. Activities covered by the office for which resources are available to support and guide the research community include human subject’s protections, animal welfare, biosafety, export controls, conflicts of interest, and research misconduct.

As many of you are aware, the past few months have brought significant changes to the way the Office of Research Compliance and Assurance conducts business in the administration of processing IRB, IACUC and IBC research protocols. Times of transition can be challenging, but our overarching goal is to streamline our processes and appreciate the patience while the regulatory committees transition to a paperless, online process.

The Office of Research Compliance would appreciate your feedback on our Customer Satisfaction Survey to assist in our continuing efforts to improve quality and delivery of services. All responses are confidential. Please click on the following link to proceed.

http://www.surveymonkey.com/s/ORW3NH7

IRBNet News

The transition from paper to digital protocol management has been a huge change in the manner by which our oversight committees operate. This change has allowed for both improvements in transparency and instant access to status information for Investigators and committee members.

In an effort to ease this transition we have developed a series of short one page directions on the various tasks which both Investigators and committee members may need to perform. This can be found at the web address below. If you desire a topic which is not already prepared please let us know. The information sheets are located at:

http://www.southalabama.edu/researchcompliance/irbnethelp.html
When can IRB projects be closed and no longer require continuing review?

The DHSS Office of Human Research Protections (OHRP) considers a research project to continue to involve human subjects as long as the investigators conducting the research continue to obtain:

- Data about the subjects of the research through intervention or interaction with them; or
- Identifiable private information about the subjects of the research.

Therefore, a research project no longer involves human subjects once the investigator(s) have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the IRB-approved protocol are complete, the research project no longer requires continuing review. Furthermore, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further continuing review is necessary. At such time, the investigator can submit a final report form to the IRB to close out the study. This form is located in IRBNet in “forms and templates”.

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Employees Obtain Certification

Congratulations to Ms. SuzAnne Robbins, IRB Compliance Specialist, for passing the Certified Institutional Review Board Professional (CIP) examination. This is a rigorous examination that requires broad knowledge in the field of human subject’s research administration. Additionally, Ms. Dusty Layton, Director, Research Compliance, passed the CIP examination and thus continues to retain her certification status. CIPs have the option to recertify by completing continuing education requirements. However, continuing education may only be used as a basis for recertification once in a six-year period, then certification must be sought by re-examination.

The CIP Certification program:

- Promote the ethical conduct of research by strengthening the professional administration of IRB
- Validate an individual’s professional experience and mastery of the body of knowledge determined by national experts to be essential to competent IRB administrative practices
- Demonstrate the credential holder’s high level of dedication to his/her profession
- Encourage personal growth and professional development
- Strengthen the respective professional by providing an established body of relevant knowledge and national standards.
Research Compliance Prepares to Comply With New Public Health Service (PHS) Rules on Conflict of Interest Regulations

The Institution is working towards revising its Financial Conflict of Interest policy to comply with the new PHS rules on conflict of interest by August 24, 2012. Agencies within the Public Health Service follow:

- Department of Health and Human Services (HHS)
- Agency for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Federal Occupational Health (FOH)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

The Office of Research Compliance is partnering with the University Conflict of Interest Committee to formalize procedural changes need to comply with the new regulations. Some of the significant changes include, but not limited to:

- A new de minimis threshold ($5,000) for disclosure of significant financial interests. However, the University has a zero dollar threshold for which the more stringent disclosure requirements apply.
- A new significant financial interest category – all travel regardless of dollar threshold that is related to the investigator's institutional responsibilities that is reimbursed or sponsored by sources other than Federal, state, or local government agency, an U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education must be disclosed.
- Disclosure of financial conflict of interest details by investigator who transfers to USA from another institution at which the investigator had a financial conflict of interest on a PHS sponsored award.
- Required conflict of interest training prior to their engaging in PHS funded research, and thereafter every four years, or when an instance of non-compliance occurs, or when the Institution’s policy changes related to disclosure requirements.
- For USA subreceipts, in the absence of a sub-recipient having a PHS compliant policy, USA policy must flow down its policy; however, disclosure need only relate to the specific award in question.
- Failure of investigators to meet disclosure requirements or failure of Institutions to act timely on disclosures will require a retrospective review of the facts or determine if any research results were biased and, if so, what mitigation plan needs to be put in place.
- Financial conflict of interests must be reported to the PHS awarding component and must include a description of the significant financial interests, nature of the financial conflict of interest, and details of the management plan. All reports to the agency must be updated annually.
University’s Plan to Provide Financial Conflict of Interest Training

The PHS Conflict of Interest regulation requires that each investigator complete training prior to engaging in the research and subsequently every four years. The University’s Conflict of Interest Committee supported the recommendation made by the Office of Research Compliance to adapt the Conflict of Interest online training module offered by the Collaborative Institutional Training Initiative (CITI). As many of you are aware, the CITI Program is utilized by USA Research Compliance to ensure training is received by faculty, staff, and students engaged in a variety of regulated research activities. Individuals will receive an automatic notification upon completion of training and the program retains a log of all training documentation.

We will notify campus as soon as the training is available, as Investigators will be required to take the training by August 24, 2012 if actively engaged in a PHS project.

The Department of Health and Human Services has the new rule, FAQs and other relevant information posted at: http://grants.nih.gov/grants/policy/coi/

Universal Precautions

How careful are your basic lab practices? Of course, we all assume that those working in laboratories with bacteria, human cells, and other potentially bio-hazardous material are trained up front on what the proper PPE for an area might be and how/when to use it. All too often, though, we become complacent.

A recent study in the “Proceeding of the National Academy of Sciences” demonstrates how even the most careful of scientists can cause problems when careful is just not careful enough. Invasive, albeit hardy, species have begun to spring up in the barren, frigid wasteland of Antarctica. Plants normally only seen in places like South America have been discovered growing during the “warmer” part of the year. Invasive species pose a threat to several of the fragile ecosystems of the area. Is it global warming, or some ancient spore causing mischief? Nope, after questioning 5,600 visitors to the area and searching 853 pieces of baggage, it seems the people that had no intention of bringing along seeds are doing do on their very person. Many of the people are the very scientists that are arriving to protect and conduct research on preserving the area.

For more information read: http://www.pnas.org/content/early/2012/02/27/1119787109.full.pdf+html?sid=92e4c0c9-4a41-40be-9e76-8a4966e9b210

Now a seed is small, but much of what biomedical researchers work with every day can number in the thousands on the surface those same seeds. Though you cannot see them, researchers must always be aware of proper safety habits to keep from spreading “work” to themselves and others. This, of course, includes taking off your gloves when leaving the lab or switching between activities.

Social science: Open up online research, Nature, Dec. 7, 2011
"...Collecting public musings can create ethical dilemmas for researchers. The messages may be publicly available, but the individuals writing them might not realize just how public they are, and might be surprised when their words are preserved or placed in another context..."