



University of South Alabama
Research Compliance News

Research Compliance Updates: New Programs to Be Implemented

Export and Technology Controls:

Export controls have become a hot compliance topic over the last several years. Export Controls are US laws that regulate the distribution of controlled technology, information, equipment, software or services to foreign nationals and certain foreign countries. Information/technology that is publicly available, technology which is a result of fundamental research, technology that is educational or included in certain patent applications are not subject to the regulations. Researchers should also be aware of when collaborating with others from foreign countries or traveling abroad may be affected by the regulations. In particular, researchers are at the front line of export controls because they (1) control the scope of the research project, (2) make decisions about equipment or technology and to whom it may be transferred and (3) penalties for non-compliance are costly. More information and Frequently Asked Questions on this topic will soon be posted on the Office of Research Compliance website.

The Office of Research Compliance and Assurance is working towards development of a compliance plan and policies relevant to this topic. Training sessions will be initiated after implementation of this new policy. If you have an export question in the meantime, please contact Ms. Layton at 460-6625.

Responsible Conduct of Research: NSF Funding Requires RCR & Ethics Training

Responsible conduct of research is an ongoing process of reconciling regulations, guidelines, best practices and standards and ethics to promote integrity in proposing, planning, conducting, reporting and reviewing research.

Institutions receiving awards from the National Science Foundation (NSF) are required to provide training in the responsible conduct of research (RCR), survival skills, and research ethics under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act that was signed by President Bush on August 9, 2007.

The process is underway for RCR online instruction to be achieved through the Collaborative Institutional Training Initiative (CITI) program to meet this federal requirement. For more information on the COMPETES Act, go to <http://science.house.gov/>. The full article is available at http://ori.dhhs.gov/documents/newsletters/vol15_no4.pdf.

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Need help with compliance related issues?

The Office of Research Compliance and Assurance encourages individual or group meetings with your department or students. We want to hear from you with problems or questions... creating a dialogue is beneficial for both researchers and compliance operations

Education Practices to Be Strengthen

Human subjects training in the upcoming academic year aimed at strengthening our educational practices will include the:

- Continue annual workshops on topics specific to social science, behavioral and educational research practices.
- Ongoing classroom sessions for students are available by request. The IRB 101 for students covers the basics of human subject's research ethics, regulations and the IRB process. Email dlayton@usouthal.edu to schedule a session.
- Implement continuing education. Various training alternatives are currently being evaluated.
- Educational materials such as brochures are being developed for both the student investigator and researchers conducting clinical research.

Let us hear from you if you have any recommendations or specific requests for educational materials.

*** REVISED IRB FORMS ***

The IRB has revised the following forms: continuing review, amendment and a new final report form. The continuing review form should be submitted at least 30 days before the study expiration date. Please remember that if you are making any changes to your protocol and/or consent document during the continuation process, you will have to submit a request for approval of an amendment specifying all of the modifications to the consent and/or protocol.

All forms and applications should be downloaded directly from the human subject's website. Do not store copies of forms on your local machine. Using an expired or out-of-date form may delay a timely review of your IRB submission.



The Institutional Biosafety Committee and Annual Biosafety Inspections:

The overall purpose of the Institutional Biosafety Committee (IBC) is to ensure that the use of potentially biohazardous and recombinant DNA materials are used safely and responsibly, that these materials are used in well controlled areas and meet regulatory guidelines. This is achieved by requiring a registration form to be submitted and filed with the IBC to identify what, where, and how the materials will be used. The use of non-human primates, human cell lines, blood, and tissues, in addition to Select Agent materials require registration and approval. To further enhance employee safety and compliance with institutional and federal policies, the IBC conducts annual inspections. The 2007 inspections will be scheduled between Thursday, December 6th – Tuesday, December 11th. All researchers with IBC approved registrations will be notified in advance. The USA Biosafety Manual and Exposure Control Plan includes a copy of all biosafety level compliance checklists. A self-inspection is encouraged in advance of your scheduled IBC inspection in order to eliminate or minimize any cited deficiencies.

New Bloodborne Pathogen Training Materials

The OSHA's Bloodborne Pathogen (BBP) standard outlined in 29 CFR 1910.1030 details what employers must do to protect workers whose jobs put them at potential risks of coming into contact with blood and other potentially infectious materials. Workers exposed to these pathogens are at risk for illness, thus the standard requires employers to train employees on initial assignment, then at least annually thereafter. Additionally, employees must receive lab specific/specialized training to ensure proper handling and safety of biohazardous materials. The new training handout and post test materials are available on the Biosafety website at: <http://www.southalabama.edu/com/research/biosafety.shtml>

It is anticipated that an online method of training will be implemented in 2008. All new methods of biosafety training and practices will be evaluated and approved by the IBC. More in-depth information about BBPs is located on OSHA's website at: <http://www.osha.gov/SLTC/bloodbornepathogens> and on needlesticks at: <http://www.osha.gov/needlesticks>

Biosafety Amendment Form Now Implemented

An amendment form will be required to IBC registration(s) if any aspect of the research changes. A list of changes that would necessitate an amendment includes the following changes:

- | | |
|--------------------------------------------------|-----------------------------------------------------------------|
| * Project title | * Investigator/Status (<i>ie, name change, room location</i>) |
| * Research personnel (<i>removal/addition</i>) | * Procedures |
| * Addition of biohazardous agents | * Inclusion of animals |

The use of this form will provide researchers with specific information that is required for an adequate review of changes being proposed in the research project. Amendments are not to be implemented until approved by the IBC.

A copy of this new form is available at: <http://www.southalabama.edu/com/research/pdf/ibcamendmentform.pdf>



New Site for Animal Care and Use Training

All investigators and key personnel who participate in the conduct of animal use research must be appropriately trained. The IACUC Office is currently transitioning training and USA training data records to the **Collaborative Institutional Training Initiative (CITI)** web-based course site to satisfy this requirement for USA researchers.

To use this site, check with the IACUC Office to see if your records are able to be transferred or if or if you need to enter as a New User. When entering your email in the registration information, be sure to use a USA email account to ensure so that you receive notification of renewal. Select a "learner group" and view the list of modules required for each learner group. Complete the required modules and any associated quizzes. Training does not have to be completed in one sitting, and may take anywhere from 40 minutes to one hour per course.

Examples of selected courses:

Working with the IACUC Course – the basic course required for ALL researchers who plan to use laboratory animals or plan to supervise such work.

Researchers are also required to receive training for appropriate species-specific modules, i.e.,

- studies that involve mice
- studies that involve rats
- studies that involve frogs, or other amphibians.
- studies that involve rabbits
- studies that involve pigs

If you have questions about this site or are unsure of which training group to select, please contact the IACUC office at 460-6863 or email mdesv@usouthal.edu

Articles on Research Ethics / Links of Interest

- [New FDA drug center raises ethical questions, MSNBC, Oct 14, 2007](#)
"The Food and Drug Administration is moving with unprecedented speed to launch a drug research center to be paid for by companies it regulates...It's an ambitious undertaking that puts regulators and companies in a relationship unlike that of any other industry..."
- [The Food and Drug Administration's Oversight of Clinical Trials, US Dept Health and Human Services Office of the Inspector General, Sep 28, 2007](#) (pdf)
- [NIH genetic database "a good start", The Scientist, Sep 6, 2007](#)
"Researchers say the new NIH policy for sharing data from genome-wide association studies will increase interest in studies linking genotypes to diseases while securing the anonymity of study participants...Institutions will need new consent procedures to inform subjects that their genetic data will be available not just to the researchers conducting a study, but to other members of the scientific community who apply for access, and potentially to law enforcement officials and insurance companies..."
- [US Office of Research Integrity Newsletter, ORI, Sep 2007](#) (pdf)

Newsletter archives are available through the Office of Research Compliance website at:
<http://www.southalabama.edu/com/research/>