New Conflict of Interest Requirements for PHS Funded Researchers

New federal regulations governing financial conflicts of interest (FCOI) related to PHS-funded research went into effect on August 24, 2012. The new rules impact investigators funded by any entity comprising the PHS, including NIH and all of its centers and institutes. Additionally, the rules apply to investigators funded by the: American Cancer Society; American Heart Association; American Lung Association; Arthritis Foundation; Juvenile Diabetes Research Foundation; Lupus Alliance; Lupus Foundation of American; or the Susan G. Komen Foundation. The FCOI policy reflects new regulatory requirements to include expanded disclosure requirements and investigator training.

Each Investigator, defined as any person responsible for the design, conduct, or reporting of such research must disclose to his/her Supervisor any financial interest and those of his/her family members that reasonably appear to be related to institutional responsibilities (regardless of whether such financial interests are related to research). As described in the FCOI policy, investigators submitting proposals to a PHS agency or other sponsor that adopts PHS standards should be aware that disclosure of financial interests is required prior to proposal submission. The University Transmittal Form now incorporates a Financial Conflict of Interest Certification form to certify disclosure is on file at the time of grant application. Investigators who have a current disclosure form on file do not have to complete a separate disclosure for each grant application, unless a new financial interest is acquired or a change in an existing financial interest occurs.

The regulations have implemented consequences if there is failure to comply, for example, if an FCOI is not identified or managed in a timely manner. This includes failure by the Investigator to disclose, failure by the Institution to review or manage an FCOI, or not complying with the management plan. These circumstances may require the University to conduct a retrospective review of the Investigator’s activities and the research project to determine whether the research performed during the period of noncompliance was bias in the design, conduct, or reporting of such research.

Investigators receive FCOI training from the University prior to engaging in research at USA and at least every four years thereafter. USA facilitates training by use of the Collaborative Institutional Training Initiative (CITI) FCOI training modules. Once an individual has completed the CITI training, the trainee will receive an automated notification of completion of FCOI training and the program keeps a record of training documentation.

The University’s revised Financial Conflict of Interest policy provides the process for the disclosure of financial conflict of interests of Investigators, management/reporting of any Investigator financial conflicts of interest, public accessibility, and training requirements. For additional information please contact Dusty Layton for more information, 460-6625 or dlayton@southalabama.edu
Public Health Service (PHS) Financial Conflict of Interest Regulations: New Subrecipient Policy Confirmation

The University of South Alabama is responsible for ensuring compliance with the new PHS regulations by subrecipient institutions, as these regulations flow down to subrecipients on PHS awards. This new policy confirmation requires the Prime Awardee (USA) to confirm that the subrecipient institution has a PHS compliant financial conflict of interest policy before any subcontract or subaward is established. The Federal Demonstration Partnership (FDP) has developed a website so institutions can certify they are compliant with the new PHS regulations.

USA’s business processes require that for new and renewal proposals involving subrecipients for which the University submits to any PHS agency or designated non-PHS agency, the Principal Investigator shall check to see if the proposed subrecipient is listed on the FDP Clearinghouse designating a PHS compliant institutions at: http://sites.nationalacademies.org/PGA/fdp/PGA_070596. Subrecipient(s) designated on the FDP list will be provided on the University Transmittal sheet as outlined in the Conflict of Interest section and no further action is required. Any subrecipient(s) that is not listed in the FDP Clearinghouse will be required to submit a Subrecipient Financial Conflict of Interest Policy Commitment Form and Disclosure Form as part of the standard subrecipient package available at: http://www.southalabama.edu/researchcompliance/phsrepository.html. If the subrecipient organization(s) is not listed on the FDP they should be invited to sign on the Clearinghouse list provided they have a PHS compliant policy. If eligible, once the institution is posted on the Clearinghouse list the subrecipient should notify the USA Principal Investigator or departmental administrative contact.

The objective of the FDP Clearinghouse is to provide a quick mechanism for institutions to validate that a proposed subrecipient has a PHS compliant policy. The use of this tool reduces administrative burdens of submitting additional forms to verify they have an updated PHS financial conflict of interest policy.

UPDATE: Four additional non-PHS organizations have been added to the list of agencies that have adopted the PHS Financial Conflict of Interest Regulations

U.S. Public Health Services Agencies
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs
- Office of the Assistant Secretary for Health
- Office of the Assistant Secretary for Preparedness and Response
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Non-PHS organizations
- American Cancer Society
- American Heart Association
- American Lung Association
- Arthritis Foundation
- Juvenile Diabetes Research Foundation
- Lupus Alliance
- Lupus Foundation of America
- Susan G. Komen for the Cure

Completion of the annual conflict of interest disclosure form ensures PHS funded researchers and the Institution are compliant with federal regulations designed to safeguard objectivity in research. The PHS policy requires disclosure of all monetary financial or management interest in an outside company or other entity as it relates to your institutional responsibilities. The institution (i.e., designated official such as department chair or supervisor) determines if a PHS-funded investigator has a potential conflict of interest related to the PHS-funded research. If so, it should be determined if the disclosure is considered an actual conflict and if the financial interest could directly and significantly affect the design, conduct, or reporting of NIH-funded research. If yes, the financial interest must be reported to the federal granting agency by the Office of Research Compliance and Assurance.
**Guidance for Determining if a Financial Conflict of Interest Is Related to PHS-Funded Sponsored Projects**

To facilitate the disclosure of related financial interests, a guide has been developed to assist USA’s designated institutional official(s) (i.e., Department Chair or Supervisor) in determining if a financial conflict of interest is related to an Investigator’s PHS funded research and, if so related, whether it constitutes a financial conflict of interest. The “Guidance for Determining if a Financial Conflict of Interest is Related to PHS-Funded Sponsored Projects” is posted at: [http://www.southalabama.edu/researchcompliance/phscoirules.html](http://www.southalabama.edu/researchcompliance/phscoirules.html)

It is encouraged that designated officials delegated to review conflict of interest disclosure forms involve the Investigator in determining whether a financial interest is related to PHS-funded research activity. Ultimately, the Institution is responsible for determining if such financial interests related to PHS research could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. This method of review is applied for the disclosure, review, and assessment of all disclosed financial conflict of interests regardless of the funding source.

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**NIH NOTICE**

National Institutes of Health’s (NIH) Requires Prior Approval Request for Specified Changes Involving Human Subjects

The NIH has announced that certain changes to human subjects research pertaining to an awarded project will require “prior approval request” to the awarding component. As noted in NIH Notice: NOT-OD-12-129, an addition/change to the human subjects study design or protocol may be defined as:

- Going from non-human subjects research to human subjects research (exempt or non-exempt);
- Going from exempt to non-exempt human subjects research; or
- Going from "no clinical trial" to "includes a clinical trial".

Also, prior approval is required if any of the following situations occur during the project period:

- New inclusion of certain subject populations – pregnant women, human fetuses, and neonates, prisoners or children
- Any change to the study protocol that would result in an increase in risk to subjects; or
- Any new information that comes to light after a study is underway which indicates a higher risk level to participants than previously recognized.

To seek agency approval, a request must be endorsed by the Office of Health Systems Grants Administration or the University Office of Sponsored Programs. Furthermore, a change in scope triggers a peer review process. The changes listed above for human subjects studies may not be implemented until the agency has granted prior approval and the USA IRB has provided approval for the modification(s).
CLINICAL RESEARCH: New Required Data Elements for ClinicalTrials.gov

ClinicalTrials.gov has issued new requirements increasing the number of data elements to be submitted to the ClinicalTrials.gov website for trial registration. As of December 1, 2012 the following data elements will be required to post for new studies:

- Responsible Party
- Primary Completion Date
- At least one Primary Outcome Measure

Email Use with Human Subject Participants: Preventing Common Errors

Researchers are increasingly utilizing email in order to organize and oversee research activities. For example, email may be of value in facilitating study advertising/recruitment, managing study enrollment/participation arrangements, carrying out surveys/ interviews, follow-up with participants, and other similar tasks. Be remindful that the use of email can create unintentional disclosure of participant data to others, which violates confidentiality of the participants. Please remember to check your emails when routing to human subject participants to ensure you are using the bcc (blind copy) as the feature when sending emails to multiple individuals without disclosing names or email addresses of other study participants. If a breach in confidentiality occurs, please notify the IRB office.

Users that may experience difficulty in accessing the existing on-line HIPAA Research training tutorial should utilize the PDF training document available in IRBNet under “forms and templates” as an alternative. If the PDF version is used and all content has been covered a certificate of completion will be generated to serve as your record of training. The Office of Research Compliance and Assurance will be evaluating other training solutions for long-term use.
Material Data Safety Sheets for Infectious Substances

Pathogen Safety Data Sheets (PSDSs) (previously titled Material Safety Data Sheets for infectious substances) are technical documents that describe the hazardous properties of a human pathogen and recommendations for work involving these agents in a laboratory setting. These documents have been produced by the Public Health Agency of Canada as educational and informational resources for laboratory personnel working with these infectious substances. Many of the Pathogen Safety Data Sheets have recently been updated. The PSDS can be accessed at http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php. You may use this resource to complete a risk assessment which may be useful in completing the biohazard application for review by the Institutional Biosafety Committee.

Source: Public Health Agency of Canada

IACUC-Approved Protocols, Grant Applications Must Be ‘Congruent’

When submitting a grant application that proposes to conduct animal research, the grantee institution is required to attest to NIH that the research described in the proposal is congruent with any corresponding protocols approved by the institutional animal care and use committee (IACUC).

However, it is not necessary for the IACUC to review a grant application prior to submission. The PI simply must site either an existing protocol number(s) or utilize Just-In-Time procedures when allowed.

In Form 398 and SF424 applications, the PI must complete the Vertebrate Animal Section (VAS) which requires a detailed description of the proposed use of animals in the research. A template for the VAS section is available on the USA website, here.

Although the PI does not need to obtain IACUC approval prior to submission of the grant application to meet the congruence requirement, it is important for PI's to ensure that the description of the use of animals in the proposal corresponds to the protocol eventually submitted for IACUC approval. If an existing protocol is indicated in a proposal which is funded, the PI is expected to amend the respective protocol to include the new funding source.

The IACUC performs an evaluation for congruence between proposals and animal use protocols when PIs indicate that the protocol is funded via extramural funds. This applies to both new protocols and amendments which change funding source(s).

To access an NIH webinar on the congruence requirement, please visit http://grants.nih.gov/grants/olaw/news.htm#20120612
**TIPS & REMINDERS**

**Responsible Conduct of Research Training**

Responsible Conduct of Research or RCR training is required for all students and post-docs conducting research at USA as per institutional policy. Please view the following link for details: [http://www.usouthal.edu/researchcompliance/rcrtraining.html](http://www.usouthal.edu/researchcompliance/rcrtraining.html). At the graduate level, training may be completed via the Introduction to Research Methods course (IDL 577) or the RCR training module located at [www.citiprogram.org](http://www.citiprogram.org).

Importantly, as an ongoing extension of the America COMPETES Act, undergraduate, graduate, and postdoctoral researchers are **required** to have completed RCR training if they are working on NSF-funded research regardless of whether or not they are being fiscally compensated for their activities. As per, the September 2012 OIG Management Activities, “NSF is challenged to provide more oversight on institutional implementation of these (RCR program) requirements and provide meaningful guidance regarding Responsible Conduct of Research (RCR) training” (43).


**Dual Use Research of Concern**

In the interest of compliance with the NIH Office of Biotechnology Activities, the Institutional Biosafety Committee is adding a brief checklist regarding Dual Use Research of Concern (DURC) items to the IBC Application. Dual use research is that which has the potential to “be misused or threaten public health or national safety.” When reviewing protocol applications and amendments, the IBC will make the final determination if the principal investigator has any DURC. To learn more about DURC, review the following link: [http://oba.od.nih.gov/biosecurity/biosecurity.html](http://oba.od.nih.gov/biosecurity/biosecurity.html).

**NIH Exemption & IBC Oversight**

As per NIH Guidelines, determining whether or not an experiment is exempt is to the discretion of the principal investigator. PIs initially assess physical and biological containment levels for rDNA research for experiments, the guidance for which is indicated in Sections II and III and Appendices A, B, C, G, and I of the Guidelines. Exempt Experiments are covered in Section III-F. In cases falling under section III-A through III-E, Experiments Covered by the NIH Guidelines, the judgment to be reviewed and approved by the IBC as part of its responsibility to independently assess the containment levels required as per by the NIH Guidelines for the proposed research. Review areas of exemption at: [http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm).

**Exporting Information**

As Cloud Computing becomes a more attractive option for the transmission and storage of information, researchers should be mindful that Cloud Computing is not considered “secure” by Bureau of Industry Security (BIS) standards and is therefore subject to export control laws. If you think you have information or research that might be subject to export controls, contact the Assistant Director of Research Compliance, Amy Delcambre at 460-6509 or adelcambre@usouthal.edu before taking action. Also, keep in mind that transporting information that does not fall under the Fundamental Research Exemption (FRE) on computers, Smartphones, e-mail servers, or other devices could also be subject to export control laws. [http://www.usouthal.edu/researchcompliance/exportcontrol.html](http://www.usouthal.edu/researchcompliance/exportcontrol.html)
Welcome To Our Newest Member of Research Compliance

Amy Delcambre, Assistant Director, joined our staff in July, 2012. Amy joins us after four and a half years in sponsored programs administration and holds a professional certification in Research Administration. Amy manages the day-to-day operations of the Institutional Biosafety Program, Export Controls Program, and Responsible Conduct of Research Training programs as mandated by NSF and NIH.

* * * Items of Interest * * *

Former Penn State researcher sentenced to 3+ years in federal prison for grant fraud

A former Penn State University professor and researcher accused of grant fraud has been fined $660,000 and sentenced to nearly three and a half years in prison.

Source: Tech Transfer E-News, Wednesday December 12, 2012

NIH Director Francis Collins! He’ll be blogging at directorsblog.nih.gov, discussing science, medicine, and public health news, and sharing biomedical research discoveries that are, in his words, “game changers, noteworthy, or just plain cool”.

Source: Office of Extramural Research, NIH, Extramural Nexus, November, 2012.

Have a Question or a Comment?

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Questions or Suggestions?

We welcome your input and suggestions for future newsletter articles.

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