



A Review: Registration of Research Databases and Computer Applications Involving Human Subjects

Investigators may establish research databases involving protected health information (PHI) to be used in the conduct of a study or for use in future research. PHI is any information, including demographic information that is transmitted or maintained in any medium that is created or received by a health care provider, health plan or health care clearinghouse. As such, the establishment of a research database using electronic PHI (ePHI) in settings covered by the HIPAA privacy and security rules must be reviewed and approved by the Office of Research Compliance and Assurance as part of the IRB application process. Types of data protected by HIPAA include electronic databases/computer applications containing ePHI stored on a computer, PDA, memory card, USB drive, or other electronic media. The IRB is concerned with ensuring that the confidentiality of participant's research records is maintained whether it is paper and/or electronic storage.

Furthermore, the HIPAA Security Rule adopts national standards for administrative, technical, and physical safeguards to ensure the confidentiality, integrity, and availability of ePHI collected, maintained, used or transmitted by covered entities. The Security Rule requires covered entities to implement basic safeguards to protect ePHI from any unauthorized access, alteration, deletion and transmission. The investigator must provide and maintain database security, including physical security and access. They are also responsible for workstation security such as the following examples, computers are not visible by unauthorized individuals, workstations are adequately logged off before exiting the system, and setting a screensaver with password protection to start-up after a set time period of inactivity. It is crucial that all portable devices are adequately secured including hand-held, notebook, and laptop computers, PDA's, cell phones and thumb drives. Encryption must be used when transporting ePHI on any mobile computer device. Furthermore, email containing ePHI to addresses outside the GroupWise system must be encrypted. Although it is considered best practice that emails should not contain PHI, except within the USA GroupWise system.

The [Research Database Registration](#) form is used to track the use of such systems containing ePHI and addresses physical location, workstation use and security, transmission security and subject's authorization to add such information to a research database. Please note that the Office of Research Compliance and Assurance will continue to conduct its annual risk analysis to assess security risks and safeguards. In coordination with Thad Phillips, USA HIPAA Security Officer, a new component of this review will include a periodic physical/technical security review of research databases used for human subjects research. If you need additional information on this topic or have questions please contact Dusty Layton, dlayton@usouthal.edu

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Managing Research Protocols..... New Online System Forthcoming

The Office of Research Compliance and Assurance has plans to launch a new paperless, integrated web-based system for the submission, signing, tracking, review, and approval of information related to human subjects, animal care and use, and biosafety activities. An obvious advantage of an online system is that the compliance staff, approving officials, committee members, principal investigators, and clinical research study staff, can track and manage protocols electronically in real-time, thus increasing efficiency. Through this web-based system, protocols are centrally stored, organized, and available anytime of the day from any location with internet access. Investigators, clinical research study staff, and committee members can access and review a protocol's history throughout its life-cycle. Ultimately, this new process will facilitate committee meetings, allowing for meetings to be paperless, giving the reviewers convenient access to protocol information and history. More details to follow later this Summer, with implementation planned for early Fall.



NIH Prepares to Issue Significant Modifications to Conflict of Interest Regulations

The "Report on Research Compliance ", published by the by National Council of University Research Administrators and Atlantic Information Services, noted in the March 17, 2011 issue that the Office of Management and Budget (OMB) is reviewing NIH's final rule imposing new requirements for managing and reporting on financial conflicts of interest. Typically regulations are reviewed and released by the OMB within 90 days of this process, so we are staying tuned for more information. The proposed modifications to amend the current Conflict of Interest rules was issued in May, 2010 as a Notice of Proposed Rule Making in order to increase accountability, transparency, and strengthen public trust in the conduct of research using public funds. The federal regulations (45 CFR §46) require individuals who seek research funding from PHS or NSF to "ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research."

The proposed rule calls for significant changes to current conflict of interest regulations related to research activities. A brief highlight of some of the recommended changes includes:

- Investigators will be required to make an annual report of all financial interests related to their professional responsibilities.
- The investigator may not limit disclosure by making his or her own assessment of whether the outside activity relates to current research. The responsibility and authority to make that determination rests exclusively with the institution.
- Investigators is to receive training related to conflicts of interest
- All interests that the institution determines give rise to a conflict of interest must be disclosed on a public website and remain available for five years and be updated at annually.
- Federal reporting thresholds are lowered from \$10,000 to \$5,000, and to \$0 for ownership interests (stocks, stock options, etc.) in private entities.

The NIH has published a [table](#) outlining the major proposed changes to the financial Conflict of Interest rules. The table includes a comparison of both the current rules and the proposed rule changes for various situations. It is certain that the Final Rule will require significant changes in how external interests that may relate to research are reported to institutions, as well as how they are managed. However, we are to keep in mind that some of the above proposed requirements may be modified once the final rule making is issued later in the year.



Mark Your
Calendar

RESPONSIBLE CONDUCT OF RESEARCH 2011 WORKSHOP SERIES

The continuing education in the responsible conduct of research provide opportunities that :

- *Maintain an understanding of best practices*
- *Support the university research community with key resources and contacts when they need help*
- *Improve on the understanding of regulations and processes*
- *Provide support and knowledge to faculty in the management of their research activities*
- *Develop a standardized body of knowledge for individuals engaged in research activities*

Additionally, participation in RCR workshops may be used to help satisfy NIH and NSF training grant requirements for responsible and ethical conduct of research training programs.

These sessions are instructed by Dr. Russ Lea, Vice President for Research.

Conflict of Interest/Conflict of Commitment

Date/Location: Wednesday, August 21st 9:00-10:30am, UCOM 3901

Monday, September, 19th 10:00-11:30am, UCOM 3901

Tuesday, September, 27th 2:00-3:30pm, Main Campus Library, Rm 181

Intellectual Property and Copyrights

Date/Location: Monday, October 10th, 10:00-11:30am, Main Campus Library, Rm 181

Thursday, October 20th, 2:00-3:30pm, UCOM 3901

Financial Management and Responsibility

Date/Location: Monday, November 7th, 10:00-11:30am, UCOM 3901

Thursday, November 17th, 2:00-3:30pm, Main Campus Library, Rm 181



Proposed Update to Export Control Laws

In August 2009, the President directed a broad-based interagency review of the U.S. export control system, with the goal of strengthening national security and the competitiveness of key U.S. manufacturing and technology sectors by focusing on current threats, as well as adapting to the changing economic and technological landscape. This review determined that the current export control system is overly complicated, contains too many redundancies, and, in trying to protect too much, diminishes our ability to focus our efforts on the most critical national security priorities.

As a result, the Administration launched the Export Control Reform Initiative (ECR Initiative), which will fundamentally reform the U.S. export control system. The ECR Initiative, which is not related to the President's National Export Initiative, is designed to enhance U.S. national security and strengthen the United States' ability to counter threats such as the proliferation of weapons of mass destruction.

The Administration is implementing the reform in three phases. Phases I and II reconcile various definitions, regulations, and policies for export controls, all the while building toward Phase III, which will create a single control list, single licensing agency, unified information technology system, and enforcement coordination center. (<http://www.export.gov/ecr/index.asp>)

Research Compliance Training Modules

Are you new to research? Are you hiring someone new to work in the lab? Is there work with animals or bio-hazards? Have you been frustrated in the past with all the different places you had to go to get training? Then "fruster" no more! Compliance training in Responsible Conduct of Research, Bio-safety/Bloodborne Pathogens, and Animal Care and Use training (basic and species specific) are now in one place. USA is utilizing the Collaborative Institutional Training Initiative (CITI) website for all of the above training. The human subjects training curriculum is expected to be utilized in the future. Simply go to the site at <https://www.citiprogram.org/> to create a profile, and answer the questionnaire as to what training you need to complete. The designated training courses will appear in your profile. Completion reports are automatically sent to you and the Office of Research Compliance and Assurance. They can be accessed at any time and the training is good for three years. The system will automatically notify you by email when retraining is due. If you have questions contact Alison Henry ahenry@usouthal.edu or 460-6509.



* * * **Items of Interest** * * *

The release of "The Lab: Avoiding Research Misconduct" is now available for viewing on the DHHS Office of Research Integrity web site. The video simulation allows users to assume the role of a graduate student, post-doc, research administrator, or PI and make decisions that affect the integrity of research.
<http://ori.hhs.gov/TheLab>

Podcast: Writing Your Vertebrate Animal Section

Grants Podcast produced by the NIH Office of Extramural Research (OER) features Dr. Pat Brown, Director, OLAW, who explains what must be included in your grant application if you use vertebrate animals in your research. Listen to
http://grants.nih.gov/podcasts/All_About_Grants/episodes/Animals_May_2011.mp3

[Expert panel calls for reform in human subject protections, Nature Newsblog, May 19, 2011](#)

"...Obama has asked his Commission on for the Study of Bioethical Issues to take a good hard look at whether human subjects today are adequately protected in federally funded research. At the commission's 5th meeting on 18-19 May in the Warwick New York Hotel, an invited panel's words rang loud and clear: the system may provide adequate protection, but it's a mess..."

[Revisions to NIH Guidelines for Research Involving Recombinant DNA Molecules](#)

NIH Guidelines has been revised: Amendments to Section III-E-3 and Appendix C-VII, which were published in the *Federal Register* and became effective on January 19, 2011 (76 FR 3150), serve to exempt from the *NIH Guidelines* the breeding of almost all transgenic rodents that can be housed at BL1, with the exception of rodents that contain a transgene encoding more than 50 percent of an exogenous eukaryotic virus and transgenic rodents in which the transgene is under the control of a gammaretroviral promoter.

[DHHS Office of Research Integrity March, 2011 Newsletter.](#)



Have a Question or a Comment?

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