



Ghostwriting Policy Adopted

Ghostwriting is a practice by which companies author journal articles and pay academic researchers to endorse those manuscripts by allowing the use of their names for publication. This practice misleads readers and participants, presenting work created to advance industry marketing goals as the independent work of leaders in academia. National scrutiny of ghostwriting practices has been a discussion of the University's Conflict of Interest Committee. The committee, in consultation with academic Deans issued a new policy prohibiting these activities. The policy is included in the University's Financial Conflict of Interest and Conflict of Commitment policy and states:

Individuals are prohibited from publishing articles or editorials under their own name that have been authored in whole by industry representatives. Payment from commercial entity representatives to serve as an author to which they did not substantially contribute undermines the integrity of the scientific process and is contrary to the values and principles of academia. Additionally, the International Committee of Medical Journal Editors has adopted a set of authorship principles that are viewed as the gold standard applicable for physicians and the scientific community.

Individuals listed as authors on a paper must have contributed significantly to the work. All co-authors should have been directly involved in one or more of the following activities:

- Planning some component of the work which led to the paper,
- Writing a draft of the article or revising it for intellectual content,
- Reviewing and approving the final manuscript version before it is submitted for publication.

In fact, Senator Charles Grassley of Iowa recently issued a new Congressional [report](#) calling on medical journals, medical schools and the National Institutes of Health to take additional steps to ensure the integrity of scientific publications. The intent of the report is to urge NIH to take a closer look on ghostwriting practices in its upcoming proposed new rule on conflicts of interest. In particular, it is noted that the Pharmaceutical Research and Manufacturers of America (PhRMA) principles of conduct in clinical research specify "authors should identify individuals who provide writing or other assistance and disclose the funding source for this assistance". In academic medicine, ghostwritten articles may unfairly bias physicians and their prescribing practices. These practices clearly violate the usual norms within academia.

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New HIPAA Research Authorization Template

The HIPAA Privacy Rule requires subjects to provide written authorization to collect, use and disclose protected health information for research purposes. The IRB has approved a new authorization form for this purpose. The intent of the new template is to help aid in the explanation of and the subject's understanding of the content. Therefore, the language was divided into various sections as those defined by the HIPAA Privacy Rule. The new template is now posted at: <http://www.southalabama.edu/researchcompliance/hipaa.html>. Additionally, informed consent documents should be revised at the time of continuing review for applicable studies.

Remember that HIPAA research training is required only for investigators and key research personnel who are involved in research utilizing protected health information obtained from a USA covered entity. These areas include USA's hospitals and physicians group, Mitchell Cancer Institute, the Speech and Hearing Center, Psychology Clinic, Center for Strategic Health Innovation, and the College of Nursing "Our Neighborhood Clinic". HIPAA training completed at other institutions will not qualify and thus must be completed by accessing the USA HIPAA in research on-line module tailored to meet the institutional policies on HIPAA privacy and security rules. For questions about HIPAA and research activities email dlayton@usouthal.edu



HITECH Act

Health Information Technology for Economic and Clinical Health

The American Recovery and Reinvestment Act of 2009 includes legislation known as the Health Information Technology for Economic and Clinical Health (HITECH) Act which promotes the use of electronic health records (EHRs) by providing incentives to health care providers who convert their medical records from paper files to EHRs. The HITECH Act specifically mentions that one of the purposes for doing this is to "facilitate health and clinical research. With the passage of the HITECH act placed EHRs at increased risk to the privacy and security of protected health information which modified the HIPAA requirements to mitigate these risks.

The enacted HITECH breach notification law applies to "unsecured protected health information" in electronic or paper form and requires immediate notification to the government if more than 500 individuals are affected. The breach notification rule is triggered if the protected health information (PHI) was unsecured and it compromises the security of the PHI. Unsecured PHI means "PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals

through the use of a technology". A breach that compromises the security of PHI occurs when there is a significant risk of financial, reputational, or other harm to the individual. Notably, a breach of greater than 500 requires notification to a major media outlet, posted on a public website and requires individual notification to research subjects. With the passage of this new law researchers need to be more vigilant in regards to good computing practices. The following safeguards for end users should be adopted to enhance security controls and minimize your risk of a data breach through application of the following standards:

- o Passwords
- o User access controls (restricted access)
- o Workstation security
- o Remote Access (i.e., virtual private network)
- o Portable device security such as USB, laptops
- o Recycling computers and electronic media devices
- o Utilizing USA email accounts
- o Report security incidents/breach

WHO Tool

So, you have completed your training in bio-hazardous shipping. You have obtained a certificate to ship Category A 2814 and/or Category B 3373 "stuff" as your job demands. The problem is, you don't actually send things out on a daily or weekly basis. With all of the other important responsibilities that researchers have, such details pertaining to bio-hazardous shipping requirements doesn't remain a high priority. However, that doesn't mean that you won't need to access it at a moment's notice! What to do? The Office of Research Compliance has posted a tool under the same "Bio-hazardous Shipping" heading that you went to for training



(<http://www.southalabama.edu/researchcompliance/biosafety.html>). Since the regulations in the United States are harmonized with international shipping, the World Health Organization (WHO) was able to compile the information in to a very helpful "wizard" for the shipping of bio-hazardous materials. Not only will it help you decide how to categorize what it is that you are shipping, it will give you instructions on how to package and label the items once you have them classified. REMEMBER...this does not replace the training that you must undergo, but it is a tool for those of you that are certified to use at any time. As a general reminder for determining what category your shipments belongs to, here is a list of all items that must be shipped UN2814 "Infectious Substance Affecting Humans":

http://www.iata.org/SiteCollectionDocuments/dgr50_InfectiousSubstancespdf.pdf

If the biologic you are shipping isn't on that list (for example clinical samples) then it is a UN 3373 "Biological Substance". Training for both is located on the Research Compliance website. Please contact Alison Henry 460-6509 (ahenry@usouthal.edu) for any questions.

Online Bio-safety Training

Attention Principal Investigators and research staff working with approved biological materials! The Occupational Safety and Health Administration (OSHA) requires any person that may come into contact with potential blood borne pathogens to undergo blood borne pathogen training, and the USA IBC requires all PI's and research staff working with potential biological hazards to undergo bio-safety training. The Office of Research Compliance has taken a technological step that should make the process easier when you must renew certification each year. The Office of Research Compliance will continue to track renewals and provide courtesy reminders regarding annual training. However, the exam is now posted online and can be completed via computer. Please go to the following site: <http://www.southalabama.edu/researchcompliance/biosafety.html> and look under the heading "Bio-safety Training." Read over the "Bio-safety Training Document," and then click on "Bio-safety Quiz." Simply answer the questions by pressing the "Submit" button and at the completion of the quiz you will be given a score report. If you have passed the exam, simply press the "Email" feature and the results will be forwarded to Research Compliance. The trainee will then be emailed a certificate of completion that should be maintained in the lab for three years from the date of training. If an email client other than GroupWise pops up when you email the score report, you can always copy and paste it into another email. If so, simply send it to ahenry@usouthal.edu. Additionally, hepatitis vaccination is offered as part of training and if you wish to receive the vaccination series you will need to print out the, "Vaccination Form" and return it to Alison Henry, CSAB 118.





FDA Proposes New Regulation Requiring Sponsors to Report Suspected Falsified Data

The Food and Drug Administration (FDA) proposed rule will require sponsors of clinical trials to report information specifying if any person has, or may have, engaged in falsification of data collected as part of involvement in a clinical study to the FDA no later than 45 calendar days after such time the sponsor learns of the information. This revision aims to address its certitude that sponsors are reluctant, or uncertain of the necessity of, reporting suspected data falsification in clinical trials to FDA. Since the existing regulations are not extensive and the agency has experienced trouble in the reporting of such cases, they [proposed a rule](#) to modify its regulations for reporting falsified data. FDA indicated two main goals in issuing the proposed new rule: to ensure the integrity of data relied upon by FDA to make determinations relating to safety and efficacy; and second, to protect the safety and welfare of clinical study subjects.

FDA defines “falsification of data” as “creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred,” and defines “data” as inclusive of “individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.” Sponsors would be required to report not only confirmed falsification, but also suspected falsified data. The FDA reports, “we purposely are not prosing to specify in the regulations any particular information threshold that must be met before the reporting requirements are triggered, such as the exact form, quantity, or reliability of information about possible falsification that would require a sponsor to report to FDA”. FDA’s view is that it is not feasible to codify all forms of information on possible falsification. This new rule would provide continuity with the federal government’s policy of transparency and personal accountability in order to gain the public’s trust in all areas of government activity.

Animal Care and Use: Keeping Protocol Personnel Updated

Remember, after the initial approval of an IACUC protocol key research personnel must be updated to include the hire of new staff or the removal of personnel. An IACUC amendment form must be used to update personnel, followed by completion of training and occupational health enrollment. Forgetting to add a new person on a IACUC protocol may be a minor oversight, however, it is a major violation to have individuals involved in the conduct of animal activities if prior approval by the IACUC to carryout the work has not taken place. Upon completion of an IACUC Amendment form and all IACUC compliance requirements are met, the individual will be approved to engage in animal activities.

RCR RESOURCE : COMMON MISTAKE IN AUTHORSHIP

The HHS Office of Research Integrity has posted a “Responsible Authorship Quick Guide” to promote education in the responsible conduct of research on publication practices and authorship. In particular, this resource should be of benefit for the novice researcher in preparation of proposals and manuscripts for peer review.

http://ori.dhhs.gov/education/products/niu_authorship/mistakes/index.htm



* * * **Noteworthy News** * * *

Walton, who is the author of The Research Ethics Blog, discussed the challenges of conducting research using Face Book during the annual meeting of the Canadian Society for Bioethics. She also reported it on her blog at: <http://researchethicsblog.com/2009/06/15/facebook-and-research/>

[Government Panel to Discuss Future of Research Universities](#)

A committee of the National Research Council is addressing "the top ten actions that Congress, the federal government, state governments, research universities, and others could take to assure the ability of the American research university to maintain the excellence in research and doctoral education needed to help the United States compete, prosper, and achieve national goals for health, energy, the environment, and security in the global community of the 21st century."

[Exposing the Student Body: Stanford Joins U.C. Berkeley in Controversial Genetic Testing of Students, Scientific American, Jul 6, 2010](#)

"...Stanford and Berkeley faced the same essential ethical dilemmas in creating their programs: avoiding coercion, protecting students' privacy and adequately preparing students to interpret the results of their tests. But the two universities took markedly different approaches to designing and executing their respective projects..."

[The Evolution of Consent Forms for Research: A Quarter Century of Changes](#)

Researchers at the University of Pennsylvania Law School and Columbia University published a study in the journal IRB: Ethics & Human Research that shows informed consent forms are more accurate than ever before but are becoming unreasonably long.
Los Angeles Times, June 1, 2010

Indian Tribe Wins Fight to Limit Research of Its DNA,
<http://www.nytimes.com/2010/04/22/us/22dna.html?hpw>

[FDA has finalized FAQs document and information sheet related to FDA Form 1572, "Statement of Investigator."](#)

The guidance contains significant changes from the 2008 version, including requiring study coordinators to be listed on the 1572, which means they must file financial disclosure information.