



**University of South Alabama**  
**Research Compliance News**

## Timely Topics for Researchers

Research Compliance News has been created to enhance compliance communication for the University research community. It is hoped to bring you timely information and new developments in the research compliance arena, as well as intramural announcements of interest. Your feedback and suggestions are welcomed in order to make this newsletter most helpful to you. Newsletter archives will be published and available through the Office of Research Compliance website at: <http://www.southalabama.edu/com/research/>

Research Compliance News aligns the mission of the Office of Research Compliance and Assurance to promote compliance awareness in all University research-related activities through assistance, education and communication. Sources of news items includes: Human Research Report, National Council of University Research Administrators Research Compliance Newsletter, Chronicle of Higher Education, Office of Research Integrity and all University research compliance offices.

## Research Misconduct Findings in Year 2005

The Office of Research Integrity (ORI) has published data which indicate that research misconduct remains a serious problem. "ORI opened 30 news cases and carried 59 open cases into 2006, eight more cases than the end of 2004, and highest number of cases carried forward in more than 10 years", notes Dr. Alan Price, ORI's Associate Director of Investigative Oversight. Price noted that the number of allegations received by ORI in 2005 (265) was similar to that in 2004, however, it increased 50 percent over year 2003.

Six individuals were debarred from receiving federal funds ranging between two years to a lifetime, as well as prohibited from serving in any advisory capacity to Public Health Service (PHS) for three years. In one case, the respondent was restricted for his lifetime. The life time debarment was given to Eric T. Poehman, Ph.D., a former professor at the University of Vermont, who was found to have falsified and fabricated data in 19 grant applications totaling \$2.9 million for more than a decade. Poehlman was known as a leading specialist on metabolic changes during aging in which he overstated the effect of menopause on women's health in medical journals.

Source: Office of Research Integrity Newsletter, March, 2006  
<http://ori.dhhs.gov/publications/newsletters.shtml>

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## Witness to Consent: When is it required?

The FDA does not require the signature of a witness when the subject reads and is capable of understanding the consent document, as outlined in 21 CFR 50.27(b)(1). A witness is required if the individual is:

- Unable to read the consent to verify the accuracy and completeness of information provided or
- Physically unable to sign the consent

The role of the witness is to be present during the entire consent discussion to attest the adequacy of the consent process and to the subject's voluntary consent. It is important to note that if the intent of the regulation were only to certify the validity of the subject's signature, witnessing would also be required when the subject reads the consent. Additionally, when a witness to consent is required, the individual must be a third party not connected with the research or a relative of the participant.

USA does not require the signature of a witness on a consent form unless it is required by the code of federal regulations. If the sponsor requires this signature be available, the IRB requests that the sponsor have written procedures explaining who may be a witness, and what the witness signature signifies. If a witness signature line is provided on the consent form it must be signed for each consent.

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For complete information on informed consent documentation visit the FDA website information sheet at:  
<http://www.fda.gov/oc/ohrt/irbs/appendixb.html>

## What can I expect to happen if selected for an IRB compliance audit?

The purpose of an IRB audit is to assure the integrity of clinical research and confirm adherence to institutional, state, and federal regulations governing research, including the adherence to Good Clinical Practices (GCP), safety and welfare of human subjects and Institutional Review Board (IRB) policies. The process is designed to be educational and collaborative. The Office of Research Compliance and Assurance strives to work with investigative research teams to identify the root of non-compliance and to develop a plan for remediation through on site monitoring, development of policies, and educational programs.

The process starts when the Office of Research Compliance contacts the principal investigator by letter informing them that their study has been chosen for audit and requests materials to be available during the audit. Next, the audit is conducted and typically includes review of the following study documentation: IRB correspondence, subject records, data collection forms, subject's signed informed consents, and if applicable; interviews with relevant parties, sponsor's regulatory binder and/or test article accountability. An audit report is presented to the Institutional Review Board for comment/recommendations. A follow-up letter is forwarded to the Investigator acknowledging findings from the audit and required corrective action plan if applicable.

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### Investigator Site Audits

Assess adherence to:

- Federal regulations
  - USA IRB guidelines
  - IRB approved protocol
  
  - Provide education
  - Determine rights/welfare have been adequately protected
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## Are your consent forms at 8<sup>th</sup> Grade Reading Level?

Perhaps the most common problem encountered with informed consent documents is that they are often written at a reading level several grades higher than the average subject would understand. One of the essential elements of informed consent is that “*the information that is given to the subject or the representative shall be in language understandable to the subject or the representative*”. Frequently, IRB approval of research is delayed over inadequate consent forms that have either too much or too little information, that are confusing, or that are written above the average subject's reading level. Consent forms should be written for the average participant's level of understanding, by keeping in mind the 8th grade reading level of the average American adult, and by being careful to avoid technical language or terminology.

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*As researchers, we are ethically and legally responsible to disclose the facts, risks, and discomforts.*

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Many word processing programs can determine a document's reading level. The following website located at: [http://www.research.usf.edu/cs/irb\\_docs/readability.pdf](http://www.research.usf.edu/cs/irb_docs/readability.pdf) (source: University of South Florida) is recommended for use as a guide in order to potentially improve consent readability.

## IRB Exempt Review Process

The IRB implemented a new application for exempt studies in April. The new application includes the six categories of exempt research in which the investigator will be asked to indicate the category for the research. Basic questions that are needed for a review are included in this two page application. All survey instruments used with the research [surveys, questionnaires, interview questions] must be sent for review in order to determine if exempt status is applicable. Approval will not be given for an exempt study, rather a determination of exempt status will be provided. Furthermore, a project declared exempt status does not need to be reviewed on a continuing basis. The IRB will send a letter to the Investigator/Student Advisor to determine if the research project remains active and continues to meet the qualification for exempt status. Additional information on this new application and review process is available on the IRB website at: <http://www.southalabama.edu/com/research/humansubjects/index.shtml>

Requests for Exemption will be reviewed as they are received and should allow up to seven days for a response. It is our goal to provide a more expeditious review of exempt studies through utilization of this new application.



## New IRB Database Application

A new feature of the IRB database named the "IRB Viewer" has recently been implemented for use by faculty and staff conducting human subjects research. This new database application will allow registered users READ-ONLY access specific to each individual Investigator's protocol(s). The Investigator will now have the ability to view their protocol(s) historical and current data directly from his/her personal computer. To learn more about this feature and installation set-up, contact the Office of Research Compliance at 460-6625 or email [dlayton@usouthal.edu](mailto:dlayton@usouthal.edu)

It is anticipated that providing real-time electronic data to Investigator's will assist overall efforts in monitoring issues related to an individual's protocol.

## Research Ethics Articles

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Research Misconduct, Retraction, and Cleansing the Medical Literature: Lessons from the Poehlman Case," By Harold C. Sox, MD, Drummond Rennie, MD, [\*Annals of Internal Medicine\*](#), Vol. 144, Issue 8, March 7, 2006;

"The Doctor's World: For Science's Gatekeepers, a Credibility Gap," By Lawrence K. Altman, M.D., [\*The New York Times\*](#), May 2, 2006

"South Korean Scientist Is Indicted for Fraud in Stem-Cell Scandal", By Lila Guterman, [\*The Chronicle of Higher Education\*](#), May 15, 2006

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## Noteworthy News:

### Department of Comparative Medicine Announces IACUC Consulting Hours

Department of Comparative Medicine faculty have reserved office hours ( see <http://www.southalabama.edu/com/research/animalcare/index.shtml> ) to meet with researchers individually to discuss IACUC animal protocols and protocol design. Hours and faculty specializations are also listed on the website.

Bookmark the IACUC website:

<http://www.southalabama.edu/com/research/animalcare/index.shtml> as it is the source for IACUC submission deadlines, protocol amendment forms, GRANITE directions, training forms, and DCM consult hours.



## Use of Biohazard Symbol

Biological hazard warnings signify an actual or potential presence of a biohazard. The Occupational Safety and Health Administration (OSHA), as well as CDC & NIH guidelines require the biohazard symbol on certain items within the laboratory setting. Improper use of the symbol can cause problems for non-laboratory personnel in the event of an emergency thereby potential affecting the response in such a case.

As required by OSHA [1910.1030(g)(1)] labels must include the universal biohazard symbol (the term “biohazard”) must be affixed to:

- Containers of regulated biohazard waste
- Refrigerators or freezers containing blood or other potentially infectious material
- Containers used to store, transport or ship blood or other infectious material
- Equipment such as incubators or centrifuges that are used for the processing of infectious agents, potentially infectious agents or human-derived materials.
- The entrance door for laboratories

Under no circumstances should anything containing a biohazard symbol be disposed of in the regular trash. Also, shipping boxes/packaging materials, etc. that is marked with the biohazard symbol should have the label removed before placing in the regular trash. For additional reading on this topic, a two page article summarizing the need for a symbol to warn of potential hazards which is entitled “Biohazards Symbol: Development of a Biological Hazards Warning Signal” can be accessed on the web at:

<http://www.mabsa.org/1967-10-13-science-paper-biohazard-symbol.pdf#search='Biohazards%20Symbol%3A%20Development%20of%20a%20Biological%20Hazards%20Warning%20Signal>