



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

## Enhancing the Process of Informed Consent

A special educational session entitled “Are We Making Ourselves Clear? Improving Participants Understanding” was offered to Investigators, Study Coordinators, Research Nurses and IRB members as a grass roots initiative towards improving the process of informed consent. Topics covered included an overview of the AAMC Strategic Planning Meeting on Informed Consent held in May, 2007, whose goals are to develop strategies leading to a common usage of short and readable consent documents, using comprehensible language to facilitate increased level of understanding and enabling potential participant’s to truly make informed decisions about study participation.

The main thrust of information presented focused on impediments that contribute to the lack of understanding and retention of consent documents, improving readability through incorporating health literacy initiatives, and implementation of materials to assess level of comprehension such as “Teach Back” principles. The AAMC has proposed an approach as recognizing informed consent as a process that requires a toolkit by using supplemental materials and identification of several steps to achieve these goals. Currently, the AAMC has been charged with the creation of a working group to model templates for research of differing complexities and risk.

The literature is fairly consistent in documenting barrier’s to participant’s understanding to include problems recalling and retaining information, evaluating evidence and probabilities, failure to define medical jargon/technical information and the reliance on using consent forms alone. The gist is that informed consent has become far too long in length and far too dense in language for the majority to actually read and understand them. The Office of Research Compliance is taking a proactive role in the development and implementation across all clinical research study sites by using various mechanisms for the purpose of strengthening the overall process of informed consent. One major obstacle identified is health literacy or the ability to read, understand and act on health information. Unfortunately, individuals with low health literacy typically do not disclose their difficulty in reading or comp rending health related information. Written materials for participants must explain complex information including the purpose of the study, detailed study procedures and confusing privacy laws. Therefore, a series of best practices will be developed to help study teams more easily describe complicated information in “plain language”, assess level of understanding and intervening to assist low health literacy patients. It is noted “asking that patients recall and restate what they have been told” is one of eleven top patient safety practices based on strength of scientific evidence. (*AHRQ, 2001, Report on Making Health Care Safer*)

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## IRB Basics: Eight Required Elements of Informed Consent

Federal regulations specify the type of information that must be disclosed during the consent process and how consent must be documented. Unless a waiver or alteration of the informed consent process has been approved by the IRB, the following information is required to be disclosed to potential research subjects:

### Element 1

- The study involves research
- the purpose of the research
- the expected duration of participation
- the procedures to be followed, including identifying any procedures that are experimental

### Element 2

- any foreseeable risks/benefits

### Element 3

- any benefits to subjects or others

### Element 4

- any alternatives to the research or treatment options that may be advantageous

### Element 5

- the extent to which confidentially or records will be maintained

### Element 6

*(only required for studies > than minimal risk)*

- whether compensation or medical treatment is available injury occurs
- what the treatment consists of, or where further information can be obtained

### Element 7

- whom to contact for answers to questions about the research
- whom to contact for answers regarding research subjects rights
- whom to contact in the event of a research related injury

### Element 8

- participation in the study is voluntary
- refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled

### SIX ADDITIONAL ELEMENTS

*The regulations require these additional elements be included when are they relevant to the study.*

#### Additional Element 1

- the procedure/treatment may involve risks that are currently unforeseeable

#### Additional Element 2

- participation may be terminated by the investigator

#### Additional Element 3

- additional costs to the subject that may result from participation

#### Additional Element 4

- the consequences of a subject's decision to withdraw and the procedure to be followed to ensure an orderly termination

#### Additional Element 5

- the subject will be informed of any significant findings that may affect continued participation

#### Additional Element 6

- approximate number of subjects involved in the study

In addition to the above required elements,  
USA IRB has additional informed consent criteria in template format such as:

**HIPAA language:** for the use and disclosure of protected health information for research

**Storage of Biological Specimens:** regulations set criteria for use of patient specimens for research

**Medical Bill of Rights:** inform potential subjects their rights when being recruited for clinical research studies



## Export Control Concerns: Laptops or GPS Equipment

Export controls are essential to research institutions because our work depends so much on the open exchange of ideas with people from other countries. Export controls regulate materials, technologies and ideas that are shipped from the U. S. or taken to other countries by American travelers or disclosed to foreign nationals working here in the U.S. In essence, these controls are intended to protect the U.S. economy and trade, and to advance foreign policy goals, while keeping technologies and information that could potentially be used to harm the U.S. and its citizens from landing into the hands of terrorists.

Keep in mind, US export control laws may apply to laptop computers, global positioning system equipment (GPS) and their associated software. The regulations vary based on which country you are traveling to and for what purpose you intend to use your laptop or GPS. Also, note that the information contained in your laptop files may be subject to export control as well. A license may be required to export the laptop, GPS, and a denial may pertain if the researcher seeks to export to an embargoed country. Researchers export their laptops or GPS when they take equipment abroad to assist them with their research, allow an individual in a foreign country to use their laptops or GPS, or allow a foreign national access to their laptops or GPS within the United States (this is defined as a deemed export). However, there are fundamental research and public domain exclusions that may apply so the researcher is free to export the equipment. Prior to discussing technology or making a presentation while traveling abroad, you should verify that the technology, information, and/or commodities qualify for an exclusion. Export control issues that warrant careful consideration in regards to laptops and GPS equipment are:

- Does the software contain source code for encryption software or mass market encryption products?
- Is the equipment, software, and/or technology on the US Munitions List?
- Will the equipment or software be put to a military or outer space use?
- Could the research be used in the development of weapons of mass destruction?

Export controls regulations note that laptops and GPS equipment be kept under “effective control” at all times when traveling outside the US. Furthermore, US Customs officials are authorized to review the contents of travelers’ laptops, as well as many foreign governments that have regulations in place granting authorization to seizure travelers’ computers and review of their contents. Additional information on Export Controls can be found on our website at: <http://www.southalabama.edu/com/research/exportcontrol.shtml>

Articles of interest...

***Traveling Abroad with Laptop Computers and Other Electronic Media: What You Need to Know (10/31/2006)***, provides helpful suggestions in the event your laptop is seized  
[http://www.acte.org/resources/view\\_article.php?id=92](http://www.acte.org/resources/view_article.php?id=92)

***A February, 2008 news article in Computerworld “5 Things You Need to Know About Laptop Searches at US Borders”***, highlights items to be aware of if customs seizes your PC  
[http://www.computerworld.com/action/article.do?command=viewArticleBasic&taxonomyName=mobile\\_devices&articleId=9062299&taxonomyId=75&intsrc=kc\\_top](http://www.computerworld.com/action/article.do?command=viewArticleBasic&taxonomyName=mobile_devices&articleId=9062299&taxonomyId=75&intsrc=kc_top)

***A February, 2008 news article from CNN.com entitled “Suit: Airport searches of laptops, other devices intrusive”*** <http://www.cnn.com/2008/TRAVEL/02/11/laptop.searches/index.html> regarding lawsuits from customs agents for lengthy questioning and invasive searches.



## Follow-up: NSF Funding and Responsible Conduct Training

The Public Health Service (PHS) through the Office of Research Integrity has defined RCR to include the following Core instructional areas:

- Data acquisition, management, sharing and ownership
- Mentor/Trainee Responsibilities
- Publication practices and responsible authorship
- Peer Review
- Collaborative Science
- Human Subjects
- Research Involving Animals
- Research Misconduct
- Conflict of Interest and Commitment

In follow-up to the November, 2007 Research Compliance newsletter, 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. Read more information on the COMPETES Act at: <http://science.house.gov/> The NIH implemented a similar requirement several years ago for trainees supported by NRSA and research training grants (T32 and T34).

In order to facilitate RCR course access, the Office of Research Compliance has created step-by-step instructions for accessing RCR online instruction available via the Collaborative Institutional Training Initiative (CITI) program. This method of instruction is to be utilized for complying with this federal requirement. Additionally, information on addressing RCR in grant applications is available on the Research Compliance website at: <http://www.southalabama.edu/com/research/conduct.shtml>

## IACUC Spring Inspections Are Approaching....

Semi-annual inspections of all animal housing and procedure areas are scheduled for June 9<sup>th</sup> – 10<sup>th</sup>. Investigators are contacted in advance regarding specific dates and timeframe for which the designated area will be visited. Two IACUC members will inspect all areas where animals are housed for longer than 12 hours and areas where any procedures and surgical manipulations on any species are conducted. This is a good time to look at your standard lab practices and note any deficiencies by conducting a self-inspection using the checklist posted on the IACUC website at: <http://www.southalabama.edu/com/research/animalcare.shtml>

Also posted is a list of common deficiencies identified during inspections and their appropriate corrective action prepared by the IACUC Office. Please review these findings to ensure that these will not be observed in your laboratory. The IACUC Office will work with you to ensure that corrections are made and request documentation verifying deficiencies have been corrected. The University of South Alabama along with the IACUC is committed to maintaining the integrity of and working to enhance our overall Animal Care and Use Program. Your cooperation is essential in helping make our program a continued success.

## IACUC News You Can Use

\* The new Granite server password is designed not only to have the sufficient alphanumeric symbol strength, but also to be easier to remember for USA insiders like faculty, staff, and students. **\$thPw63** is the contraction of our USA mascot's name **SouthPaw** (minus the vowels, plus a dollar sign for the "S") and **1963**, the year of the school's inception.

\* Don't forget to use the proper Internet Explorer (Safari) bookmark <https://asp.topazti.net/Citrix/topaz/auth/login.aspx> to enter Granite.

\* All of your training needs and documents, from online courses to amendments to adding personnel via protocol amendment, can be found at the IACUC website: <http://www.southalabama.edu/com/research/animalcare.shtml>. Look in the first box, Training, at the first link "Training Requirements" and the subsequent listing of all links in order which are listed below.



**Recent News** (source: PRIM&R newsletter)

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Ross J, Hill K, Egilman D, Krumholz H. "Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents From Rofecoxib Litigation." **JAMA**. April 16, 2008; 299(15). **Full Text:** [Here](#).

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Nixon N, Forman L. "Exploring Synergies Between Human Rights and Public Health Ethics: A Whole Greater than the Sum of its Parts." **BMC International Health and Human Rights**. January 31, 2008, 8(2). **Full Text:** [Here](#).

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**Controversial Clinical Trial Draws Renewed Criticism, for Withholding Damning Results**

"A study testing a blood substitute called PolyHeme, which was previously criticized as unethical, has now been taken to task along with other artificial-blood research for causing unnecessary deaths," writes the [Chronicle of Higher Education](#).

"The clinical trials, many of which were reported late or not at all in peer-reviewed journals, have now been analyzed together to show that patients who received the experimental treatments were 30 percent more likely to die, and were almost three times as likely to have heart attacks. The analysis was published online in The Journal of the American Medical Society."

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**\*\* Noteworthy \*\***

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The Office of Research Integrity (ORI) opened 14 news cases for oversight review in 2007 and carried 39 cases into 2008, as noted in the March issue of ORI's quarterly newsletter. The average processing time per case was about seven months. The newsletter also contains a case summary and information about articles published by ORI-funded authors.

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The Task Force on Industry Funding Medical Education has recommended a ban on all industry gifts to academic institutions and supports the use of campus wide centralized systems to handle drug samples. These recommendations are among many contained in the task force's report, which also suggests the development of an educational program that will assist students, trainees, and faculty to gain the skills necessary to adhere to high ethical standards.

*Source: Report on Research Compliance*

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