



University of South Alabama
Research Compliance News

IRB SPOTLIGHT

Information Sheet Versus Consent Form

The purpose of the consent form and information sheet is the same, as both documents outline the information required for participants to make an informed decision regarding study participation. The key factor in determining which consent document to use primarily depends on the design and procedures of an investigator's study. A consent form is not necessary if the study qualifies for an exemption, however the process of consent must continue to take place. In this instance an information sheet may be used for obtaining verbal or implied consent.

Implied consent (i.e., a prospective subject is informed about a study where participation consists only of filling out an anonymous questionnaire; the person completes the questionnaire and, by doing so, agrees to participate in the research) means that the subjects are read a verbal version of a consent form and give their verbal consent in place of written consent to participate. When this method is used, the IRB must approve a written summary of what is to be said to the subject or the representative. The researcher obtaining verbal consent should sign and date the information sheet to document each subject's consent.

The "Information Sheet", used as an oral script, is an introduction to the questionnaire/interview/survey, and should be placed before the survey/questionnaire/ interview or as a stand alone document. The IRB will consider approving such requests based on appropriate justification and information regarding the consent process. The IRB provides a template for the researcher to complete by filling in study specific information. The template is available at:

<http://www.southalabama.edu/researchcompliance/pdf/infosheet.doc>

Studies that qualify for expedited or full board review are required by federal regulations to obtain signed documentation of consent. Research activities may be reviewed by the IRB through the expedited review procedures if they (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the nine categories authorized by [45 CFR 46.110](#) and 21 CFR 56.110. Researchers must include all required elements of consent unless the study qualifies for a waiver of consent or documentation of signed consent. The elements of consent are outlined at:

<http://www.southalabama.edu/researchcompliance/pdf/consentform.pdf>

Contact SuzAnne Robbins in the IRB Office at srobbins@usouthal.edu for additional questions you may have concerning the informed consent process.

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Announcements

Research Compliance Welcomes Alison Henry

We welcome Alison Henry who has joined the staff in the Office of Research Compliance and Assurance as Assistant Director in May. Alison is an alumna of Virginia Tech and Texas A&M, having earned a Master's and Bachelor's degree in Food Science and Technology. Ms. Henry will assist in administrating various compliance functions that support the University's research programs with emphasis on Export Controls, Biosafety and Responsible Conduct of Research.

The Office of Research Compliance is working on the development and implementation of policies to cover many areas of operations where there are potential implications related to export controls. Export control laws are federal regulations that govern transmission of certain information, technologies, and/or commodities to foreign nationals while they are in the U.S or overseas to anyone, including U.S. citizens. Penalties for non-compliance with these federal laws are severe and impact the researcher as well as the institution.

Alison can be reached at 460-6509 or ahenry@usouthal.edu



New Edition: On Being a Scientist

This guide promotes responsible conduct in research and provides information on how to conduct research responsibly, avoid misconduct such as fabrication, falsification and plagiarism and include case scenarios (with answers in the appendix) at the conclusion of each chapter. Also, the guidance includes information on the significant role of conflicts of interest in ethical decision making and the role of digital communication technologies.

The guide contains "an overview of the professional standards in science and explains why adherence to those standards is essential for continued scientific progress. While directed primarily toward graduate students, postdocs and junior faculty in an academic setting, this guide is useful for scientists at all stages in their education and careers, including those working for industry and government," as the authors explain.

The guide is available from the National Academies Press at <http://books.nap.edu/>

Plan To Travel Outside the United States? Stay Tuned - Updates to the Request Process are Under Review

Over the past year USA has been reviewing research/export control compliance (US federal regulations) and risk management issues associated with foreign travel (outside the continental US). Procedures are currently under review for a new enhanced process whereby all the necessary export control, "Fly America", restricted party screening and sanctioned country review (via Visual Compliance, a web based export control management tool), export certification, country security (state department, 24/7 assistance) review, and emergency contact information will be addressed PRIOR to proceeding with the formal departmental and college/administrative approvals via the respective requests for professional leave or travel forms. As currently envisioned travelers will receive this review documentation to be then attached to the formal departmental/college/admin unit requests for final authorization, ticket purchase, and travel planning based on the information provided. Information on these new procedures and forms are forthcoming. These new procedures and the related federal regulations affect all areas of USA foreign travel including hospitals, research, academic collaborations, USA business travel, and transactions such as sending/sharing items with individuals and organizations outside of the United States. As details become available they will be updated to the USA travel web page at:

<http://www.southalabama.edu/travel/index.html> and advisory information will be posted via email and other announcements this coming Fall. For additional foreign travel resources please go to: <http://www.southalabama.edu/oie/scholar.html> Questions about foreign travel may be directed to jimellis@usouthal.edu



New RCR Tools: Best Practices in Image Processing

Three RCR videos on image guidelines were developed at the University of Alabama at Birmingham through support of the Office of Research Integrity's Resource program to "create effective teaching methods and formulate standards for image manipulation and acceptable ways to process images in science" as explained by the Office of Research Integrity." The videos cover information such as modifications to images, reporting image changes, and saving copies of the raw data. These new web modules are available at: <http://tinyurl.com/qj8ro4>



Summarized from the FBI release dated July 1, 2009:

Former University of Tennessee Professor John Reece Roth Sentenced to 48 Months in Prison for Illegally Exporting Military Research Technical Data

KNOXVILLE, TN—On Wednesday, July 1, 2009, John Reece Roth, 72, of Knoxville, Tennessee, was sentenced to 48 months in prison for violating the Arms Export Control Act by conspiring to illegally export, and actually exporting, technical information relating to a U.S. Air Force (USAF) research and development contract. Upon his release from prison, Roth will serve a term of two years supervised release.

These illegal exports by Dr. Roth of technical information, known as “technical data,” related to his illegal disclosure and transport of restricted military information associated with the USAF contract to develop specialized plasma technology for use on an advanced form of an unmanned air vehicle (UAV), also known as a drone. The illegal exports by Dr. Roth of military technical information involved specific information about advanced plasma technology that had been designed and was being tested for use on the wings of drones operating as a weapons or surveillance systems. The Arms Export Control Act prohibits the export of defense-related materials, including the technical data, to a foreign national or a foreign nation. Even after repeated warnings to the contrary, Dr. Roth continued to relay information about the project to one of his graduate students who was a citizen of the People’s Republic of China without an export license.

After a trial in September 2008, Dr. Roth was convicted of conspiring with Atmospheric Glow Technology, Inc., a Knoxville, Tennessee technology company, of unlawfully exporting in 2005 and 2006 fifteen different “defense articles” to a citizen of the People’s Republic of China in violation of the Arms Export Control Act. This law prohibits the export of defense-related materials, including the technical data, to a foreign national or a foreign nation. These “defense articles” related to different specific military technical data that had been restricted and was associated with the USAF project to develop plasma technology for use on weapon system drones.

Dr. Roth was also convicted of one count of wire fraud relating to defrauding the University of Tennessee of his honest services by illegally exporting sensitive military information relating to this USAF research and development contract.

Incorporating RCR into the Pathway of Independence

This Responsible Conduct of Research (RCR) program of instruction is coordinated through the Office of Faculty Affairs and the Office of Research Compliance and Assurance. The program is designed to stimulate and foster ethical and professional standards, by weaving together issues related to grants writing and development of independent science with those related to responsible conduct of research in a case study/discussion format. In the Spring cycle 2009, we recruited training faculty from among several colleges, institutes, and research administration offices across campus. Each of the 6 workshops was attended by 23-30 individuals including postdoctoral fellows, graduate students and junior faculty. Workshops evoked lively discussion and generated positive evaluations. We plan to offer this series each spring term in subsequent years.

Comments from RCR course.....

“The importance of keeping records on every experiment done”

“How to deal with authorship and the importance of data management”

“This platform is a great vehicle to introduce junior faculty and post docs to the need to become more proactive”

“Interactions with colleagues and mentors were invaluable”

“The frank and elaborate discussions of the issues/problems.”



NIH Guidelines on Stem Cell Research



SOURCE: AP Photo/Ron Edmonds

President Barack Obama is applauded by members of Congress, and others, after signing an executive order on stem cells and a Presidential Memorandum on scientific integrity, Monday, March 9, 2009, in the East Room of the White House in Washington.

On March 9, 2009 President Obama lifted the ban on Federal funding for stem cell research. These guidelines establish policy and procedures under which NIH will fund research in this area, while helping to ensure that research is “ethically responsible, scientifically worthy, and conducted in accordance with applicable law.” The guidelines reverse funding requirements imposed by the Bush administration which restricted federal research funds from using roughly 21 stem cell lines created prior to August 9, 2001. On May 24, the U.S. House of Representatives passed legislation to allow federal funding of research with new lines of human embryonic stem cells developed from excess embryos at in-vitro fertilization clinics. As of July 7, the [final Guidelines on Human Stem Cell Research](#) took effect. As an addition to the new guidelines, NIH has vowed to develop a website listing all approved stem cell lines created prior to July 7th, so that investigators would know which lines NIH has confirmed eligible for federal funding.

Furthermore, Institutional Review Boards are responsible for reviewing and approving research protocols to create new human embryonic stem cell lines, and the use of certain specified procedures involving embryonic stem cells. The new Guidelines enable ethical and responsible research that can only be carried out through the process of voluntary informed consent. Therefore, written informed consent for research must have been obtained from the embryo donor or donors.

Articles on Research Ethics / Links of Interest

- “*Stimulus Funds for Science Raise Concern About Misconduct*”, Scientific American, 07/2009. About \$31 billion in stimulus funds will go to science. Can watchdogs keep track of those funds?
<http://www.scientificamerican.com/article.cfm?id=stimulus-funds-for-science-raise-concern>
- “*New study: Science journal editors’ views on publication ethics: results on an international survey*”, Source: Journal of Medical Ethics, 2009 Jun;35(6):348-53.
The purpose of this study was to survey U.S. medical school faculty to assess financial arrangements between investigators and industry to learn about investigators’ first hand knowledge of the effects of industry sponsorship on research.