



University of South Alabama
Research Compliance News

Assessing Level of Risk and Type of IRB Review

IRB review is based on the level of risk to the subjects and the types of subjects involved in the research study. The researcher should evaluate the risk and the subject population to determine which type of review may be appropriate for the research study. There are three levels of review for research, exempt, expedited and full board review. The majority of social science, behavioral and educational research is expected to fall in the exempt or expedited categories. Intervals for continuing review, in the absence of problems, are often set to a default of one year. However, the IRB may determine that more frequent intervals are appropriate. Research investigators will be notified 60 and 30 days in advance of expiring studies in order to initiate the IRB for continuing review. The IRB office conducts a preliminary review to evaluate the risk and determine if the risks are reasonable in comparison to the anticipated benefits of the research to the subjects.

Review of exempt research protocols addresses the same elements as review of non-exempt research protocols. However, exempt review is typically faster than non-exempt review, because protocols do not need to be assigned to a committee member for review. In exempt review, administrative staff checks that: all parts of the protocol and consent documents (if applicable) are present, that the research purpose or question will be addressed by the research methods and instruments, that the recruiting and consent processes are not coercive to subjects and that the researcher informs the participants adequately of any risks and benefits to them for being in the study.

Levels of risk are:

Less than minimal risk: research in which there is no known physical, emotional, psychological, or economical risk. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.) and falls in an exempt category.

Minimal risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Greater than minimal risk: research procedures that may include risk beyond that ordinarily encountered by subjects (e.g. maximal exercise testing, experimental drugs, biologics or medical devices, stressful psychological testing, use of special populations). This research requires full review by the IRB.

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Clinical Research Listserv

A listserv will soon be available to provide a forum for clinical research support professionals to discuss issues in support of clinical trials at USA. Members of the listserv may include investigators, clinical coordinators, trial managers, research nurses, The listserv was created for its subscribers to ask questions and to clarify the process for issues germane to clinical research operations, best practices and IRB requirements and federal policies. The CRSS Listserv sends out IRB announcements and administrative/compliance issues are also discussed via this forum. An email to clinical research support staff will be sent providing additional information and member subscription.

Statement of Investigator- Form FDA 1572

The Food and Drug Administration (FDA) recently published a draft guidance that contains suggestions about how to successfully complete the Form FDA 1572, Statement of Investigator. This form is required for clinical research studies involving drugs/biologics/devices regulated by the FDA and is the investigator's agreement to perform the study according to applicable federal regulations under 21 CFR 312. The investigator's signature on this form constitutes the investigator's affirmative assertion that he/she is qualified to conduct the study and constitutes the investigator's commitment to abide by the FDA regulations.

In particular, the two most common inquiries in completion of the form are Block #1 clarifying if co-investigators should be listed and is it acceptable to have two investigators? Additionally, Block #6 clarifies who should be listed as a sub investigator. The purpose of this block is to capture information about individuals who will be assisting the investigator, who makes a direct and significant contribution to the data and depends on whether the individual is performing significant study-related duties.

For additional questions and answers about the Form FDA 1572 access the document at:
<http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl.pdf>

Update on Conflict of Interest and Commitment Policy: Training Workshops Scheduled

The University recognizes a shared responsibility amongst faculty and administrators to ensure that they conduct themselves in an unbiased manner and serve the goals of the University. Thus, objectivity is paramount in scientific research and the basis for public trust. University employees must ensure the integrity of their academic interests by taking measures to avoid potential conflict of interest and/or conflict of commitment. Because the perception of conflict of interest or commitment may vary from person to person and the diversity of personal relationships, the most effective approach towards addressing conflict of interest or commitment is to establish a system under which employees disclose and obtain evaluation of potential conflict. Thus, University employees must now disclose potential financial conflict of interests annually each year by September 30th.

Training sessions have been scheduled to heighten the awareness of these new policies and reporting procedures, along with a case-based approach to learning these principles to help foster a culture of compliance throughout the University. Contact Ms. Layton @ 460-6625 or dlayton@usouthal.edu if interested in signing up for a scheduled workshop conducted by the Vice-President for Research.

Remaining Workshops:

Friday, September 26	10:30am
Wednesday, October 1	12:30pm
Monday, October 6	12:30pm
Friday, October 10	10:30am
Tuesday, October 14	10:30am
Tuesday, October 28	12:30pm
Friday, November 7	10:30am



Export Controls: University of Tennessee Professor Indicted

John Reece Roth, Emeritus Professor of Electrical Engineering at University of Tennessee Knoxville, was indicted on April 15, 2008, on 18 counts of violation of export control laws for sharing non-public information. Roth had violated the law by providing information to two graduate students working with him and by carrying information about the project on a computer to China. Most counts involve the "deemed export" rule, under which communication of non-public technical information to a foreign national is "deemed" an export to the national's home country. Roth, an expert in plasma research, agreed to serve as a subcontractor on a U.S. Air Force project awarded to Knoxville technology firm Atmospheric Glow Technologies Inc., where Roth's former student worked. The project involved the development of advanced plasma actuators for use on the wings of Air Force drones. Therefore, the project fell under the auspices of export control laws as it involved a defense munitions system.

Knoxnews.com reported that "The FBI, U.S. Bureau of Immigration and Customs Enforcement, and the Air Force's Office of Special Investigations launched a probe in May 2006, seizing a laptop and documents from Roth as he returned from a trip to China. Testimony showed those seizures led to proof that Roth took information about the project to China, where he had been lecturing." After a seven day trial, Roth was found guilty of conspiracy to violate the Arms Export Control Act together with 15 separate illegal exports of military technical data. The law prohibits the export of defense-related materials, including the technical data, to a foreign national or a foreign nation.

A word of caution..... International travel becomes more complicated and specific queries must be asked before one travels, especially when carrying laptops or other storage devices. The Office of Research Compliance and the Office of International Education has worked collaboratively towards the development of forms and new policies that captures potential export control issues germane to travel abroad. Thus, the responsibility is on the individual to investigate and comply with the law.

Roth's sentencing has been set for January 7, 2009.

Institutional Animal Care and Use (IACUC): Q & A's

Q: Is it permissible to grant administrative extension of IACUC approval in order to avoid expiration?

A: NO. Public Health Services (PHS) states the following provisions at IV.C.2. of the PHS policy that IACUC review must take place at least once every three years. The IACUC may not extend the three year approval by any means other than IACUC review and approval using the procedures of IV.C.2. When IACUC approval expires, the animal protocol is no longer valid. Continuation of animal activities beyond the expiration is a serious violation of PHS policy.

Q: What is considered a significant change to a project that would require IACUC review?

A: Examples of changes considered to be significant include, but are not limited to, changes:

- in the objectives of a study
- from non survival to survival surgery;
- resulting in greater discomfort or in a greater degree of invasiveness;
- in the species or in approximate number of animals used;
- in Principal Investigator;
- in anesthetic agent(s) or the use or withholding of analgesics;
- in the method of euthanasia; and
- in the duration, frequency, or number of procedures performed on an animal.

Changes in personnel other than the PI need not be considered significant provided that an appropriate administrative review mechanism is in place to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in the Occupational Health Program, and meet other criteria as required by the IACUC. The IACUC has some discretion to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis.



Q: Who Should Submit a Animal Use Protocol?

A: Any investigator wishing to utilize animals in teaching or research is required by the University and by Federal and State laws to obtain approval from the IACUC before the work is begun. Most funding agencies require verification of this approval before funds will be released to the University. The form can only be submitted by a faculty member of the University as the Principal Investigator (P.I.). Non-faculty members (e.g., Post-doctoral Fellows, graduate students, etc.) may be named as a protocol associates, but must have a faculty sponsor who will assume ultimate responsibility for the animal work.

Q: Does the PI on a grant have to be listed as PI on an animal protocol?

A: No. The University’s transmittal sheet used for processing grants may list the PI on a grant with an approved IACUC protocol in which he/she is a protocol associate. However, the IACUC will verify at the time of award that the approval covers the work being funded.

*** * Increase in Number of Animals * ***

The NIH, Office of Laboratory Animal Welfare considers a less than 10% increase as a minor change for rats and mice only. This request for increase in the number of rodents not covered by the USDA and not in Pain Category E may be submitted for expedited approval via the IACUC amendment form. Additions are limited to a one-time increase of 10% or less in the number originally approved. However, for all other species an increase of one animal would be considered a significant change requiring IACUC protocol review and approval.

Recent News *source: Public Responsibility in Medicine and Research (PRIM&R) newsletter*

Researchers Question Wide Use of HPV Vaccines

An article in the [New York Times](#) reports on a study published in the New England Journal of Medicine that concludes that two vaccines against cervical cancer are being widely used without sufficient evidence about whether they are worth their high cost or even whether they will effectively stop women from getting the disease, two articles in this week’s New England Journal of Medicine conclude.

Both vaccines target the human papillomavirus, a common sexually transmitted virus that usually causes no symptoms and is cleared by the immune system, but which can in very rare cases become chronic and cause cervical cancer.

Shorter Review Cycles at CSR Help Some New Researchers

A featured article in the [NIH Record](#), the employee newsletter for the National Institutes of Health, describes efforts by the NIH Center for Scientific Review to shorten review cycles to assist new investigators submitting R01 applications. Scores and critiques of submissions are released within 10 days of the review meeting, and candidates can resubmit their applications in the following review round instead of having to wait out a round.

NIH is presently completing a qualitative and quantitative assessment of the shorter review cycles, the results of which will direct efforts to shorten review cycles for other applicants.



Recent News continued.....

NIH has announced the availability of a Web-based tutorial related to the "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." In its release notice, NIH states, "As part of NIH's continuing educational efforts to improve and enhance compliance with Financial Conflict of Interest (FCOI) requirements, we developed a Web-based tutorial which reviews the requirements of and the responsibilities for compliance with these Federal FCOI regulations. The tutorial is designed for use by institutional officials responsible for managing NIH funded grants, cooperative agreements and/or contracts, and for individuals who are responsible for the design, conduct or reporting of NIH-supported research."

The tutorial may be accessed on the Office of Extramural Research, Conflict of Interest Page.
<<http://grants.nih.gov/grants/policy/coi/index.htm?>

Next Stop, Don't Block the Doors: Opening Up Access to Clinical Trials Results

[PloS](#) medical editors report on the trend of research institutions to open access to clinical trial results. The article notes that this development is just the beginning of expanded access in light of a new FDA rule that will come into effect in September and will require all clinical trials results be made publicly available on the internet through an expanded 'registry and results data bank.' "

NIH announces changes to enhance and improve peer review

NIH Director Elias A. Zerhouni, M.D., announced "critical changes to enhance and improve the NIH peer review system" at the meeting of the Advisory Committee to the Director, marking the end of a year-long effort to strengthen NIH peer review, reports [NIH News](#).

The [Implementation Plan Report](#) consists of four main priorities:

- 1 - Engage the Best Reviewers
- 2 - Improve Quality and Transparency of Reviews
- 3 - Ensure Balanced and Fair Reviews Across Scientific Fields and Career Stages
- 4 - Develop a Permanent Process for Continuous Review of Peer Review

The NIH also posted an [Overview of Enhancing Peer Review at NIH](#) on its website.

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