



University of South Alabama
Research Compliance News

New Rules for Reporting Clinical Trials

In 2005 the International Committee of Medical Journal Editors ([ICMJE](#)) required that certain clinical trials be entered in a public registry (i.e., [ClinicalTrials.gov](#)) before enrolling the first patient, as a condition of consideration for publication. Congress has now expanded the scope of clinical trials to include mandatory reporting of Phase II-IV trials and subsequent reporting of results with the enactment of the [FDA Amendments Act of 2007](#) (Title VIII). All new Phase II-IV clinical trials will need to be registered by September 27, 2008. See NIH Guide Notice [NOT-OD-O14](#) for more details. Competing grant applications submitted to the NIH on or after January 25, 2008 that include applicable clinical trials should include information about registration (i.e. *the NCT number, the Brief Title and the name of the responsible party*) in the Human Subjects Section of the Research Plan.

Responsibility for registering trials lies with the lead sponsor of the clinical study; therefore, most "industry sponsored" trials will be registered by the study sponsor. However, all investigator-initiated studies or those who hold an IND or IDE that meet the eligibility criteria, will need to be registered by the investigator prior to study enrollment, where applicable.

The following "applicable clinical trials" that MUST be registered generally include:

- Trials of drugs and biologics: Controlled, clinical investigations other than Phase 1 investigations, of a product subject to FDA regulation
- Trials of devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.

Furthermore, the FDA has the authority to enforce compliance with these clinical trial registry requirements. The NIH will post a notice outlining infractions if the sponsor fails to register any trial which meets the eligibility criteria, fails to submit trial results, or submits false data or information. Monetary penalties for failure to comply with the requirements of the Act may also be imposed by the FDA. Any person who violates the provisions of the Act will be subject to penalties up to \$10,000. After 30 days of notification, uncorrected violations could incur additional \$10,000 daily penalties until the violation is corrected.

"ClinicalTrials.gov is expected to freeze results requirement in April to provide sufficient time for data providers to use and suggest modifications before the database 's congressionally imposed Sept 27 start date". An appointed working group will advise the National Library of Medicine board on issues associated with expansion of ClinicalTrials.gov and "provide guidance on initial implementation issues and longer-term strategies for enhancing: data content and format; procedures for submitting, storing and posting information; quality assurance; provision of summary information for the general public; and the scope of clinical studies included in the database." The newly passed 2007 FDA Amendments Act will lead to new regulations governing the content of informed consent to include an explanation of how researchers plan to enter the data about the study into the ClinicalTrials.gov database.

For additional information regarding access the to protocol registration system at ClinicalTrials.gov visit: <http://prsinfo.clinicaltrials.gov/>

Inside This Issue

	PAGE
<u>Human Subjects:</u>	
New Rules for Reporting Clinical Trials	1
Who is SACHRP?	2
IRB Viewer	3
Helsinki Declaration Being Revised	3
<u>Biosafety:</u>	
Dangerous Goods Shipping Workshop	3
<u>Recent News:</u>	
Noteworthy Information	4

Contact us at:

Office of Research Compliance
CSAB 128
251-460-6625 (Office)
dlayton@usouthal.edu



Who is SACHRP?

Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP (**Secretary's Advisory Committee on Human Research Protections**) was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects. After approval by HHS Secretary, SACHRP recommendations are then finalized by the Office of Human Research Protections (OHRP) into new guidelines and on occasion modifications of the Common Rule. Some recommendations develop from formal reviews completed by other advisory groups and panels, for example the National Academy of Sciences. These objectives are met through establishment of subcommittees composed of experts in their respective fields. Based on their review and assessment of topics selected by the full SACHRP committee, the subcommittee develops recommendations for consideration by the SACHRP. The full committee who meets three times during the course of a year, then votes on all final recommendations and forwards them to the Secretary of HHS. "SACHRP's goals are to maximize human subjects protection while at the same time reducing unnecessary regulatory burden that do not contribute to the process", says Samuel Tilden, SACHRP Chair.

Examples of SACHRP activities that have provided continuance and improvement in the protection of human subjects include:

- Recommendations on Subparts C (prisoners) and D (minors) resulting in guidance from OHRP
- Human Research Protection Program Accreditation (*certification of accreditation organizations; incentives that could/should be in place to motivate organizations to achieve HRPP accreditation and potential impact of accreditation*)
- Harmonization of HIPAA and the Common Rule
- Workshop and Conference on IRB Review Models <http://www.aamc.org/research/irbreview/start.htm>
- International Research

"The SACHRP has recently completed a set recommendations for revising guidance materials on exemptions", says Tilden. Additionally, changes to are being proposed that would affect two expedited review categories, notably categories 5 and 7 due to confusion in interpretation amongst the research compliance community. These major changes in existing regulations are the direct result of deliberations and recommendations of the SACHRP.

"Currently, SACHRP has two active subcommittees reviewing all provisions of Subpart A of the Common Rule and Inclusion of Individuals with Impaired Decision Making Capacity", explained Tilden. The Office of Research Compliance will be closely following these activities and any changes specific to Subpart A and in OHRP guidance. It is also noted that SACHRP has voted on recommendations regarding responsibilities and training of investigators for further consideration by OHRP.

SACHRP serves as an important group examining concerns by assessing their importance to the general research community and those particular items of public interest. For additional information and previous meeting agendas and presentation materials on SACHRP activities go to: <http://www.hhs.gov/ohrp/sachrp>



Electronic Viewing of IRB Data

In July, 2006 the IRB made available an interface tool that would allow investigators to access their IRB study approval(s). The IRB "viewer" allows users read-only access to their protocol information once a user name and password is requested and created. The IRB encourages the use of this application, as it provides a secondary method of communication and improved service by assisting the study sites in their efforts to monitor issues specific to each individual's protocol(s).

If you would like access, please send an email to srobbins@usouthal.edu and provide a username and password for the application. You will be notified when your registration has been completed and provided instructions for downloading the IRB View Icon on your desktop.

Helsinki Declaration Being Revised

The World Medical Association (WMA) has initiated a review of the Declaration of Helsinki for the first time in seven years. The [*Declaration of Helsinki*](#) is the WMA's best-known policy statement. It was first adopted in 1964 and has been amended five times since, most recently in 2000. Proposed changes include extra protection for participants in medical research, the ability of the public to access a register of all clinical trials, and a statement clearly declaring that the well-being of the individual takes precedence over all other interests. Progress reports will be posted on the WMA web site. Read more http://www.wma.net/e/press/2007_14.htm

Dangerous Goods Shipping Training Workshop

By federal law, all individuals who have responsibilities for packaging and/or shipping hazardous/infectious substances are required to participate in certified training every 2 - 3 years (according to what/how you ship). Therefore, any USA employee who packages and/or ships hazardous/infectious substances must attend this training.

The Offices of Research Compliance and Safety and Environmental Compliance are hosting a Department of Transportation (DOT) Hazardous Materials Transportation One-Day Workshop on **March 13, 2008**. The workshop will be held in Room 264 of the Mitchell College of Business.

The training will cover air transportation, shipper responsibilities, packaging demonstration, etc. in as much detail as necessary for the participants to be in complete compliance with regulations. Training is also required when shipping on dry ice as a refrigerant. For all biological materials, a material transfer agreement (MTA) must be filled out for the materials that are being shipped off campus. You can contact the Office of Technology Transfer at 460-7932 for additional information. DOT will provide you with a Certificate of Attendance at the end of the session. We will administer a Post-Test at the conclusion of the session and will provide a Certificate of Completion of the training upon successful completion of the Post-Test.

Registration is required no later than March 4, 2008.

To register for the training, please email dlayton@usouthal.edu or call 460-6625.



Recent News (source: PRIM&R newsletter, January 2008)

F.D.A. Requiring Suicide Studies in Drug Trials - "After decades of inattention to the possible psychiatric side effects of experimental medicines, the Food and Drug Administration is now requiring drug makers to study closely whether patients become suicidal during clinical trials," reports [The New York Times](#).

"The new rules represent one of the most profound changes of the past 16 years to regulations governing drug development. But since the FDA's oversight of experimental medicines is done in secret, the agency's shift has not been announced publicly."

"The drug industry, however, is keenly aware of the change. Makers of drugs to treat obesity, urinary incontinence, epilepsy, smoking cessation, depression and many other conditions are being asked for the first time by the drug agency to put a comprehensive suicide assessment into their clinical trials."

Doctors Report Transplant Breakthrough - "In what's being called a major advance in organ transplants, doctors say they have developed a technique that could free many patients from having to take anti-rejection drugs for the rest of their lives," the [San Francisco Chronicle Reports](#).

"The treatment involved weakening the patient's immune system, then giving the recipient bone marrow from the person who donated the organ. In one experiment, four of five kidney recipients were off immune-suppressing medicines up to five years later."

Ties Are Cited as Issue in Spine Study - "Some of the nation's most prominent spine surgeons hailed it as a medical breakthrough," writes [The New York Times](#).

"In a study of nearly 240 patients with lower back pain, the doctors said that the Prodisc, an artificial spinal disk, had worked much better than conventional surgery in which patients' vertebrae were fused."

"As a surgeon, it is gratifying to see patients recover function more quickly than after fusion and return to their normal activities more easily," Dr. Jack E. Zigler, a well-known spine specialist and one of the study's lead researchers, said in a 2006 news release announcing the latest results of the Prodisc clinical trial."

"As it turns out, Dr. Zigler had more than a medical interest in the outcome. So did doctors at about half of the 17 research centers involved in the study. They stood to profit financially if the Prodisc succeeded, according to confidential information from a patient's lawsuit settled last year."

**** Noteworthy ****

The DHHS Office of Human Research Protections has released the 2008 edition of the International Compilation of Human Subject Protections. The 2008 version lists about 900 laws, regulations, and guidelines from 84 countries on human subject protections. Many of the listings include the web address, allowing the reader to link directly to the law, regulation, or guideline of interest. New this year is a separate listing of the standards that govern research involving embryos, stem cells, and cloning. <http://www.hhs.gov/ohrp/international/>

For those interested in the views of the presidential candidates on health, research and science issues, two outstanding resources are available on line: 1) "Your Candidates, Your Health" sponsored by *Research!America* in partnership with the AAMC and other interested organizations, and 2) "Science & Technology in the 2008 Election," sponsored by AAAS in partnership with AAU. <http://www.yourcandidatesyourhealth.org/> and <http://election2008.aaas.org>

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