



UNIVERSITY OF SOUTHERN CALIFORNIA
Human Subjects Newsletter



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Susan L. Rose, PhD, Executive Director

Revised Policy: Significant New Findings/Information (SNIF) Addendum

The Significant New Information/Findings (SNIF) policy was revised. The purpose of the policy is to improve the method for sharing new information with research participants.

Beginning **7/1/08**, researchers **MUST** submit a SNIF for use in disclosing significant new information to participants already enrolled in studies.

More information on the policy is available at:

http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/New_Findings_Memo.pdf

iStar "Sandbox" Back in Action

A practice site on iStar is available to assist training new users. The "sandbox" is for classroom instruction or to gain familiarity with the iStar system. Once an iStar account has been created, users are can log in to the "sandbox" site.

The "sandbox", or training site can be found at: <http://istartraining-chla.usc.edu>

Clinical Trials Registry: Requirement Enforced

Title VIII of the Food and Drug Administration Amendments Act of 2007, expands the federal registry requiring registration of all clinical trials, other than Phase I, and requires significantly more content. As of December 26, 2007 new data for initial registration became required, reaching back to include some clinical investigations that began before the law was passed.

- **ClinicalTrials.gov:** <http://www.ClinicalTrials.gov>
- **NIH—Clin Trials Registration:** <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html>

FDA No Longer Requires Declaration of Helsinki for International Research

The FDA now requires that international studies be conducted in accordance with good clinical practice, including review and approval by an independent ethics committee. The final rule updates the standards for the acceptance of foreign clinical studies not conducted under an IND.

More Info: <http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-9200.htm>

Contact Information

Office for the Protection of Research Subjects (OPRS)

Phone: (213) 821-1154

Email: oprs@usc.edu

Web: <http://www.usc.edu/admin/provost/oprs>

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