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**New IRB Policy and Template: Significant New Information/Findings**

The IRB has developed an improved method to provide significant new study information to previously consented subjects. This innovative method uses a simple one page document that clearly identifies the new information, and contains a signature line for subjects to sign.

More information on the policy and template is available at: [http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/New_Findings_Memo.pdf](http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/New_Findings_Memo.pdf)

**Health Sciences IRB Informed Consent Template Revised**

The Health Sciences Informed Consent template has been revised and is available online: [Template and Instructions for Adult Informed Consent](http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/ICF_Announce.pdf). Please use this updated template for all NEW studies. It is not necessary to replace already approved Informed Consent Forms.

A summary of the revisions to the template are available at: [http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/ICF_Announce.pdf](http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/ICF_Announce.pdf)

**Health Sciences IRB (HSIRB) Welcomes New Director**

Please join us in welcoming Sandra Jean, MS, CIP as the new director of the Health Sciences IRB. Sandy rejoins the USC Human Subjects Protection Program after previously working for the HSIRB as an administrator. Sandra brings a wealth of knowledge, varied experience, and high energy to the HSIRB. Ms. Jean can be reached at sjean@usc.edu or (323)-223-2340.

**USC IRB Student Mentor Featured in National Publication**

Urvi Patel, the IRB Student Mentor, was featured in the January 2008 issue of the IRB Advisor. The article focuses on Ms. Patel's role as an advisor to students trying to navigate the IRB process, her time spent as an IRB member, and her useful contributions to the entire Human Subjects Protection Program. The article is available online: [Student Mentor Serves on IRB, Helps Other Students Navigate System](http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/New_Findings_Memo.pdf), IRB Advisor (Jan 08).
News/Articles

- Research vs. Quality Improvement: A National Debate?
  The following articles are related to the recent OHRP inquiry into a John Hopkins Medical Center “quality improvement program” that used a checklist to reduce the number of infections in ICUs across several hospitals. The program was subsequently halted and John Hopkins was issued a Determination Letter from OHRP which believed the quality improvement program was in fact human subjects research.

  A. A Lifesaving Checklist, NY Time, (Dec 30, 2008):

     http://www.hhs.gov/ohrp/news/recentnews.html#20080115

  C. Clear results, disputed method, Baltimore Sun (Jan 12, 2008)
     http://www.baltimoresun.com/news/health/bal-te.checklist12jan12,0,6565270.story

  D. A Basic Hospital To-Do List Saves Lives, NY Times (Jan 22, 2008)

  E. Pointy-Headed Regulation, NY Times (Jan 27, 2008)

  - Supreme Court Hears Medical Device Case, NY Times (Dec 6, 2007)
    http://www.nytimes.com/2007/12/05/washington/05bizcourt.html

  - Guinea Pigging, New Yorker, V83, I42; pg. 36 (Jan 7, 2008)
    http://proquest.umi.com/pqdweb?did=1409279421&sid=1&Fmt=3&clientId=5239&RQT=309&VName=PQD (available only to USC network users or New Yorker subscribers).

  - WAYS TO IMPROVE INFORMED CONSENT ARE TESTABLE, STUDY SAYS, John Hopkins Medicine (Jan 12, 2008)
    http://www.hopkinsmedicine.org/Press_releases/2008/01_11_08.html

  - Doling out the placebo effect, LA Times (Jan 14, 2008)
    http://www.latimes.com/features/health/la-he-placebo14jan14,1.4887792.story

  - Supreme Court dismisses appeals in test drugs case, LA Times (Jan 14, 2008)

  - Antidepressants Under Scrutiny Over Efficacy, WSJ (Jan 17, 2008)
    http://online.wsj.com/article/SB120051950205895415.html

  - F.D.A. Requiring Suicide Studies in Drug Trials, NY Times (Jan 24, 2008)
    http://www.nytimes.com/2008/01/24/washington/24fda.html?_r=1&oref=slogin

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