

**USC** UNIVERSITY OF SOUTHERN CALIFORNIA  
**Human Subjects Newsletter**



Published by the Office for the Protection of Research Subjects (OPRS)  
Susan L. Rose, PhD, Executive Director

## iStar Emails Stopped if “Spam” Filters On

It has come to the attention of the iStar technical team that notifications and other correspondence emailed on the behalf of iStar are being routed to individuals’ “junk/spam” email folders. These email messages include approval notices, expiration notices, and other types of correspondence. Because of the time sensitivity related to most of these messages, it is important that you receive them. Take a moment to designate [istar@chla.usc.edu](mailto:istar@chla.usc.edu) as a safe sender in your email program.

## Congratulations to Dr. Richmond/USC School of Pharmacy on the New Professional Doctorate Program in Regulatory Science (DRS)

The new doctorate program will be a great complement to the current and successful Master in Regulatory Science offered at the School of Pharmacy. The new program addresses the complex regulatory and reimbursement paths required to market medical and foods products internationally. The proposed 64-unit professional doctorate is a novel, specialized program of study that cultivates research, leadership and inquiry skills for advanced students in the emerging profession of global regulatory science. Again, congrats!

[Our NEW professional DOCTORATE in Regulatory Science!](#)

## 2008 USC IRB Satisfaction Survey Results Available

The results of the 2008 Annual IRB/STAFF Survey are in. The Office for the Protection of Research Subjects (OPRS) uses this annual survey to evaluate and improve the Human Subjects Protection Program. Survey participation is voluntary and responses are anonymous. The survey was designed by the OPRS, and incorporates suggestions/improvements from previous years. All aspects of the Human Subjects Protection Program are rated including: staff, the IRB committees, iStar (online IRB application system), education, websites, and overall customer satisfaction.

The survey was administered through [surveymonkey.com](http://surveymonkey.com) and distributed via the Human Subjects Listserv to over 4,000 subscribers; 308 participated. [Results of the 2008 USC IRB Survey](#)

## Clin Trials Registry and IRB Role Expanded by FDA/NIH

Title VIII of the Food and Drug Administration Amendments Act of 2007, expands the federal registry in several important ways. First, it is no longer limited to trials of drugs intended to treat serious or life-threatening diseases, but rather requires registration of all clinical trials, other than Phase I, and requires significantly more content. As of December 26, new data points for initial registration became required, even reaching back to include some clinical investigations that began before the law was passed. NIH has also been directed to expand [ClinicalTrials.gov](http://ClinicalTrials.gov) to include trial results. By this fall, sponsors will have to submit results information about approved products, and soon thereafter, adverse event data will be required on the site.

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

## IRB Student Mentor Chosen for “Student Recognition Award”

Urvi Patel, the IRB Student Mentor, was chosen for the 2008 USC Student Recognition Award which honors graduate/professional and undergraduate student leaders who have demonstrated a noteworthy level of commitment to leadership, involvement, service and scholarship at the University of Southern California. Urvi has served as the USC IRB Student Mentor/Member for the last two years in addition to pursuing a Ph.D. in Psychology. While performing in these three capacities, Urvi has also been invited to present her research at numerous conferences throughout the U.S. and asked to serve as a guest lecturer at several local universities. She is truly deserving of this award. Congratulations Urvi!



Urvi Patel, IRB  
Student Mentor

## New Articles

**HSP and Accreditation: Growing Pains and Successes Mark First Seven Years**, *Medical Research Law & Policy Report*, Vol. 07, No. 04, (Feb 20, 2008) [http://www.uni-cornllc.com/file\\_download/1](http://www.uni-cornllc.com/file_download/1)

**Cigarette Company Paid for Lung Cancer Study**, *NY Times* (March 26, 2008)  
<http://www.nytimes.com/2008/03/26/health/research/26lung.html>

**Report Claims Clinical Trials Miss Many Populations**, *Washington Post* (April 1, 2008)  
<http://www.washingtonpost.com/wp-dyn/content/article/2008/04/01/AR2008040102092.html>

**Merck Wrote Drug Studies for Doctors**, *NY Times* (April 16, 2008)  
<http://www.nytimes.com/2008/04/16/business/16vioxx.html?th&emc=th>

**Eight Years after Jesse’s Death, Are Human Research Subjects Any Safer?**, *Hastings Center Report*, Vol. 38, Number 2 (March-April 2008)  
[http://muse.jhu.edu/journals/hastings\\_center\\_report/v038/38.2gelsinger.pdf](http://muse.jhu.edu/journals/hastings_center_report/v038/38.2gelsinger.pdf)

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