

# USC UNIVERSITY OF SOUTHERN CALIFORNIA Human Subjects Newsletter

Published by the Office for the Protection of Research Subjects (OPRS)  
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## American Recovery & Reinvestment Act (ARRA): USC IRBs to Facilitate Approval

USC researchers applying for ARRA funds can be assured that the USC IRBs will facilitate IRB review and approval for those projects. ARRA grant applications that have been funded or will likely be funded shall receive priority review by the IRB. Only research projects with a promise of funds should be submitted for IRB review.

**More information on ARRA IRB process can be found at:**

[http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news\\_items/ARRA\\_Announce.pdf](http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/ARRA_Announce.pdf)

## Good Clinical Practice (GCP) Education Now Mandatory

A new education requirement has been mandated as part of USC efforts to promote the highest ethical standards in the conduct of clinical research. By January 1, 2010, all principal investigators and key personnel conducting clinical research/clinical trials that require Full Board IRB review must complete GCP training. These studies will not be approved until the training requirement is met. The GCP requirement does not apply to research that is determined to be Expedited or Exempt. GCP training is available on the CITI website and can be accessed through the link below.

**More information on the GCP requirement and the training course can be found at:**

<http://www.usc.edu/admin/provost/oprs/training/gcp.html>

## IRB Student Mentor Receives 2009 Student Recognition Award



The IRB student mentor, Erica Lim, was recognized and honored for her outstanding leadership, volunteerism, and commitment to the campus and community as part of pre-commencement ceremonies held on May 14<sup>th</sup>. While pursuing a Masters in Social Work (MSW), and serving as the IRB student mentor and IRB committee member, Ms. Lim also played an active role in voter registration drives, hosted women's rights workshops in Central America, and supported dialogue regarding Middle East peace talks among Israeli and Arab populations (locally and abroad). This is the 2<sup>nd</sup> year in a row the IRB Student Mentor has received this honor (Urvi Patel—2008). Congratulations Erica!

Erica Lim displaying her Student Recognition "bling" in front of Tommy Trojan. *Photo: Argellis Ortiz*

## 2009 USC IRB Satisfaction Survey Results Available

The 2009 IRB satisfaction survey results are available online ([2009 USC IRB Survey: Results](#)). Nearly 500 human subjects researchers participated in the survey, a record number in its

four year history. Respondents generally had positive remarks regarding the IRBs and the entire HSPP (Human Subjects Protection Program). The goal of the survey was to find areas of the HSPP that needed improvement. Thanks again to all who participated, your feedback is important.

## New Brochures Created for Faculty Advisors and Principal Investigators

Two new brochures have been published as resources for those conducting human subjects research:



### [Are You a Faculty Advisor? The ABCs of Human Subjects Responsibilities](#)

This brochure is for Faculty Advisors (FA) serving on student IRB projects. It provides a brief overview of the FA role and also includes tips for navigating the IRB process from the FA perspective.



### [Are You Conducting Research Using Human Subjects? A Guide for Investigators](#)

This brochure is designed to guide Principal Investigators through the IRB process. It includes information on defining human subjects, the levels of IRB review, and informed consent requirements.

Additional USC human subjects research brochures can be found at:

<http://www.usc.edu/admin/provost/ops/training/brochures.html>

## Conflict of Interest and Consent Stamping: iStar Upgrades

The financial Conflict of Interest (COI) questions in iStar have been amended to reflect expectations of the AAMC (Association of American Medical Colleges) and federal agencies. An additional change has been made to the approved Consent documents which will now be automatically converted to PDFs and stamped with the study expiration date.

iStar upgrades memo:

[http://www.usc.edu/admin/provost/ops/private/docs/ops/news\\_items/Announce\\_031008.pdf](http://www.usc.edu/admin/provost/ops/private/docs/ops/news_items/Announce_031008.pdf)

## IRB/iStar Training Videos Available on HSPP Website

IRB training videos are available as an aid to understanding the IRB process. While the videos are directed toward new investigators, they also serve as a refresher for more experienced researchers. The videos cover all aspects of the IRB process including: the iStar IRB application system, the informed consent process, how to determine the level of IRB review, how to submit amendments, and more. The videos are offered in segments so investigators can choose ones they want to watch. Share a link to these videos with your students and colleagues.

IRB/iStar Training Videos: <http://www.usc.edu/admin/provost/ops/training/videos.html>

## Articles of Interest

- [New Drugs Have Allure, Not Track Record](#) *NY Times* (May 19, 2009)
- [Fighting for a Last Chance at Life](#) *NY Times* (May 17, 2009)
- [Pfizer Will Provide Prescriptions for Free to Jobless](#) *NY Times* (May 14, 2009)
- [3 Researchers at Harvard Are Named in Subpoena](#) *NY Times* (March 27, 2009)
- [Report of the International Bioethics Committee of UNESCO \(IBC\): ON CONSENT](#) *UNESCO* (2008)