

USC UNIVERSITY OF SOUTHERN CALIFORNIA
Human Subjects Newsletter

Published by the Office for the Protection of Research Subjects (OPRS)

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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 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/opr/private/docs/opr/news_items/Announce_031008.pdf

OPRS Host Visitors from Changhua Christian Hospital (CCH) of Taiwan



Faculty from Changhua Christian Hospital (CCH) in Taiwan visited USC on February 25th to learn about the AAHRPP accreditation process. A tour of the new County/USC hospital and GCRC (General Clinical Research Center) was arranged for the visitors. Special thanks to Priscilla Mak (County USC) and Susie Nakao (GCRC) for meeting with the CCH team and leading tours of their respective facilities.

From L-R: Peter Mestaz (USC), Dr. Chin-San Liu (CCH), Dr. Boris Wang (Quest Diagnostics), Dr. Shu-Chen Liao (CCH), Dr. Susan Rose (USC), and Dr. Luke Yeween Huang (CCH)

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/opr/training/videos.html>

Human Subjects/IRB Education Sessions Offered in April

Basic Human subjects education sessions, open to interested faculty, staff, and students, are routinely offered on both the Health Sciences Campus (HSC) and University Park Campus (UPC). The education sessions cover the IRB application process and human subjects basics.

Education sessions can be arranged for classrooms, faculty or staff meetings, or other groups. To arrange for a separate education session, contact the oprs@usc.edu.

- **University Park Campus:** [April 2, 2009](#)
- **Health Sciences Campus:** [April 30, 2009](#)

AAHRPP is Coming Back...USC to Apply for Reaccreditation in 2009

The University's Human Subject Protection Program (HSPP) accreditation status will be reassessed in 2010. Preparations for this are already in progress as the reaccreditation application is due September 2009.



Accreditation is the responsibility of Office for the Protection of Research Subjects (OPRS). Reviewers from AAHRPP, the accrediting body, will visit USC to ensure that the university meets or exceed accreditation standards.

Education and updates will be provided to the university research community because all are part of the accreditation process. Efforts underway include: improving existing policies and practices, providing extensive education and outreach on current and new best practices, identifying and eliminating systemic problems, and keeping human subjects research stakeholders involved. Stay tuned for more updates and information as the reaccreditation process unfolds.

Articles of Interest

- [Drug Maker Said to Pay Ghostwriters for Journal Articles](#) *NY Times* (December 12, 2008)
- [Study Refutes Claims on AIDS Drug Trials](#) *NY Times* (January 28, 2009)
- [B&D Consulting Comments on AHRQ Assessment of Third-Party Payment Impact on Clinical Trials and Evidence Base](#) *B&D Consulting* (Jan. 28. 2009)
- [U.S. HIPAA Privacy Rule Fails To Adequately Protect Patient Privacy And Hampers Health Research](#) *Science Daily* (February 4, 2009)
- [U.S. to Compare Medical Treatments](#) *NY Times* (February 16, 2009)
- [Ethical and Scientific Implications of the Globalization of Clinical Research](#) *NEJM* (February 19, 2009)
- [Outsourcing of Drug Trials Is Faulted](#) *NY Times* (February 19, 2009)
- [A Push to Spell Out a Drug's Risks and Benefits](#) *NY Times* (February 26, 2009)
- [Senator Asks Pfizer About Money to Harvard](#) *NY Times* (March 4, 2009)
- [Prosecutors Plan Crackdown on Doctors Who Accept Kickbacks](#) *NY Times* (March 4, 2009)
- [No Legal Shield in Drug Labeling, Justices Rule](#) *NY Times* (March 5, 2009)
- [Should Physicians Inform Relatives of Genetic Risks, Without the Consent of the Patient?](#) *Medscape Today* (March 5, 2009)