Notice to All iStar Users: iStar Web Address (URL) Change

"There is a problem with this website's security certificate"

iStar users who receive this message must access iStar through the new web address: https://istar.usc.edu

Part I of AAHRPP Reaccreditation Application Submitted

The OPRS is pleased to announce the submission of Part I of the AAHRPP Reaccreditation Application and continues preparations for a comprehensive site visit in the spring. The research community will be kept apprised of this effort because many researchers and IRB members will again be involved.

For more information on the AAHRPP Reaccreditation Process Visit: http://www.usc.edu/admin/provost/oprs/aahrpp

FDA Announces Rules for Expanded Access to Investigational Drugs for Treatment Use

The final rule, “Expanded Access to Investigational Drugs for Treatment Use,” amends regulations on expanded access to investigational new drugs for treating patients. The final rule clarifies existing regulations and adds new types of expanded access for treatment use. Under the final rule, expanded access to investigational drugs for treatment use will be available to:

- individual patients, including in emergencies
- intermediate-size patient populations
- larger populations under a treatment protocol or treatment investigational new drug application (IND)

For more information visit: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm172492.htm

USC Issues Institutional Conflict of Interest (ICOI) in Research Policy

USC has implemented an Institutional Conflict of Interest in Research (ICOI) policy. The objective of the policy is to “promote the highest ethical standards in the conduct of research in situations where institutional conflicts of interest may occur, and to determine those instances when an ICOI is unacceptable.

Continued on next page...
An ICOI may occur when a financial interest of the University (e.g., investments held by the University in a company) has the potential to bias research conducted by its employees or students, or creates an unacceptable risk to human subjects.

The policy requires investigators who know of an ICOI to disclose it to the Vice Provost for Research Advancement (VPRA) who will then take the appropriate steps to address the conflict with a team of appointed experts.

The Institutional Conflict of Interest (ICOI) in Research policy can be found at: http://policies.usc.edu/policies/InstitutionalConflict090109.pdf

FWA (Federalwide Assurance) and IRB Registration Numbers Available on OPRS Website

The OPRS website now lists USC FWA registration numbers and IRB Registration numbers. This information is oftentimes requested by federal and private grant agencies, and by pharmaceutical industry sponsors so it was imperative to have them easily accessible.


IRB Student Mentor Office Hours Available

The fall office hours for the IRB Student Mentor, Argelis Ortiz, are provided below. Mr. Ortiz is available to assist any student with the IRB application process. Please take advantage of this resource.

IRB Student Mentor Contact Info: Argelis Ortiz, irbgara@usc.edu or 213-821-1154

IRB Student Mentor Fall 2009 Office hours:
- Tuesday 9:00—5:00
- Thursday 8:00—12:30
- Friday 9:00—4:00

Human Subjects Education Session Schedule: AY 2009-2010

Below is the AY 2009-2010 schedule for Human Subjects Education sessions. These courses serve as an introduction to human subjects research and the IRB process. The OPRS is also available for group or individual sessions as needed by contacting the oprs@usc.edu.

University Park Campus:
- November 5, 2009
- December 3, 2009*
- February 4, 2010
- March 14, 2010
- April 1, 2010

Health Sciences Campus:
- November 19, 2009
- January 14, 2010
- March 18, 2010
- May 6, 2010
*Advanced session
What is the CITI human subjects "refresher course"? Can I take it?

The human subjects "refresher course" is offered to investigators/key personnel who have previously completed a human subjects training course. The "refresher course" is not intended for those completing human subjects training for the first time (the basic course is designed for them). To complete the "refresher course" login into CITI, "Add a course or update your learner groups", and elect "refresher course" when prompted.

I Need to Complete GCP Training and the Human Subjects "Refresher" Course, Must I Take Both?

NO! Investigators/key personnel that complete GCP training DON’T need to complete the human subjects "refresher course" (the course offered in CITI after the initial three year certificate expires). The GCP course will fulfill the "refresher" human subjects training requirement for three years from the date it is completed. However, the human subjects "refresher course" does not fulfill the GCP training requirement. GCP training is a one time requirement while human subjects education is required every three years.

Did You Know? Helpful Website Resource

The USC HSPP is proud to have such a dynamic and comprehensive human subjects research website. In the next few Human Subjects Newsletters, web resources will be highlighted so the USC research community can continue to take advantage of them. The first highlight is below.

- **Model IRB Applications** are provided as a resource for those submitting an iStar application for the first time. The annotated model applications provide a response for each question in the iStar application so users can get an idea of what a proper answer looks like. Take advantage of this resource or share with others.

  The model applications can be found at: [http://www.usc.edu/admin/provost/oprs/research/templates.html](http://www.usc.edu/admin/provost/oprs/research/templates.html)

**Articles of Interest**

- [Senator Moves to Block Medical Ghostwriting](http://www.nytimes.com), NY Times (August 19, 2009)
- [Research Trove: Patients' Online Data](http://www.nytimes.com), NY Times (August 25, 2009)
- [Medical Editors Push for Ghostwriting Crackdown](http://www.nytimes.com), NY Times (September 17, 2009)
- [Medicare Data Could Cut Health Care Costs](http://www.npr.org), NPR (September 29, 2009)