“We heard you”…10 Fixes Resulting from the 2009 IRB Survey

As an AAHRPP accredited human subjects protection program, the USC HSPP routinely makes improvements to the program based on national best practices and local monitoring and oversight. In addition, the annual USC IRB Survey provides additional insights into improvements the respondents suggest. The link below provides some examples of improvements suggested in 2009 by respondents to the survey.

We are open to suggestions at anytime so feel free to contact us at: oprs@usc.edu or (213) 821-1154.

10 Fixes Resulting from the 2009 IRB Survey:

Reaccreditation and Site Visit for USC Human Subjects Protection Program Early 2010

Preparations have already begun on the extensive reaccreditation application process, precedes a rigorous 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. The annual accreditation materials for this year have been approved by AAHRPP, the accrediting body: AAHRRPP Approves USC 2009 Annual Report

New Brochures for Mentors and Medical Students

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

**Guide to Human Subjects Research For USC Medical Students**
This booklet provides guidance for medical students who conduct biomedical, social and behavioral research or otherwise participate in research activities while at the Keck School of Medicine (KSOM).

**Mentoring USC Student Researchers**
Mentoring is the social foundation of research. It is the mentor who has the potential to draw the best from the student by acting as an adviser, teacher, role model, motivational friend and supportive advocate. This booklet serves as a guide and overview of that process.

All USC human subjects research brochures can be found at:
http://www.usc.edu/admin/provost/oprs/training/brochures.html
Good Clinical Practice (GCP) Education 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/ops/training/gcp.html

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" (course offered in CITI after 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.

iStar Improvements to Aid Investigators

The iStar technical team, having completed a successful move of servers to USC, would like to highlight three specific improvements to be launched in July that many investigators will find helpful:

1. Copy Study, a new function that allows investigators to copy an existing study and use it as a template to complete a new one.

2. Changes to iStar questions are making the application easier and clearer.
3. **NHSR (Not Human Subjects Research)** applications are available for both campuses, UPC and HSC. These applications are for investigators whose project may not be considered human subjects research yet need a determination of NHSR by the IRB. The application is three pages long and can be accessed by clicking on “Does my project qualify as Not Human Subjects Research?” tab in iStar.

**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.

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<tr>
<th>University Park Campus:</th>
<th>Health Sciences Campus:</th>
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<td>September 3, 2009</td>
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*Advanced session

**iStar Training to be Offered in AY09-10**

iStar training will be provided on each campus at least once per semester in the upcoming academic year. The sessions will be announced through this newsletter so please stay tuned. These sessions are open to anyone in the USC research community.

**CITI Program Unavailable from 8/03—8/08 for System Upgrades. PLAN ACCORDINGLY!**

On Monday, August 3rd, at approximately 8 AM EST, the CITI Program web site will be taken offline for a system upgrade. CITI expects the downtime to be approximately five days. Please complete your work and log off prior to this time. Contact the CITI helpdesk for more information citi@usc.edu or (213) 821-5272.

**Articles of Interest**

- [Drug Agency May Reveal More Data on Actions](#), NY Times (June 1, 2009)
- [IRB Accountability RFI](#), FASEB (June 3, 2009)
- [The FDA as a Public Health Agency](#), NEJM (June 11, 2009)
- [Bionic Eye Sheds Light on Blindness](#), MSNBC (June 16, 2009)
- [Grant System Leads Cancer Researchers to Play It Safe](#), NY Times (June 28, 2009)