CITI Good Clinical Practice (GCP) Course Offers CME Credits

Pharmaceutical companies and other research sponsors often require researchers to undergo GCP training. The CITI GCP course provides training on: human subjects protections, well-designed trials, assuring accurate data collection, maintaining a compliant audit trail, reporting adverse events, and handling research records.

The optional GCP program under the aegis of CITI is highly recommended for all biomedical researchers and staff. CME/CEU credits are available through the University of Miami for completing the CITI GCP course. Up to 4 AMA PRA Category 1 credits are available for a fee of $60. CME credits are also available for completion of the mandatory Human Subjects Research course.

- CITI GCP Course: [http://www.usc.edu/admin/provost/oprs/training/gcp.html](http://www.usc.edu/admin/provost/oprs/training/gcp.html)
- Info on CME Credits: [https://www.citiprogram.org/citidocuments/cme/index.htm](https://www.citiprogram.org/citidocuments/cme/index.htm)

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

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

The reaccreditation process is again being spearheaded by the Office for the Protection of Research Subjects (OPRS) and encompasses more than just an application. While the application serves as the blueprint for the HSPP, AAHRPP will also visit USC to ensure that practices mirror policies and that the USC HSPP meets or exceed accreditation standards.

The OPRS will keep the university research community informed, prepared, and ready to be part of the accreditation process. OPRS efforts underway include: improving existing policies and practices, providing extensive education and outreach on current and new best practices, identifying and eliminating problems, and keeping all human subjects research stakeholders up to date.

Please stay tuned for more updates and information as the reaccreditation process unfolds.

Student Mentor Available to Assist Students with IRB Process

The OPRS has two IRB Student Mentors who assist student researchers with the human subjects research process: Argelis Ortiz (MSW student) and Erica Lim (MSW student). In addition to mentoring students they also serve on the UPIRB Committee as voting members. Please take advantage of this excellent resource or inform your students and/or colleagues about it.

Student Mentor Contact Info:
irbgara@usc.edu, (213)-821-1154, or
[www.usc.edu/admin/provost/oprs/research/mentor.html](http://www.usc.edu/admin/provost/oprs/research/mentor.html)
Human Subjects/IRB Education Sessions Offered

Education sessions on the Human Subjects/IRB process are offered on a routine basis at UPC and HSC. These introductory education sessions are an excellent opportunity for new investigators (faculty, staff, or students) to learn about the IRB process and human subject protections at USC.

The sessions also serve as an excellent refresher for more experienced investigators. Sessions are also available by request by contacting oprs@usc.edu

Dates for the upcoming Human Subjects/IRB Education Sessions:

- **University Park Campus:** February 05, 2009 at 12:00 in CUB (New Credit Union Bldg), 3rd Floor
- **Health Sciences Campus:** January 29, 2009 at 12:00 in McKibben Hall (MCH) 256

REMINDER!!! Significant New Findings/Information (SNIF) Addendum

Researchers MUST submit a SNIF Addendum to the IRB for use in disclosing significant new information to currently enrolled participants. A SNIF should only be used if the new information may affect a subject’s willingness to continue participation.

More information on the policy is available at: [http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/New_Findings_Memo.pdf](http://www.usc.edu/admin/provost/oprs/private/docs/oprs/news_items/New_Findings_Memo.pdf)

UPIRB to No Longer Stamp Study Recruitment/Advertisement Documents

In meeting current best practices, the UPIRB has elected to discontinue stamping study recruitment and advertisement documents. The documents are still required to be reviewed and approved by the UPIRB, but the approval date stamp will no longer be included on these documents. Stamping recruitment and advertisement documents is not a federal regulation, and often times prolongs the approval process. **But remember, these documents still need to be submitted to the IRB for review and approval.**

REMINDER: iStar Changes Implemented in October

What has changed and how will it affect you? In addition to the numerous bug fixes and the system upgrade that helped boost performance, there are many other significant changes including the Continuing Review and Amendment applications. The changes and announcement made in October are included in the memo below in case you missed them.

iStar Changes (October 2008)


Articles of Interest

- [F.D.A. Is Lax on Oversight During Trials, Inquiry Finds](http://www.nytimes.com/2009/01/12/business/12fda.html), NY Times (Jan. 12, 2009)
- [FDA lets drugmakers advise doctors on unapproved uses](http://www.reuters.com/article/health/fda-lets-drugmakers-advice-doctors-on-unapproved-uses-idUSL2N0F819220090112), Reuters (Jan. 12, 2009)
- [FDA Scientists Ask Obama to Restructure Drug Agency](http://online.wsj.com/article/SB123628033518246787.html), WSJ (Jan. 8, 2009)
- [Helsinki discords: FDA, ethics, and international drug trials](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)62013-7/abstract), The Lancet (Jan. 3, 2009)