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**AAHRPP Related Changes...What Has Been Done at USC? What Should I know?**

Obtaining AAHRPP accreditation required changes to numerous parts of the Human Subjects Protection Program (HSPP) including policies and procedures, the iStar application system, and human subjects protection practices. A series of live education sessions are planned throughout the AY2007-08 to explain these changes, and impact on faculty, staff, students, and IRB members/staff conducting human subjects research.

A webpage with summaries of these AAHRPP changes and resources to help address them are available at: [http://www.usc.edu/admin/provost/oprs/aaahrpp](http://www.usc.edu/admin/provost/oprs/aaahrpp).

**iStar Changes**

The iStar program has been updated to reflect AAHRPP accreditation changes and requirements. The following are links to two announcements regarding these changes. Please take a moment to review them.

- [iStar Changes Implemented on October 12th](http://www.usc.edu/admin/provost/oprs/aaahrpp) (changes to Amendments, Reportable Events and HIPAA!)
- [iStar Changes Implemented on 7/12](http://www.usc.edu/admin/provost/oprs/aaahrpp) (general iStar application changes)

**HSPP Website Improvements Noted**

Recent improvements to the homepage and the addition of footer links to every webpage have made the entire website easier to navigate and visually more appealing. If you haven’t already, please visit and “bookmark” the HSPP website for access to a wealth of human subjects resources and information including iStar, CITI, and information on protecting subjects. If you have any suggestions or requests for other links or information please email [oprs@usc.edu](mailto:oprs@usc.edu).

USC HSPP Website: [http://www.usc.edu/admin/provost/oprs](http://www.usc.edu/admin/provost/oprs)
Continuous Quality Improvement Launched by OPRS

The OPRS is undertaking a new quality assessment program of the IRB and PI interface, as part of its AAHRPP accreditation requirement. This program will involve assessing randomly selected PIs and examining their research and IRB records.

Study records, such as informed consents, questionnaires, regulatory documents, etc...will be evaluated to see that they are as described in the iStar application. Findings and recommendations, if any, will be discussed with the PI.

This assessment will involve only a few studies per month out of all active IRB studies. Please stay tuned for more information.

CITI (Human Subjects Edu): Two New Courses Announced

Two new optional courses are available in CITI. They are described below.

- **Good Clinical Practice (GCP)**
  This optional program is highly recommended for all biomedical researchers and staff. GCP training provides knowledge necessary for protecting human subjects, for well-designed trials, for assuring accurate data collection, for maintaining a compliant audit trail, for reporting adverse events, and for handling research records accordingly. Pharmaceutical companies and other research sponsors monitor investigator compliance with GCP, and may require training.

- **The Responsible Conduct of Research (RCR)**
  This optional course is available to all USC researchers and staff. The course provides comprehensive training in the 9 core areas of RCR (mentoring, data sharing, authorship, etc). Classroom instructors of research methods courses can use this online tutorial as an adjunct to class instruction.

Feedback Sought on CITI Program

We are requesting submission of any ideas, suggestions, or complaints regarding the CITI course so they can be addressed. Send to oprs@usc.edu. Expect in the next few months some improvements to the CITI program to streamline the system and improve usability.

“Key Personnel” Human Subjects Education Requirement

Students and faculty advisors, be aware that as of October 1, 2007, all “key personnel” listed in an IRB application (including Faculty Advisors) must complete CITI human subjects training. A short course was created in CITI to expedite compliance for those faculty advisors who only serve as an advisor and do not conduct their own human subjects research. For questions regarding CITI or the training policy visit the OPRS website (http://www.usc.edu/admin/provost/oprs) or email oprs@usc.edu.

- **Reminder of Human Subjects Education Requirement** (announcement of policy enforcement)
- **CITI (Human Subjects Education)** (link to FAQ/login instructions page)
Human Subjects Education Sessions on the UPC and HSC

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

Also, individual sessions can be arranged for classrooms, faculty or staff meetings, or other groups. To find out when the next education session is offered click on the links below or to arrange for a separate education session, contact the oprs@usc.edu.

Upcoming Sessions:
- Health Sciences Human Subjects Education Session (10/18/07)
- University Park Human Subjects Education Session (11/08/07)
- Session Handouts/Education Materials

Session info can also be found at: http://www.usc.edu/admin/provost/oprs/oprs/education.html

News/Articles
- Headway in developing a faster-acting antidepressant; Los Angeles Times (August 27, 2007)
- Iowa settles stuttering study lawsuit; USA Today (August 2007)