Moving Forward with a Fully Accredited Human Subjects Protection Program—Academic Year 2007-2008

July 05, 2007

To the Human Subjects Research Community:

I would like to take the hiatus of summer to reflect on what has been achieved as well as the commitments that are forthcoming.

USC became an AAHRPP accredited institution for the protection of human subjects on June 15, 2007. As an AAHRPP accredited institution, USC is acknowledged as having a program that exceeds regulatory requirements and is recognized as a leader in the human subject protections arena.

Creating a USC wide Human Subjects Protection Program (HSPP) has been a challenging and lengthy process. It required establishing a team approach that involved all members of the Human Research community including Faculty, staff and students, which enabled an excellent system to be created.

Please read below for more information about current accomplishments and future initiatives for the HSPP.

Sincerely,

Susan L. Rose, Ph.D
OPRS Executive Director

Looking back since the accreditation process began, here is an overview:

- It took two years from the initial pre-application (1000+ pages) to the “response” submission to AAHRPP’s site visit report.
- The formal AAHRPP application was over 1400 pages long and essentially described the entire HSPP on paper.
- The 3-day site visit in March 2007 consisted of 60 interviewees across both campuses, involved all four USC IRBs, was conducted by 5 AAHRPP site reviewers, and required more than 60 education sessions over several months to prepare all interviewees.
- The written response to the AAHRPP site visit report was 600+ pages, addressed 27 different elements—all requiring changes to HSPP Policies and Procedures, iStar, IRB practices, and education.
The upcoming academic year will build on education practices:

- **Change to CITI Policy for Faculty Advisors**
  In the Fall 2007, all Faculty Advisors designated on student IRB applications will be required to complete the online CITI human subjects education program. Student projects will not receive IRB approval if the designated Faculty Advisor does not complete CITI education. More information on this policy enforcement will be distributed later.

- **New CITI Modules Available on Good Clinical Practices and Responsible Conduct of Research, and others**
  Optional education will be available in Fall 07 on Good Clinical Practices (GCP), Responsible Conduct of Research (RCR), International Research, and advanced education for experienced human subjects researchers.

- **Ongoing In-Person Education Sessions**
  Individual, classroom, faculty, and group education sessions are available by request, and monthly education sessions are planned for Fall 07. These sessions, which cover the basics of human subjects research regulations and ethics, are designed for new/beginning researchers. The sessions have been well received and beneficial for conducting research. Invitations for specialized sessions come from many schools including RSOE, Keck, Marshall, Annenberg, Pharmacy, Psychology and others. If you would like more information, please contact the oprs@usc.edu.

- **Brochures and Education Materials**
  The “Should I Participate in Research?” brochure was updated to include research terms that are easier to understand, updated contact and research information, and a list of informational websites on research and participating in it. This brochure is aimed at potential human research subjects/participants to help them make informed decisions about whether to participate in a study or not. The brochure is being distributed at medical clinics and offices throughout the LAC+USC Medical center, and available to all researchers for their own distribution.

An extensive library of brochures and educational materials can be downloaded from the OPRS website (http://www.usc.edu/admin/provost/oprs/training/brochures.html), and are also available in hard copy.

- **Continuous Quality Improvement (CQI)**
  The goal of CQI is to ensure that USC human subject researchers are to meet and exceed basic requirements and expectations. CQI is achieved through assessing researcher compliance, IRB compliance, IRB practices, and assessment of research records, documents, forms, and iStar applications.

  Investigators may be randomly selected to receive a routine audit, or audits may be for cause. These audits proactively enhance human subjects protections and should not be interpreted as punitive. During a visit, Investigators are encouraged to discuss any areas of concern with IRB processes. The CQI program will involve a joint effort between the OPRS office, and the School of Pharmacy’s Regulatory Science Program.
USC/UCLA IRB Retreat October 26, 2007
This all day event will include a morning discussion of IRB issues and an afternoon speaking engagement of topics covering both biomedical and social behavioral research. The retreat is aimed at IRB members, staff, and invited guests. All invitees must RSVP.

Resources for Human Subjects researchers are being updated:

- Updated Online USC Policies and Procedures for Protecting Human Subjects
  These policies and procedures are now consistent with the AAHRPP accrediting body elements and reflect our current practices. They include detailed descriptions of regulatory requirements, IRB practices, types of IRB submissions, and application and review requirements. It is intended to be a comprehensive manual of the components of the Human Subjects Protection Program, and how they work together to protect human subjects. It is also a good reference for looking up IRB terminology and for explanations on how and why the IRB operates.
  

- HSPP Website Revised
  The updated HSPP websites provide a wealth of information to USC researchers and subjects. The revised, more intuitive, user-friendly websites receive approximately 50,000 hits per month. Visit the site for the latest news, IRB forms, education sessions, brochures, and links to iStar, CITI, UPC/HSC and regulatory agencies.

- Human Subjects Newsletter
  The Newsletter is used by OPRS as a tool to disseminate important policy changes, announcements, education session availability, and more to the research community at USC. Subscribers include representatives from schools and departments, university wide. To join the Newsletter, send an email request to the oprs@usc.edu.

- iStar Enhancements
  Enhancements are continually being made to increase efficiency, usability, and user satisfaction, as well as linking it with planned research administration products.

  In early 2007, the iStar server was upgraded to increase processing and stability. The online IRB application system provides a more efficient IRB review system and serves as a useful tracking mechanism.

- Updated IRB Application (iStar) Questions
  Some questions in iStar applications have been modified to meet accreditation requirements and to keep up with regulatory changes. Before the revised application questions are put into production, a list of changes will be sent to all iStar users to highlight the changes and provide guidance for answering them.
Other Information

- **HSPP Annual Survey**
  The annual customer satisfaction survey, sent out through the Newsletter, elicits anonymous feedback on the Human Subjects Protections Program from the USC research community. Responses are tabulated and program improvements are made based on researcher comments and suggestions.

- **USC—A National Presence**
  As an AAHRPP accredited institution, USC joins other top tier research institutions in its mission of protecting human subjects participating in research, and exceeding expectations. USC’s educational materials have been widely adopted and OPRS personnel are on the faculty and planning committees for national conferences.