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Changes to Human Subjects Protection Program Due to AAHRPP: Detailed Handout Available Online

An education handout covering AAHRPP related changes to the Human Subjects Protection Program (HSPP) is available online. The handout walks through modifications and additions to iStar, updated Policies & Procedures, IRB/Investigator practices, guidelines and checklists, and more. Take a moment to review these changes as they affect all human subjects research stakeholders. AAHRPP Related Changes to the HSPP (AY2007-08)

HIPAA Research Authorization Revisions/Instructions: Clarified

The HIPAA research authorization has been revised to assist researchers in properly identifying the healthcare providers from whom they want to obtain protected health information. Specifically, the section entitled, "Authorization to Obtain and Use Health Information from Provider for Research Study," has been revised to list categories of possible health care providers. This should result in the authorization form that is more complete and accurate. The revised authorization, dated September 2007, is effective immediately.

The new HIPAA Authorization forms (dated 9/2007) are for New Studies only. It is not necessary to replace/amend prior HIPAA forms in ongoing studies. For any questions regarding this matter please contact the Office of Compliance at (213) 740-8258.

Please also refer to the revised research authorization instructions for assistance in completing the form or call the Office of Compliance at (213) 740-8258.

- USC HIPAA Authorization Form (English; Spanish)
- HIPAA Authorization Form Instructions
Serious Adverse Events/Unanticipated Problems: Increase in Reporting Time to IRB

Reporting Serious Adverse Events/Unanticipated Problems to the IRB should occur as soon as possible, but no later than 10 days of the investigator becoming aware of the event. For more information on this change and to see the revised policy online, please visit the HSPP Policies and Procedures: HSPP Policies and Procedures (Ch. 14.4, Page 182)

Policies and Procedures: Latest Version Available Online

The HSPP (Human Subjects Protection Program) Policies and Procedures have been updated and are posted on the website. The updated version is dated November 2007. The P&Ps provide guidance and information for investigators conducting all types of human subjects research. Please refer to these P&Ps in the preparation and conduct of human subjects research available at: http://www.usc.edu/admin/provost/oprs/policies/hspp.html

NIH Invites Clinical Investigators to Join CRpac Listserv

The National Institutes of Health (NIH) Program on Clinical Research Policy Analysis and Coordination (CRpac) invite you to subscribe to their new broadcast listserv, “CRpac News.” As someone involved in the conduct or oversight of clinical research, you may be interested in listserv’s announcements concerning new and proposed federal policies, upcoming conferences, and new resources.

- If you wish to subscribe, please send a message to: listserv@list.nih.gov
- In the body of the message (no subject header needed), simply type: subscribe CRpac_News
- If your email program is set to insert a signature line, you will want to delete that text before sending in your request
- More about the CRpac Program and its aims can be found at: http://crpac.od.nih.gov/

HSPP Staff to Attend National Human Subjects Research Conference

Select staff from the HSPP team will be attending the 2007 Annual PRIM&R (Public Responsibility in Medicine and Research) conference December 1st-4th in Boston. PRIM&R is the professional society for the human subject research community and serves as an education and networking opportunity for HSPP staff. The OPRS Executive Director, Susan Rose, will again serve on the faculty at this event. The IRB offices will continue to operate during this time.

CITI Program Updated…More Improvements to Come

The CITI (human subjects education) program has been updated to streamline the enrollment process and instructions. Also, please expect more improvements to CITI’s navigation features, and the removal of unnecessary links, extraneous information, and unused pages. Visit the CITI website to view these changes.

- USC CITI Program FAQs
- CITI Website
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 to Be Announced Via Listserv. Please stay posted or visit website below.

- Human Subjects Education Website
- Session Handouts/Education Materials

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.

News/Articles

- USC: Moving Forward with a Fully Accredited HRPP  AAHRPP Advance (Fall 07, V3, N4)
- New Booklet Educates IRB Community Members  IRB Advisor (Oct. 07, V4)
- The Drug Advertising Blame Game  Pharma Marketing Blog (August 1, 2007)
- The Dysregulation of Human Subjects Research  JAMA (2007;298(18):2196-2198)
  Note: Article only available to USC network users or JAMA subscribers
- Strange Bedfellows on Health Privacy: ACLU & Microsoft  WSJ Health Blog (Oct. 19, 2007)

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