



## Human Research Protection Program

### HRPP Bulletin

No. 8 – June 2005

Committee on Human Research  
Quality Improvement Unit

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### **CHR TO BEGIN EMAILING CONTINGENT AND RETURN LETTERS AND THEIR ATTACHMENTS**

As of June 6, 2005 the CHR will begin emailing the signed Contingent and Return letters and their attachments as Adobe PDF files. These will be emailed to the designated PIs, Co PIs, and Contacts as identified on the CHR Application Form. Once the study has received final approval the original blue copy of the Contingent or Return letter will be included in the approval packet that is mailed. If you are unable to receive documents electronically please contact the CHR Office at 476-1814 and other arrangements will be made.

### **ALL KEY PERSONNEL IDENTIFIED ON THE CHR APPLICATIONS MUST COMPLETE THE ONLINE UCSF HUMAN SUBJECT PROTECTIONS TRAINING COURSE**

The CHR requires that all Key Personnel at UCSF or affiliated sites complete the online UCSF Human Subject Protections Training Program. This has been included in the Key Personnel section of the CHR Application Forms. This educational requirement meets the educational requirements for NIH grant submissions. As a reminder, Key Personnel at other non-affiliated sites do not have to complete the UCSF training.

### **UCSF GUIDE FOR THE RESEARCH USE OF HUMAN BIOLOGICAL SPECIMENS: COLLECTING, BANKING, AND SHARING SPECIMENS**

The Office of Research and the HRPP web sites both have posted this [Guide](#) to help support investigators who wish to use human biological specimens in their research and/or those researchers who intend to establish or manage specimen banks and repositories to be used by others for research. The goal is to provide practical information in a user-friendly document for researchers to help them navigate the policies and procedures at UCSF.

### **ACCREDITATION UPDATE**

Representatives from [The Association for the Accreditation of Human Research Protection Programs](#) (AAHRPP) will be making a site visit at UCSF from Monday, June 6<sup>th</sup> through Thursday, June 9<sup>th</sup>. Over 70 people will be interviewed during this visit, including members of faculty, researchers, research staff, and HRPP staff as well as campus leadership. AAHRPP Council will review the results of this site visit and UCSF's response at its September 2005 meeting. UCSF is the second of the UC campuses to seek and, presumably, obtain this accreditation.

## **CHR BACKLOG**

Since April the CHR has been receiving an enormous influx of renewal applications. To avoid having studies expire, the CHR must give priority to reviewing renewal applications over new applications. As a result, the CHR currently has a large backlog of new full committee applications. Expect delays of at least an additional 6-7 weeks for new full committee studies to be placed on an agenda. There will be similar delays with some new expedited review applications. The influx of renewals is expected to slow down over the summer, and then pick up again in September.

## **QUALITY IMPROVEMENT UNIT SITE VISITS**

To help assure ongoing post-approval monitoring and assessment of research under the oversight of the UCSF Committee on Human Research (CHR), the Quality Improvement Unit (QIU) conducts regular "Routine Site Monitoring" reviews of study operations for a number of randomly selected research projects. These site-level review visits are specifically directed toward those research projects that lack formal on-site monitoring. The goals of this random monitoring process are:

- to assist sites in implementing studies in accordance with regulatory requirements and CHR guidelines and
- to help investigators and their staff improve their protections of human research participants.