

Human Subjects Protection Program (HSPP) Bulletin

<http://www.research.ucsf.edu/chr/index.htm>

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New Name

The Human Subjects Protection Program (HSPP) is the name for the expanded program that now includes not only the Committee on Human Research (CHR) but also a Quality Improvement Unit (QIU). The QIU performs both not-for-cause and for-cause audits of research involving human subjects, as is required by UCSF's agreement with DHHS to assure compliance with the federal regulations. The addition of this unit now allows UCSF to provide a full circle of protection for research subjects and researchers by having a program that includes education and training, committee review and approval, and post-approval monitoring.



The HSPP Bulletin

As part of HSPP's educational outreach, this *Bulletin* will contain important information for researchers who involve human subjects in their research (even if the only involvement is use of biological specimens or review of medical records). The *HSPP Bulletin* will be delivered at least quarterly by e-mail and as a PDF attachment with hotlinks and will also be posted on the CHR, soon-to-be HSPP, website.

Recruitment Guidelines

New guidelines for recruiting human research subjects have been posted on the CHR website at [http://www.research.ucsf.edu/chr](#). As requested by researchers, these new guidelines clearly explain the types of recruitment activities that are likely to be approved by the CHR. The guidelines also take into account new protections for personal privacy under HIPAA. Abbreviated recruitment guidelines are posted on the HIPAA website.

Updated HIPAA information

Updated information for HIPAA has been posted to the CHR website. The updated documents include the following: a revised English and Spanish UCSF Subject Authorization form, a new HIPAA Decision Diagram, a revised HIPAA Decision Tree, a revised HIPAA Supplement, a revised Waiver of Consent/Authorization form, a revised set of abbreviated recruitment guidelines, and a revised PowerPoint. Also, please note that if you take the on-line tutorial on HIPAA and Research a certificate of completion will be available for printing, although this information will not be recorded in Research Online.

Because the best way to approach HIPAA at UCSF has not been finalized and because we are working in conjunction with the other four UC medical schools, additional revisions will be forthcoming. We will keep you informed of any significant changes and/or hoped for improvements in the system.

A word of caution: The CHR strongly urges you *not* to embed HIPAA language in the consent form. The other UC campuses do not allow such embedding and the CHR experience so far has been that attempts to embed the language have not been very successful. Most likely, embedded language will not be allowed in biomedical consent forms by the end of the summer.