



Human Research Protection Program

HRPP Bulletin

No. 7 – March 2005

Committee on Human Research
Quality Improvement Unit

3333 California St., Suite 315
San Francisco, CA 94118

tel: 415/476-1814
fax: 415/502-1347

UPDATED WEBSITE, APPLICATIONS, CONSENT FORMATS, GUIDELINES

As part of preparing an application for accreditation* of UCSF's Human Research Protection Program, extensive changes have been made to the HRPP website, starting with a reorganized [HRPP Home Page](#). The changes overall are intended to make it easier to apply for CHR approval, to provide better guidance, and to bring UCSF into better compliance with national standards. Highlights are listed below, but many other pages have small revisions.

Applications: Most of the CHR applications have been revised to improve coordination with the Conflict of Interest Advisory Committee. In addition, the new forms for renewals and modifications have been posted, along with instructions for their use:

- [Status Report for Renewals & Major Modifications \(Continuing Review\)](#)
- [Checklist for Renewals & Major Modifications \(Continuing Review\)](#)
- [Modification Request for Minor and *Administrative* Changes](#)
- [Checklist for Minor and *Administrative* Changes](#)
- [General Instructions: Renewal Application](#)
- [General Instructions: Modification Request](#)

Consent Guidelines and Samples: A new format for consent forms uses questions and answers instead of static headings. The CHR members have commented over the last few years that consent forms written in this format are much more participant-friendly. The revised UCSF format is based on a sample consent form that was developed and tested for subject understanding over a period of several months by the National Cancer Institute.

HRPP has two new guidelines and 5 new sample forms. The new format should be used for new applications. **Important Note:** After June 2005 the old format will be accepted only for renewals and modification of studies originally approved with the old style consent forms.

- [Consent Guidelines](#)
- [Consent Form Standards – Section by Section Discussion](#)
- **Sample forms:**
 - [Biomedical](#)
 - [Biomedical - Cancer](#)
 - [Social or Behavioral](#)
 - [Simple Blood Draw](#)
 - [Specimen Collection](#)

Other New or Revised Guidelines:

- **Conflict of Interest**
 - [Investigator Conflict of Interest and CHR Review](#)
- **Types of Research**
 - [Social and Behavioral Research](#)
 - [Research Using Human Biological Specimens](#)
 - [Mandatory Companion Studies: Registries, Data Banks, Collections of Biological Specimens or Genetic Materials](#)
- **Vulnerable Populations**
 - [Pregnant Women, Fetuses, Neonates, or Human In-Vitro Fertilization](#)
 - [Those with Cognitive Impairments](#)
 - [Prisoners](#)
- **Working with Other Institutions**
 - [Working with Other Institutions – Collaborating with Researchers at Academic Medical Centers, Hospitals, Clinics and Practices within the United States and at International Locations](#)
 - [Working with the Centers For Disease Control and Prevention \(CDC\)](#)
- **Quality Improvement Unit**
 - [Overview of Activities](#)
 - [Frequently Asked Questions about the QIU](#)

NEW REQUIREMENT FOR SUBMISSION OF GRANT APPLICATIONS TO THE CHR

New applications for CHR approval of federally-funded studies should now include one copy of the approved or pending grant application. The federal government requires the CHR to compare the grant application to the CHR submission to ensure that there is close similarity in the study aims, research design, methods, sites of research activities, and project personnel, and that there are no other significant discrepancies.

IMPORTANT REMINDER: CHANGE IN EXPIRATION DATES

To remain in compliance with Federal regulations, the CHR has changed how we assign expiration dates. For new full committee studies, the expiration date may be no more than one year after the date the study was reviewed at the convened meeting. It is no longer acceptable, for example, to assign an expiration date based on the date requested changes were approved by a Chair in the office.

However, for continuing review (i.e., renewals) Federal guidance now allows the CHR to approve studies for up to one year plus 30 days. When a renewal is approved within 30 days prior to the expiration date, the new expiration date will usually be one year from the old expiration date.

In summary, expect shorter approval periods for the first year of the study and longer approval periods for renewals. For more details and examples please see [Determining Expiration Dates](#). The committee and the office realize this will require increased attention to preparing the correspondence as quickly as possible after a meeting, but it will also require investigators to respond as quickly

as possible to correspondence so that the first year approval periods are not unduly truncated.

*For anyone interested in learning more about the HRPP accreditation process, please refer to the [Association for the Accreditation of Human Research Protection Programs](#) (AAHRPP) website.