



## Human Research Protection Program

### HRPP Bulletin

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**Committee on Human Research  
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## **ACCREDITATION INFORMATION**

As part of its continuous effort to improve service to the research community, UCSF is in the process of preparing an application for accreditation of its Human Research Protection Program. The application will be submitted by the first of March of 2005 to the [Association for the Accreditation of Human Research Protection Programs](#) (AAHRPP). There are three primary reasons for UCSF to seek accreditation at this time:

- ◆ its program is in compliance with federal regulations. Once accredited, an institution is less likely to be audited by the federal regulators and, therefore, less likely to experience sanctions or disruptions in funding, as has occurred at other major biomedical research institutions in the past.
- ◆ Research Protection Programs. All UC campuses are committed to this standard. UCSF prefers to be among the first of the campuses to become accredited, and among the first of the institutions nationwide.
- ◆ requires that we become accredited so that we may continue to do research involving the VAMC.

You will have already noticed a number of changes in the program that have occurred during the last year. Changes will continue at a slightly faster pace these coming months, but we will keep the research community informed of these by way of more frequent editions of this HRPP Bulletin and the [What's New](#) section of the HRPP website.

## **CHANGE IN EXPIRATION DATES**

To remain in compliance with Federal regulations, the CHR must change 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.

## **MAJOR MODIFICATIONS AND RENEWAL APPLICATIONS**

By the end of this month, the CHR will issue new instructions and forms for the submission of modifications and renewal applications. The major change will be a new form called "Status Report for Renewals and Major Modifications." Using this form will allow all major modifications to be treated as renewals, and approvals of major modifications will have an expiration date of up to one year from the date of committee review or one year from the previous expiration date, whichever is longer. Researchers will no longer find they need to submit a renewal application shortly after a major modification has been approved.

There will also be improved guidance about what changes should be considered Major, Minor, or Administrative modifications. Another new form, the "Modification Request for *Minor* and *Administrative* Changes," will make it easier to submit and review small changes in a study. Please watch the [What's New](#) section of the HRPP website for these new forms and instructions.

## **RECENTLY REVISED AND NEW GUIDELINES AND FORMS**

The Human Research Protection Program continues to update and add to the guidelines and forms available on its website in order to make it easier for researchers to move forward with their research while enhancing the protection of human research subjects and compliance with regulations. If you have suggestions for improving our efforts and making them more useful, please e-mail us at [chr@ucsf.edu](mailto:chr@ucsf.edu). Latest guidelines include:

- [Minors in Research](#) (*December 2004*)
- [Use of Inactive Interventions \(e.g., Placebos\) in Place of Potentially Effective Therapy](#) (*October 2004*)
- [Informed Consent for Research Subjects Who Do Not Read, Speak, or Understand English](#) (*Revised December 2004*)
- [Medical Records Review](#) (*Revised December 2004*)
- [Who Must Have CHR Approval Before Enrolling Subjects](#) (*October 2004*)
- [Administrative Review for Human Research Studies Not Being Conducted by a UCSF Principal Investigator But Accessing UCSF Facilities, Patients or Personnel \(Faculty, Staff, or Students\)](#) (*October 2004*)

- [For Research Volunteers web page](#) (November 2004)
- [Information for Prospective Volunteers brochure](#) (November 2004)
- [For Researchers and Staff web page](#) (November 2004)
- [PI Roles and Responsibilities](#) (November 2004)
- [Clinical Research Coordinator Roles and Responsibilities](#) (November 2004)

## **CLINICAL RESEARCH EDUCATIONAL NEEDS ASSESSMENT (CRENA)**

All personnel engaged in clinical research activities are welcome and encouraged to complete this needs assessment. This brief survey asks questions about your research training and what additional training or education you feel you need to maintain excellence in your clinical research activities. The information from this survey will give us a better idea of what researchers already know, and would like to learn, about clinical research in order to help us develop education and training programs specifically suited to those working in clinical research at the site level. This survey was developed by the staff of the Quality Improvement Unit to assess the training/educational needs of our research community here at UCSF and our affiliate sites.

The survey should take less than ten minutes to complete. It is available at [Clinical Research Educational Needs Assessment](#) on the HRPP website.