



## Human Research Protection Program

### HRPP Bulletin

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#### **Committee on Human Research Quality Improvement Unit**

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### **Committee on Human Research - Paperwork Reduction**

#### **Combined CHR-CTSI Application for Full Committee and Expedited Review**

The applications for CHR and the Clinical and Translational Science Institute (CTSI) have been combined. The revisions to the [CHR application](#) are in Parts 1 and 2. A separate application for service utilization is still required for CTSI and should NOT be submitted to the CHR. If you are applying to the CTSI, please visit one of the CTSI Clinical Research Center web sites for more information.

<http://ctsi.ucsf.edu/index.html>

<http://gcrsfgh.ucsf.edu/>

<http://www.gcrc.ucsf.edu/>

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#### **Only 1 Copy Required For New Full Committee Applications Initial Screening.**

As the majority of the initial full committee applications require revisions and additional documentation before committee review, the CHR has revised the New Full Committee submission process as follows:

- Submit one paper copy of the complete New Full Committee Application.
- The CHR Screener will screen the application for completeness and accuracy, identify administrative issues that need to be clarified prior to CHR review, verify that consent forms use the current template samples/annotated outlines (see below), and that all supplements and appendixes are attached.
  - If revisions or additions are needed, the Screener will contact the PI or Contact within 10-working days of receipt of application and ask the PI to submit 18 copies with these changes incorporated. The revised application will be forwarded for CHR Review.
  - If no changes are needed the CHR will make the 18 copies and forward the application for agenda assignment.

Please see the [Full Committee Review Application Submission Checklist](#) for further instructions.

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## **Only 6 Copies Required (Not 18) For Renewals, Major Modifications, And Response.**

PIs are asked to submit only **six** complete sets for review of the following submissions:

- Full Committee Renewals
- Full Committee Renewals with Minor or Major Modifications
- Responses to Returns from the Full Committee

Please see the [Renewal and Major Modifications \(Continuing Review\) Checklist](#) and [Important Tips for Preparing Responses to Contingent and Return Letters](#) for additional information.

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**IMPORTANT NOTE:** IRB Committee members are receiving scanned copies of the renewals, major modifications, and responses. To facilitate the scanning process the CHR requests that at least **one** of the collated sets not be stapled but rather clipped together.

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## **Avoid Delays in Processing: Updated Consent Form Samples**

As of March 1, 2007 any application that contains consent forms that do not follow the format of the [sample forms](#) posted will be considered incomplete and returned to investigators for revision before forwarding to the CHR for review. This sample consent form has been developed by the National Cancer Institute, includes all the regulatory requirements, and is easier for subjects to read and understand.

## **Relying on other IRBs**

### **National Cancer Institute Central IRB (NCI CIRB) Initiative for Adult and Pediatric Human Research**

The Human Research Protection Program (HRPP) has negotiated an agreement with the NCI CIRB that allows investigators to rely on the NCI CIRB for all Phase 3 and some Phase 2 Cooperative Group trials.

Briefly, this means that UCSF PIs conducting these protocols will no longer have to rewrite the protocols but rather download them from the [NCI CIRB Initiative website](#) and request a Facilitated Review from the UCSF CHR.

**IMPORTANT NOTE:** At this time, the UCSF CHR will only accept initial new submissions under the CIRB program. On-going cooperative group trials already active at UCSF will not be considered for this program.

To take advantage of this process, the forms and procedures can be found on the [HRPP website](#).

## Memorandum of Understanding (MOU) for IRB Review of Multi-Campus Human Subjects Research

A Memorandum of Understanding (MOU) for IRB Review of Multi-Campus Human Subject Research has been signed by the Institutional Officials at all University of California campuses and participating national laboratories. This MOU applies to research eligible for [expedited review](#), i.e., research involving no more than minimal risk to the subject. When applicable, the MOU will allow a new research project to be reviewed by the IRB at only one UC location rather than having to go through the entire IRB process at every UC campus at which the research will take place. In addition, a separate MOU was negotiated between UCSF, UC Berkeley, UC Davis, and Lawrence Berkeley National Laboratory to accept, under certain circumstances, reviews of [initial full committee](#) studies as well.

In both cases, the PI will have to complete a [Notice of Intent to Rely](#) form requesting reliance on another IRB and submit this with the review packet.

### Close-out Report

Beginning January 2007, the electronic CHR Renewal Notice will contain a link to a new CHR Study Close-Out Report. This report will be required for Full Committee and Expedited (with Subject Contact) studies involving human subject contact that have been completed, closed or were never started. The main purpose of the Close-out report is to update the CHR about the conduct and outcome of studies so that any risks or problems that may have arisen since the last CHR review are disclosed to the study participants or others in a timely fashion. Please refer to the [CHR Study Close-Out Reporting Guidance](#) for additional information.

### Children and Minors in Research

The Human Research Protection Program has posted revised [guidelines](#), an [application supplement](#), and a [chart summarizing the applicable federal regulations](#) for involving children and minors in research. The major changes are the following:

- **Circumstances in which people under 18 can consent for themselves** are explained more clearly. The federal regulations requiring parental permission and special protections for children do not have to be applied to these minors. The revised application supplement allows researchers to treat them separately.
- **One or two parents' signature:** The CHR must formally decide whether one or two parents' signature is needed. The revised application supplement asks the researcher to address this issue. In most studies, one parent's signature will continue to be sufficient.
- The documents refer to "**children**" rather than "**minors**" and to **parental "permission" rather than parental "consent"** in most places, to conform with federal regulations.
- The documents refer to **FDA regulations** as well as the DHHS regulations.

## **Job Openings at the HRPP**

Please check out the [What's New](#) section of the HRPP website to view current open positions.