



# Human Research Protection Program

## HRPP Bulletin

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### Committee on Human Research Quality Improvement Unit

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## CHR Introductory Training

A two-hour [CHR Introductory Training](#) presentation is scheduled for the Parnassus campus N225 on Thursday, August 23, 2007 from 11a.m. to 1p.m. This training is directed towards people with limited experience in the area of preparing applications for the CHR. All are welcome to attend and registration is not required. If you have questions regarding this or other HRPP training please contact Patti Tosta at [Patricia.Tosta@ucsf.edu](mailto:Patricia.Tosta@ucsf.edu) or 514-3826.

## Revisions of the Exempt Guidelines

The Committee on Human Research has posted new [Exempt Certification and Non-Human Subjects Research Guidance](#). The changes to this guidance include refining the definition of human subjects and expanding Exempt Certification for research involving the use of survey procedures.

### Redefining Human Subjects

This revised guidance allows more studies to fall outside the definition of human subjects and therefore they do not require CHR review. It also allows investigators to self certify if they believe their study does not meet the definition of human subjects research.

IRB Review is not required if the data or the biological specimens were not collected for proposed research and no identifiers are attached. Please use the [Determining Whether Human Subjects are Involved in Research When Obtaining Private Information \(Data\) or Biological Specimens decision tree](#) to make a determination regarding your research.

### Research Involving the Use of Survey Procedures

Survey studies may now qualify for Exempt if they are:

1. Anonymous, or
2. Include identifiers but any disclosure of the human subjects responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

**Important Exception:** Expedited or Full Committee review *is* required if the survey study involves 1) patients at UCSF or affiliated institutions, 2) minors, or 3) prisoners.

Further guidance is posted on the [website](#). If you have any questions about these changes please call the CHR office at 476-1814 and ask to speak to an analyst.

## **Expansion of Studies Eligible for NCI CIRB Review of National Oncology Group Studies**

For those groups at UCSF currently participating in National Cancer Institute Central IRB (NCI CIRB) the CHR now allows the NCI CIRB to review renewals and modifications in addition to new studies. Please see the [CHR website](#) for instructions on how to transfer your existing CHR-approved study to the CIRB. Please note studies being conducted at the VA are not NCI CIRB eligible.

## **Quality Improvement Unit to Resume Site Visits**

As of last month, the Quality Improvement Unit (QIU) of the HRPP has resumed its routine site monitoring. These site-level reviews are randomly selected from full committee studies that lack frequent [formal on-site monitoring](#). The main goals of this monitoring 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.