



Human Research Protection Program

HRPP Bulletin

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Committee on Human Research
Quality Improvement Unit

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

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

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 protecting human research subjects and complying with regulations. If you have suggestions for improving our efforts and making them more useful, please e-mail us at chr@ucsf.edu. Latest guidelines include:

- [Investigational New Drugs and Biologics](#) (June 2004)
- [Investigational Devices](#) (June 2004)
- [Emergency Use and Compassionate Use of Experimental Drugs and Devices](#) (Compliance Checklist and Form) (August 2004)

- [Medical Records Review](#) (May 2004)

- [Human Biologic Specimen Collecting and/or Banking for Future Research](#) (Application Supplement) (August 2004)
This form has been revised and expanded in response to additional requirements from federal and state regulatory agencies and increasing public interest in research use of specimens and protection of donors' privacy.

- [Adverse Events \(AE\) Reporting Guidelines](#) (revised August 2004)
- [Reporting Violations and Incidents in Research Protocols](#) (June 2004)

REVISED ADVERSE EVENT (AE) REPORTING

The UCSF Committee on Human Research has significantly revised its guidelines for Adverse Event Reporting, to make AE reporting easier and more meaningful for PIs and the CHR while complying with regulations. The new guidelines and forms have been posted since July, which already has given time for additional revisions based on researchers' suggestions. The revisions include:

- [What to Report Within 10 Working Days](#),
- [What to Report at the Time of Renewal \(Continuing Review\)](#), and
- [What Not to Report](#)

More detailed information can be found at the [brief summary](#) of the revised AE reporting requirements and guidelines or at the complete UCSF [AE Reporting Guidelines](#).

KEEPING TRACK OF EXPIRATION DATES

It is important that investigators and study staff develop a system to keep track of their expiration dates. One tool available to you is Research Online. The PI, Co-PI and Contact Person can view listings of their studies, and can sort the listing by expiration date.

Please remember the renewal notices the CHR sends by email are courtesy reminders and are subject to interruption. For example, a virus or worm attack could affect the system as could network security measures intended to block spam email.