



Human Subjects Protection Program

HSPP Bulletin

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Committee on Human Research Quality Improvement Unit

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ADVERSE EVENT REPORTING

Revised Guidelines for Reporting of Adverse Events (AE) in Human

Research: The UCSF Committee on Human Research (CHR) has revised its Guidelines for Adverse Event Reporting. These revisions should make AE reporting easier and more meaningful for both the PIs and the CHR while still being in compliance with the federal regulations and national standards.

These revisions were designed to minimize the reporting of insignificant or unrelated adverse events while collecting more information on serious and unexpected adverse events that occur at UCSF and our affiliate sites. The overall goal of these revisions is to enhance human subjects protection.

The major new elements of the AE reporting guidelines include:

- Revised requirements for AE reporting;
- Revised reporting forms;
- Definitions of key components, categories and criteria for AE reporting;
- Descriptions of AEs that *should not* be reported to the CHR; and
- Clarifications of investigator roles and responsibilities.

Click here for [a brief summary](#) of the revised UCSF AE reporting requirements. Click here for the complete UCSF [AE Reporting Guidelines](#).

HIPAA UPDATES

Final Version of Authorization: One year after the HIPAA regulations became effective, the University of California has incorporated state law requirements and arrived at a final version of the Authorization to use Protected Health Information (PHI) in research. The [UCSF Subject Authorization for Release of PHI for Research](#) form, a slightly modified version of the UC form, is available on the HSPP website. A [Cancellation of Permission to Use PHI for Research](#) form is also posted, for the convenience of researchers and subjects.

HIPAA Supplement: Do *not* submit the HIPAA Supplement with new applications. The HIPAA requirements are incorporated into the current application forms. The HIPAA Supplement is needed, however, when submitting renewals and modifications that use the old application forms.

Embedded HIPAA Language in Consent Forms: Beginning the first week in July, the CHR will no longer accept embedded HIPAA language in consent forms for biomedical or treatment studies, *even for renewals*. Because state law adds additional requirements for the authorization (14 point type, a separate signature line), investigators are asked to remove any embedded HIPAA language from the consent forms. See the [HIPAA Consent Form Guidance](#) for additional details and a list of required elements. An exception will be made for studies in which the major activity is the collection of PHI.

RESEARCH ONLINE HELPFUL HINT

Granting View-Only Rights for Your Active Studies: Principal Investigators can grant view-only web access to their active studies to anyone with a Research Online User ID.* Follow the “Assign Web Access” link in the left margin of the Authorizations/Protocols Home Page. Step-by-step instructions are available through the “Help” link in the upper right-hand corner of the page. Click on “Assigning Web Access (View Only) Rights.”

Through Research Online, Principal Investigators and their designees can:

- Look up review dates
- Look up approval status
- Sort studies by expiration dates
- Post recruitment notices
- Print study summary sheets

*New users affiliated with UCSF can gain access to Research Online by clicking on the [“Request a User Name and Password”](#)