

Check List for Making UCSF-Required Additions to the NCI Consent Form

Updated July 2007

The following eight points must be addressed in the consent form before submitting to the CHR.

IMPORTANT NOTE: The NCI allows local boilerplate additions to the informed consent.

1. Add **“University of California, San Francisco” as a heading** at the top of the consent and/or assent forms.
2. **Identify the UCSF Principal Investigator** (first and last name) and the Department affiliation as soon as possible to the introduction to the consent document. For example, “Dr. Katherine Matthay and her associates in the Department of Pediatrics are carrying out this study as members of the Children’s Oncology Group (COG) . . . “
3. **Inform the research subjects where this study will take place.** This can be accomplished by adding a section headed **Where will this study take place?** or, if more appropriate, you can incorporate this information into the procedures section.
4. In the section about **privacy of medical information**,
 - a. **Refer** to the “Human Research Protection Program at UCSF” rather than “the Institutional Review Board of your hospital.”
 - b. **Refer** to the UCSF Comprehensive Cancer Center
 - c. **Inform** participants that they will also be given and asked to sign an additional Health Insurance Portability and Accountability Act (**HIPAA**) **form** that will provide additional information about the privacy of their records.
5. In the section about **costs**,
 - a. **Replace** NCI CIRB language about costs. Instead, use the UCSF standard costs language, which is as follows:

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for taking part in studies. Check with your health plan/insurance company to find out what they will pay for. Taking part in this study may or may not cost you or your insurance company more than the cost of getting regular cancer treatment. [If applicable, inform the patient of any tests, procedures or drugs for which there is no charge. Also clearly state if there are charges resulting from administration of the test or drug that will be billed to the patient and/or health plan. For example, “The NCI [or other study sponsor] is supplying [drug] at no cost to you. However, you or your health plan may need to pay for costs of the supplies and personnel who give you the [drug].”] [Include the following sentence if appropriate: “If, during the study, [study drug] becomes approved for use in your cancer, you and/or your health plan may have to pay for the drug needed to complete this study.”]
 - b. **Delete** all NCI language about costs of treatment for injury (see below).

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6. In the section about *injury*,

- a. **Fill in the name[s]** and phone number[s] for the subject to call on the study team.
- b. **Replace** the brief paragraph about injury used by the NCI. Instead, use the required UCSF treatment and compensation for injury statement, which is as follows:

If you are injured as a result of participation in this project, treatment will be available. The costs of this treatment may be covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the Committee on Human Research (collect) at 415-476-1814.

- c. **Delete** all NCI language about treatment or compensation for injury.

7. In the section about *questions*,

- a. **Fill in the name[s]** and phone number[s] for the subjects to call on the study team.
- b. **For questions about rights**, fill in as follows: "...call the Committee on Human Research (CHR) at 415-476-1814. The CHR is the UCSF Institutional Review Board ..."

8. In the *signature* section, add

- a. "You have been given a copy of the **Experimental Subjects Bill of Rights** in your own language."
- b. A signature line for the **Person Obtaining Consent**.
- c. A signature line for a **translator**, if one is used.