

**University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center
Policy and Procedure**

**Policy for Obtaining Informed Consent of Potential Patients for
Therapeutic Oncology Clinical Trials**

Purpose

This policy defines research personnel who may obtain consent (key personnel) and describes the steps required by the Key Personnel of a therapeutic clinical trial for obtaining informed consent from the patient/subject who is potentially eligible to participate in a clinical trial at the Helen Diller Family Comprehensive Cancer Center (HDFCCC). This policy applies to all therapeutic trials regardless of the type of sponsor.

Background

Informed consent is a general term for the communication process used by the investigator to facilitate an individual's educated choice about beginning or continuing participation in a clinical trial. Obtaining informed consent is an on-going exchange of information between the study participant and the research team before the start of eligibility screening and throughout the research experience. As part of the informed consent process, a discussion of the study's purpose, costs, other treatment options, and the voluntary nature of participation must occur with the patient and, if required, a legally authorized representative.

The informed consent form (ICF) is one part of the larger process of informed consent that occurs between the potential research participant and key personnel on the research team. The written contents in the ICF are governed by Federal Regulations, and by institutional policy and guidance. The ICF and any required revisions to the original must be approved by the UCSF Committee on Human Research (CHR) as the IRB of record. The approved versions serve as a reference for monitoring and auditing the conduct of participant informed consent throughout the life of the study.

An ICF must be signed by the participant and the key personnel before any study specific procedures can be conducted.

References

45 CFR 46.116; 21 CFR 50; UCSF HRPP website:
<http://research.ucsf.edu/chr/Recruit/chrRC.asp>

Definition of Key Personnel

Key personnel are defined as: all physician investigators (MD), Nurse Practitioners (NP) or Clinical Nurse III research nurses (RN or CNS) employed by the research program who are listed as "key personnel" 1) in the *CHR protocol application* and 2) on the protocol specific *Delegation of Responsibility* form (**Attachment 1**) with the role of obtaining consent. For therapeutic trials in the HDFCCC, the Clinical Research Coordinator (CRC) is **not** considered key personnel for obtaining consent, including re-consent for any reason.

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Procedures

1) Responsibilities of the physician investigator (MD) or Nurse Practitioner (NP) or qualified research nurse (RN or CNS) listed as key personnel.

a) Patient Selection:

- Determines that a patient may be a candidate for a specific clinical trial.

b) Document the Verbal Consent Process:

- Discusses with the patient/parent the prospect of clinical trial participation; including, the purpose of the clinical trial, a general description of the study, risks, possible benefits, and expected outcomes of this study, alternatives to participation and the right to refuse to participate.
- Documents the consent process in the subject's medical chart in the format recommended in **Attachment 2** of this policy.

c) Sign the Informed Consent Form (ICF):

- Contacts the CRC to obtain the most recent CHR-approved ICF.
- Preferred method is to give the subject/parent of children who are subjects a copy of the ICF to take home and review and have the patient return to sign the consent and begin screening procedures.
- When the subject/parent acknowledges that the study and study procedures have been presented in a manner that he/she understands and acknowledges they wish to participate, the subject and MD, NP, or CNS/RN signs the ICF as "person obtaining consent".

d) Re-consent when a required modification to the ICF is approved by CHR:

- The MD, NP, or CNS/RN will receive the approved copy of the consent and a summary of changes from the Clinical Research Coordinator.
- When the subject/parent understands the changes and acknowledges they wish to continue participating in the study, the subject/parent and MD, NP, or CNS/RN signs the ICF.
- Document in the subject's medical chart, the discussion of changes and the signing of the new consent.

2) Responsibilities of the Clinical Research Coordinator.

a) When contacted by the MD, NP, or CNS/RN:

- Provides a copy of the most current CHR-approved version of the ICF, UCSF Experimental Subject's Bill of Rights and HIPAA authorization for this study to them.
- Describes the visit schedule to the subject.
- Reviews with the subject their understanding of what they will do while on study and refer any questions or concerns about the science and conduct of the study back to the investigator before proceeding.
- Schedules a return appointment for the patient, if the patient is taking the consent home to read and share with significant others.

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- If the subject/parents do not speak English and no ICF is available in the subject's native language, the CRC will:
 - arrange for a UCSF interpreter to be present at the meeting, and at subsequent meetings regarding study participation.
 - provide the investigator with a UCSF Experimental Subject's Bill of Rights in the subject's native language
 - provide the translated HIPAA authorization, if a copy is available in the subject's native language.
 - ensure CHR policy on correct signing of the consent for non-English speaking patients is followed. (**Attachment 3**)

b) Distribute copies of the ICF after the consent has been signed:

- Makes 3 copies of the signed ICF, Bill of Rights and signed HIPAA authorization;
Or 4 copies if the patient will be treated in the infusion center or CCRC/PCRC
- Gives the patient a copy of the signed ICF, Bill of Rights, and signed HIPAA authorization to take home.
- Files the original signed ICF, Bill of Rights, and HIPAA authorization in the subject research source document binder as determined by the unit.
- Records the patient's UCSF medical record number on the copies of the signed ICF, Bill of Rights, and HIPAA authorization.
 - At SFGH, writes "file as an advanced directive" at the top of the ICF copy.
 - Files one copy of each document in the patient clinic chart.
 - Takes a signed copy to the Infusion Center or CCRC/PCRC at the time of the first infusion. (when applicable)
 - Sends one copy of each document to medical records.
 - At Parnassus or Mt. Zion, sends to: HIMS, Master File unit, Box 0308
 - At SFGH, sends to: Chris Elliott, Director of Health Information Services, 1001 Potrero Avenue, Room #2B1, San Francisco, CA 94110.
 - At SFVAMC, follows their procedures for filing a hard copy of the consent in the medical record.
- Registers subject into OnCore[®] CTMS, along with ICF signing date and version date of ICF.
- Tracks re-consent of study patients for the Principal Investigator.

Alternate Procedures

There are no alternate procedures to the HDFCCC policy of key personnel who can obtain consent.

Policy Approval

This policy document was approved by the following personnel on the following dates:



Eric Small, MD
Director, Investigational Therapeutics Initiative

4/27/11

Date

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Attachment 1

Delegation of Responsibility & Staff Signature Log

Protocol Title:					
CHR Approval #:					
Protocol Number:			Sponsor:		
Facility:			Investigator:		
Use One Vertical Column for Each Designee					
Designee (full name)					
Title & Position					
Delegated Activity (see codes)					
Designee Signature & Dates					
Designee Initials (signed)					
Activity Codes: 01: Informed Consent 04: CRF Entries 07: Drug Reconciliation 02: Perform Physical Exam 05: Drug Dispensing 08: Adverse Event Assessment 03: Subject Interviews 06: Drug Administration 09: Adverse Event Documentation/Reporting					
Investigator's Authorization: I hereby delegate the above significant research-related duties to the following persons and understand that the overall responsibility for conduct of the research remains with me.					
¹ Investigator's Signature: Date: ¹ Investigator must re-sign this log with any change in <i>key research personnel</i>					

Source: <http://www.research.ucsf.edu/chr/Qip/hspqTools.asp>

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Attachment 2

Document consent process in clinic chart

Suggested standardized consent process documentation which can be printed on UCSF clinic progress note.

CLINICAL TRIAL NUMBER: (insert number)

Informed consent was discussed for participation in the above referenced study with **(insert subject's name)** who has voluntarily agreed to participate by signing the consent form document on **(insert date, mm/dd/yyyy)**.

The following points were discussed and must be yes:

- Yes** **No** The UCSF Experimental Subjects Bill of Rights has been reviewed with the patient prior to signing the consent form, and a copy has been given to the patient.
- Yes** **No** Alternative treatment to the patient's disease in lieu of clinical trial participation, has been discussed with the patient.
- Yes** **No** Possible risks and possible side effects of participation in this clinical trial have been discussed.
- Yes** **No** The patient has been given the opportunity to ask questions.
- Yes** **No** The patient has acknowledged that his/her questions were satisfactorily answered.
- Yes** **No** **N/A** The requirement for the use of birth control while participating in this clinical trial was discussed.
- Yes** **No** The patient has been given a copy of signed consent form and signed HIPAA Authorization form.
- Yes** **N/A** A copy of the prohibited medication list has been provided to the patient. This list has been reviewed with the patient. The patient has been instructed to provide this list to any health care providers that may prescribe medication for the patient outside of this clinical trial.

Comments:

PRINT THE NAME OF PERSON OBTAINING CONSENT: _____

MD/NP/Qualified research RN signature

Date signed

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Attachment 3 Common Special consenting circumstances provided for helpful information

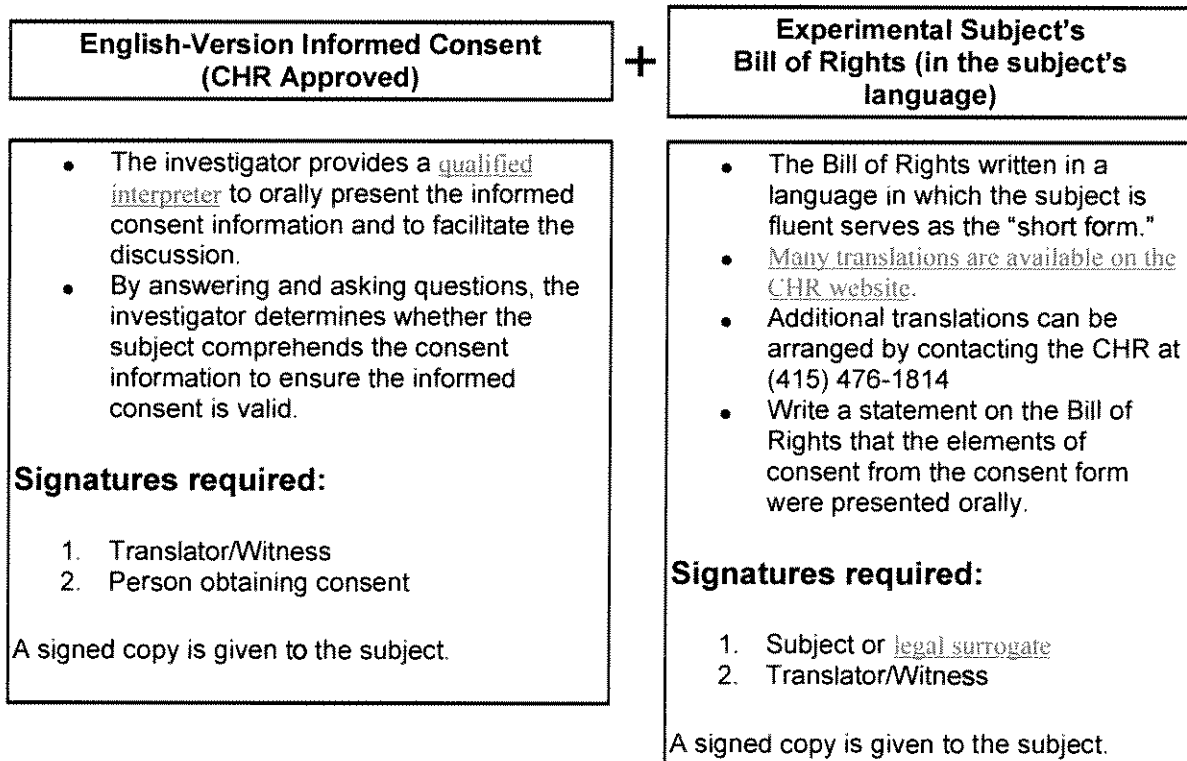
1) OBTAINING AND DOCUMENTING INFORMED CONSENT FOR NON-ENGLISH SPEAKERS:

CHR policy listed below for reference; please check their website in the event you have a subject in this category. Source: http://research.ucsf.edu/chr/Guide/chrG_SpSpeakWrite.asp#4

Preferred method is to have a translated consent form approved by CHR if you will be enrolling many non-English speaking subjects.

If the subject/parent does not speak English and no ICF is available in the subject's native language, use the CHR Flowchart below.

FLOWCHART: THE "SHORT-FORM" METHOD FOR OBTAINING AND DOCUMENTING INFORMED CONSENT FOR NON-ENGLISH SPEAKERS



IMPORTANT NOTES:

- Where the necessary signature and date lines are not printed on the consent form or Bill of Rights, they should be added by hand. Each signature line should have its own date.
- Add a statement that the elements of consent from the consent form were presented orally.
- The use of a legal surrogate must be described in the study protocol and approved by the CHR.

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Attachment 3 *Special consenting circumstances:*

2) *OBTAINING SURROGATE CONSENT:*

- Federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that consent be sought from a research subject or “the subject’s legally authorized representative” and defer to “applicable law” to define who is legally authorized. In California, Health and Safety Code 24178 specifies in detail who may serve as a legally authorized representative to give consent for an incapacitated prospective research subject. The state law uses the terms “surrogate decision-maker” or simply “surrogate” to refer to the legally authorized representative.
 - University of California Office of the President (UCOP) has designed a form for surrogates to self-certify their eligibility and has issued guidelines for following the new law.

Source: <http://research.ucsf.edu/chr/Guide/hsppGLsurrConsent.asp>

- The decision-making capacity determination should be documented in each participant’s research file by saving copies of all completed instruments/forms for that individual, as well as other relevant documents used in the process (including, of course, any consent forms).

3) *FAXING SIGNED CONSENT*

- When necessary, subjects or parents of children who are subjects may take the consent home and then fax a signed copy to the investigator.
- The key personnel consenting this subject/parent will sign the faxed copy as soon as possible.
- The subject/parent of subject need not provide the investigator with the original signed ICF.

Source: <http://www.hhs.gov/ohrp/informconsfaq.html#q16>

4) *A SUBJECT IS AT the SFVAMC*

- If the subject is enrolled at the SFVAMC, a witness signature line must also be signed by someone who is not associated with the study.

Source: <http://research.ucsf.edu/chr/VA/chrVA.asp>