

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

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

**Purpose**

This policy defines the process by which Fellows can provide informed consent for patients in a therapeutic oncology trial at the Helen Diller Family Comprehensive Cancer Center (HDFCCC). In general, if Fellows are consenting patients in a therapeutic oncology trial, they must be listed as Key Personnel as per the Committee on Human Research (CHR) definition of Key Personnel. Additionally, as per Good Clinical Practices (GCP), the Fellows must understand the study (i.e. have completed training for the trial), completed all necessary regulatory paperwork (i.e. Delegation of Authority Form and FDA 1572), and be active investigators in this research.

**Background**

All Fellows performing consenting of patients in a therapeutic oncology trial must be listed as Key Personnel on the CHR application, as well as be listed on the Delegation of Authority Form (DAL), and on the Form FDA 1572 as per the International Conference on Harmonisation Good Clinical Practices (ICH GCP).

**References**

- International Conference on Harmonisation Good Clinical Practices, Section 4.8 (ICH GCP Section 4.8)
- 21CFR50
- 21CFR312
- Guidance for Industry E6 Good Clinical Practices Consolidated Guidance, April 1996
- UCSF Human Research Protection Program (Committee on Human Research), June 27, 2012

**Process**

All Fellows involved in the consenting of patients in a therapeutic oncology trial at UCSF HDFCCC must complete the following items at a minimum before they can conduct any procedure in a clinical research trial. The Fellows must be listed as a Key Personnel in the Committee on Human Research (CHR) application. As per the Human Research Protection Program (HRPP), UCSF Key Personnel are defined as all individuals who contribute in a substantive way to the scientific development or execution of the study at or on behalf of UCSF or affiliated institutions. Typically, these individuals have doctoral or other professional degrees, although other individuals should be included if their involvement meets the definition of Key personnel. In particular, investigators and staff involved in obtaining informed consent are considered Key Personnel.

Additionally, the Fellows should be listed on the Delegation of Authority Log (DAL), since the Principal Investigator is delegating this authority of obtaining consent to the Fellow, and the

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Form FDA 1572, as these individuals are Sub-Investigators in the clinical research trial. The Fellows must also adhere to the ITR Policy for Obtaining Informed Consent of Potential Patients in Therapeutic Oncology Clinical Trials. Finally, the Fellows should fully understand the research protocol and, thus, should be trained before consenting patients in the trial.


**Alternate Procedures**

There are no alternate procedures to this policy. FOR IRB POLICIES ALWAYS CHECK THE UCSF HRPP WEBSITE FOR FORMS AND GUIDANCE.

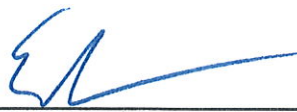
<http://www.research.ucsf.edu/chr>

**Policy Approval**

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

  
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20 May 2013  
Date

  
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5/28/13  
Date