

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

**Protocol Project Manager (PPM) Guidance Document for the Notification of  
Voluntary Holds on Study Enrollment**

**Purpose**

This guidance document defines the process by which the Protocol Project Manager (PPM) notifies the Research Program Staff (i.e., Key Study Personnel (KSP) and Research Personnel) and all governing bodies of the ITR of a voluntary hold on enrollment for all studies within a Research Program in the Helen Diller Family Comprehensive Cancer Center (HDFCCC). Additionally, this guidance document defines the process by which the PPM notifies the Research Program Staff and all governing bodies of the ITR when a voluntary hold on enrollment for all studies within a Research Program is removed.

**Background**

Research Programs are defined as collaborative cancer-focused programs comprising the activities of a group of investigators who share common scientific interests and goals and participate in competitively funded research. The timely notification of all the governing bodies of the ITR and all relevant Research Program Staff by the PPM of a voluntary hold on enrollment for all studies within a Research Program in the HDFCCC is vitally important to ensure that all members are aware that no further enrollment in the program will occur until this hold is removed by the PPM.

**References**

- UCSF Human Research Protection Program (Committee on Human Research) (current version).

**Process**

Once the Principal Investigator has determined a voluntary hold should be placed on enrollment due to issues (i.e., a shortage in Research Program staffing or issues with pertaining to the viability and treatment of a patient (i.e., drug not available), the PPM within the Research Program in the ITR will notify the various governing bodies of the ITR and all relevant Research Program Staff via e-mail within one business day of the decision to hold study enrollment. The PPM will be responsible for confirming via receipt of e-mail that all members of the governing bodies of the ITR have been notified of this hold on enrollment. The PPM will notify:

- The Research Program Staff including Key Study Personnel (KSP) which includes all clinicians (Principal Investigators, Co-Investigators, and Sub-Investigators, including Fellows)
- Research Personnel includes Lead CRCs, and CRCs
- Regulatory Affairs Unit Manager
- QA/Clinical Trials Finance Supervisor
- Post-Award Finance Manager
- Manager of the Data and Safety Monitoring Committee

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- Director of the Clinical Research Support Office
- Director of the ITR
- Site Committee Chair (if they are not included in the Key Study Personnel)

**OnCore Update:**

The PPM will update all studies in OnCore with the "Suspend Enrollment" option and update <http://clinicaltrials.gov/> to show that "accrual is on hold."

**CHR Notification:**

The PPM will submit a Reporting Form to the CHR notifying them of the voluntary hold on enrollment. Per the CHR reporting requirements, the Reporting Form should be filed within 10 business days of the decision to place the studies on accrual hold.

**Removal of Voluntary Hold:**

Once the Research Program has resolved all significant issues that may impact patient safety, the PPM will notify, via email, the governing bodies of the ITR and all relevant Research Program Staff listed above within one business day of this decision to remove the hold on enrollment.

The PPM will also submit a follow up Reporting Form to the CHR to notify them of the removal of the study hold. In addition, the PPM will update the OnCore study status to "Open To Accrual".

**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>

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**Policy Approval**

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

  
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Kate Shumate, MPA, CCRP  
Director, Scientific Programs Administration  
UCSF Helen Diller Family Comprehensive Cancer Center

  
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Date

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Alan Venook, MD  
Professor of Medicine  
Chair, Data Safety Monitoring Committee  
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Date