Data and Safety Monitoring Committee (DSMC) Guidance Document for the Notification of Research Program Staff of a Mandated Hold on Study Enrollment

Purpose

This guidance document defines the process by which Research Program Staff (i.e., Key Study Personnel (KSP) and Research Personnel) and all governing bodies of the ITR are notified by the Data and Safety Monitoring Committee (DSMC) of a mandated hold on enrollment for studies within a Research Program in the Helen Diller Family Comprehensive Cancer Center (HDFCCC). Additionally, this guidance document defines the process by which the DSMC will notify the Research Program Staff when this mandated hold on enrollment for 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 Data and Safety Monitoring Committee (DSMC) of a mandated hold on enrollment for 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 DSMC.

References

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

Process

The DSMC will place a Research Program on hold if significant issues are discovered that impact patient safety as per Section(s) VI and VII of the Data and Safety Monitoring Plan (DSMP). Once the Research Program has resolved these significant issues that impact patient safety, then the hold on enrollment will be removed by the DSMC.

Once the DSMC has determined that a mandated hold should be placed on enrollment within a Research Program, the DSMC Manager or designee will notify all Research Program Staff via e-mail within one business day of this decision to hold study enrollment. The DSMC Manager will also inform the various governing bodies of the ITR within one business day of this decision to hold study enrollment. The DSMC Manager 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. Specifically, the DSMC Manager will notify:

- The Research Program Staff including Key Study Personnel (KSP) which includes all clinicians (Principal Investigators, Co-Investigators, and Sub-Investigators, including Fellows).
University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center
Policy and Procedure

- Research Personnel including Protocol Project Managers (PPMs), Lead CRCs, and CRCs.
- Regulatory Affairs Unit Manager
- QA/Clinical Trials Finance Supervisor
- Post-Award Finance Manager
- 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 Protocol Project Manager (PPM) will submit a Reporting Form to the CHR notifying them of the mandated 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 Mandated Hold:

Once the Research Program has resolved all significant issues that impact patient safety, the hold on enrollment will be removed by the DSMC. Consequently, the DSMC Manager will notify via email the governing bodies of the ITR and all relevant Research Program Staff 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 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
Policy Approval

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

Kate Shumate, MPA, CCRP  
Director, Scientific Programs Administration  
UCSF Helen Diller Family Comprehensive Cancer Center  
7/24/15

Alan Venook, MD  
Professor of Medicine  
Chair, Data Safety Monitoring Committee  
UCSF Helen Diller Family Comprehensive Cancer Center

Date

Eric Small, MD  
Professor of Medicine and Urology  
Director, Investigational Trials Resource  
Deputy Director and Director of Clinical Sciences  
UCSF Helen Diller Family Comprehensive Cancer Center

Date

DSMC Guidance for Notification of Mandated Hold
Version 1.0  
Page 3 of 3
023July2015