UCSF Helen Diller Family Comprehensive Cancer Center

University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center

Data and Safety Monitoring Committee (DSMC) Policy for Mandated Holds on Study Enrollment

DSMC Process for Mandated Holds on Study Enrollment

Table of Contents

Purpose

This policy defines the process of a DSMC-mandated hold on enrollment due to noncompliance and/or significant issues, which significantly affect participant safety and data integrity.

Scope

This policy applies to all clinical research trials conducted under the HDFCCC.

Background

Along with other clinical research units at the HDFCCC, the DSMC has responsibility to: 1) ensure the safety of all participants enrolled in clinical research studies at the HDFCCC; and 2) ensure the scientific and data integrity of all clinical research studies. Per Section VIIIb (Data Quality Control/Remediation Process) of the Data and Safety Monitoring Plan (DSMP), the DSMC may place a trial(s) on hold if significant issues (i.e., numerous Serious Noncompliance Determinations from the IRB or a significant loss of study staff) are discovered which put study participants at risk or effects the integrity of the data in the clinical trial(s). These significant

issues need to be resolved and reviewed/approved by the DSMC prior to re-opening the study for accrual.

Depending on the scope of the identified issue, mandated enrollment holds may be for a single study only, all studies conducted by a specific Principal Investigator, or all studies conducted in a specific program.

Procedures

The process of the DSMC-mandated enrollment hold includes the timely notification of all the governing bodies of the HDFCCC and all relevant study team members in order to ensure that all HDFCCC staff are aware that no further enrollment will occur. This mandatory hold will be lifted by the DSMC after completion of all items in the DSMC-mediated Corrective and Preventative Action Plan (CAPA).

The DSMC may learn about significant issues through monitoring visits, sponsor or FDA audits, serious non-compliance reports from the IRB or any clinical research organizational unit within the HDFCCC (e.g., Clinical Research Support Office).

1.0 Enrollment Hold Notification Process

The DSMC Chair (or Vice Chair) and other committee voting members will decide if a mandated hold should be placed on enrollment for the PI's clinical trials and/or within a study program due to the significant issues. A majority (> 50% of the voting members of the DSMC Committee) must be present in quorum for this decision. In case of disagreement/indecision amongst the DSMC Committee members regarding the decision on the mandated hold on enrollment, then the DSMC Chair (or Vice Chair) will make the final decision. Once a mandated hold has been decided, the DSMC Chair (or Vice Chair) and the Administrative Director (or designee) will notify the study team members and the various governing bodies of the HDFCCC within one business day of this decision to hold study enrollment.

The DSMC Administrative Director (or designee) will notify the:

- Principal Investigator
- Sub-Investigators
- All study team members, including the:
    - Protocol Projects Managers (PPM)
    - Clinical Research Managers (CRM)
    - Clinical Research Supervisors (CRS)
    - Clinical Research Coordinators (CRC)
- Cancer Center Clinical Research Operating Committee (CCCROC) Chair and Vice Chair
- Applicable Site Committee Chair
- Clinical Research Support Office (CRSO) Medical Director
- CRSO Director
- CRSO Associate Directors
- Protocol Review and Monitoring Committee (PRMC) Chair
- PRMS Manager
- UCSF Human Research Protection Program (HRPP) Director
- HRPP Assistant Director

- NCI Program Director (if this is a NCI-CTEP trial)

The study team will then:

- Complete the reporting form(s) to the IRB of record and update Clinical Trials Reporting Program (CTRP) and clinicaltrials.gov (if applicable) with this decision to suspend accrual. Per the UCSF IRB reporting requirements, the Reporting Form should be filed within 1 business day of the decision to place the studies on mandated accrual hold.

- Report suspension to study sponsor (as applicable)

- Update the protocol status in OnCore to “SUSPENDED”

2.0 Remediation Process

The DSMC Chair (or designee) and Administrative Director, along with the CRSO Director and/or CRSO Associate Director, will work with the PI and the study team for the development of a Corrective and Preventative Action Plan (CAPA) to resolve the significant issues.

The DSMC will work with the PI and the study team to ensure that all issues are resolved prior to the study team submitting a formal request to the DSMC to lift the enrollment suspension.

Once the DSMC approves the uplifting of the mandated hold, the DSMC Chair (or designee) and DSMC Administrative Director will notify CCCROC, HRPP Director and Assistant Director, PRMC, and CRSO of accrual reopening. If applicable, the study team should update the sponsor, clinicaltrials.gov and CTRP to indicate that the study is re-opened. The DSMC Chair (or Vice Chair) and the DSMC Administrative Director will meet regularly with the study team to review progress with the opening of the trials for the next 6-12 months to ensure resolution of all issues.

If the DSMC determines that there are unacceptable toxicities as a result of the study conduct, then the DSMC can permanently suspend the trial(s). If this occurs, then notification will follow the process as outlined in step 1.0.

Policy Exemptions

None.

References

UCSF HDFCCC DSMP (version 16Sep2021)

Policy Approval

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

DocuSigned by:
Eric Small
7FCB32D327E3438...

1/31/2022

Eric Small, MD
Deputy Director
Helen Diller Family Comprehensive Cancer Center

Date

DocuSigned by:
Kate Shumate
80D38159E89D41B...

1/20/2022

Kate Shumate, MPH
Director, Administration and Planning
Helen Diller Family Comprehensive Cancer Center

Date

DocuSigned by:
katie kelley
7F538467F93949B...

1/20/2022

Katie Kelley, MD
Chair, Data and Safety Monitoring Committee
Helen Diller Family Comprehensive Cancer Center

Date

Policy contact:
John McAdams
John.mcadams@ucsf.edu

Clinical Research Policy Revision
Summary of Changes

Policy Title: Policy for DMSC-Mandated Holds on Study Enrollment
Version Date: 12/282021
Version Number: 2.0

	Section(s):
Summary of Change	The entire policy was updated to include more guidance and details on the DSMC-mandated enrollment hold process.
Revised Text	Added guidance information for the DSMC-mandated enrollment hold process, including the workflow appendices.