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

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Purpose

This policy defines the process for a DSMC-mandated hold on enrollment due to significant patient safety or data integrity issues for a study, investigator, and/or Site committee.

Scope

This policy applies to all oncology clinical research studies, investigators, and Site Committeesconducted in the HDFCCC, including the UCSF partner sites.

Background

Along with other clinical research units at the HDFCCC, the DSMC has the responsibility to: 1) ensure the safety of all participants enrolled in oncology clinical research studies; and 2) ensure

the scientific and data integrity of all oncology clinical research studies. If significant issues arise, which put study participants at risk or affect the integrity of the data in the clinical studies, the PI or site committee may place themselves on a voluntary enrollment hold. If serious issues are identified and no voluntary action is taken, the DSMC may place a study(ies)/Site Committee on a mandatory enrollment hold. If the DSMC implements a mandatory enrollment hold, the significant issues are required to be resolved and the study program's mitigation plan must be reviewed and approved by the DSMC prior to reopening the study and/or Site Committee for accrual.

Procedures

1.0 Enrollment Hold Notification Process

When a significant issue is identified that warrants a potential enrolment hold, the DSMC Administrative Director (or designee) will document:

- The circumstance of the issue – what happened, how it was identified, etc.
- Effects of the action – does it affect patient safety or data integrity
- Scope of the issue – limited to a single study, across a PI's or Site committee's portfolio or across multiple site committees in which a PI is conducting studies
- Any regulatory actions and outcomes (e.g., IRB notification)
- Any reported CAPAs and steps taken towards implementing the CAPA, including timelines
- Response or feedback from PI, study team, or Site Committee(s)

The DSMC Administrative Director will share the review with the DSMC Chair (or Vice Chair),, with input from the other committee voting members , who will then decide if a mandated hold should be placed on enrollment for a specific clinical trial, and/or the PI's other clinical study(ies), and/or within a Site Committee or across multiple site committees due to the specific issues which were identified as affecting participant safety or data integrity. The review may be done by email or virtually depending on the severity of the issue identified. A majority (> 50% of the voting members of the DSMC Committee) must be present in quorum for this decision(and/or by ad hoc communication if a timely decision requires convening outside of a scheduled DSMC meeting date). Once a mandated hold has been decided,

the DSMC Administrative Director (or designee) will notify the following within one (1) business day:

- 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
- HDFCCC Deputy Director

- HDFCCC Associate Director, Clinical Research Programs
- Site Committee Chair and co-Chairs
- 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 NCI-CTEP study)

The study team will then:

- Complete the reporting form to the IRB of record and notify Data integrity to 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 or CRSO Associate Director, will work with the PI, study team, and Site Committee Chair/co-Chair for the development of a Corrective and Preventative Action Plan (CAPA) to resolve the significant issues.

The DSMC Chair (or Vice Chair) and the DSMC Administrative Director will meet regularly with the study team to review progress of the CAPA in order to ensure resolution of all issues. The DSMC Administrative Director will report the progress on the CAPA to the DSMC at their standing meeting until the CAPA is completed. Once the CAPA has been completed, or the DSMC voting members believe that substantial progress has been made, including steps to mitigate future issues, the DSMC may vote to lift the mandated hold. The mandated hold may be lifted in a step-wise manner if necessary.

Once the DSMC approves the uplifting of the mandated hold, the DSMC Administrative Director will notify CCCROC, HRPP Director and Assistant Director, PRMC, and CRSO of accrual reopening. If applicable, the study team will update the sponsor, update OnCore, and notify Data Integrity to update clinicaltrials.gov and CTRP.

Policy Exemptions

None.

References

Current Data and Safety Monitoring Plan

Policy Approval

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

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Clinical Research Policy Revision
Summary of Changes

Policy Title: Policy for DMSC-Mandated Holds on Study Enrollment
Version Date: 01/23/2025
Version Number: 3.0

	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.