



**Office of Cancer
Centers**

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U.S. Department of Health
and Human Services
National Institutes of Health

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Alan Ashworth, PhD, FRS
Director of Helen Diller Family Comprehensive Cancer Center
UCSF/Box 0128
1450 3rd Street, Suite HD-552
San Francisco, Ca. 94143

Dear Dr. Ashworth:

University of California at San Francisco Helen Diller Family Comprehensive Cancer Center submitted a new version of the BSMP with the following edits/Updates.
Data and Safety Monitoring Plan (DSMP) (version 18Mar2024)

- *Updating the DSMC meeting structure, including how a quorum is determined and the length of service for the faculty DSMC members.*
- *Amended the DSMC dose escalation/expansion review and approval process.*
- *Added the process of the oversight of international sites for consortia trials.*
- *Added how minimal risk trials are reviewed by the DSMC.*
- *Amended the Monitoring Visit Report process by adding the Action Item Report (AIR) process for the workflow of how follow-up items from the Monitoring Visit Report are resolved with specific required timelines for completion and how remediation is incorporated as necessary.*
- *Added the review and adjudication process of Serious Adverse Events (SAE) by the DSMC Committee to ensure that the relationship and expectedness of each SAE is agreed upon by the faculty committee members.*
- *Updated the process for clinical research training for the HDFCCC Investigators through a LMS system (UC Learning) for both onboarding and continual education. Additionally, added new onboarding and continual education courses for Clinical Research Coordinators and other research staff.*
- *Updated the HDFCCC Infrastructure Chart, as well as the DSMC Organization Chart, DSMC Roster, UCSF Site Committee Chart, and all of our monitoring templates.*
- *Updated all the DSMP Monitoring Templates which are embedded in the appropriate institutional protocols.*
- *Updated our risk assessment algorithm table which is utilized by the PRMC for determining the level of monitoring for each institutional oncology-related study.*

The NCI has reviewed and approved the plan.

Hasnaa Shafik

Hasnaa Shafik MD, PhD
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