UCSF Helen Diller Family Comprehensive Cancer Center

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

# Requirement For the Principal Investigator (PI) to Notify the Data and Safety Monitoring Committee (DSMC) of Notice of Serious or Continuing Noncompliance Notifications from the UCSF Institutional Review Board (IRB)

DSMC notification process by the HDFCCC PI for Serious or Continuing Noncompliance notifications.

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## Purpose

This policy requires that all Principal Investigators (PI) in the UCSF HDFCCC contact the DSMC Chair (or DSMC Vice Chair), DSMC Director, and the designated Associate Director, Clinical Research Programs with the proposed Corrective and Preventative Action (CAPA) plan after receiving a Serious Noncompliance or Continuing Noncompliance notification from the IRB for all therapeutic and nontherapeutic trials conducted in the HDFCCC.

## Scope

The policy applies to all PIs conducting therapeutic and nontherapeutic clinical research within the HDFCCC.

## Definitions

*Serious Noncompliance* is defined as: failure to follow state or federal regulations or University policies or determinations of the IRB for the protection of the rights and welfare of study participants and that, in the judgment of the IRB, results in, or indicates a potential for a significant risk to enrolled or potential participants or others or compromises the effectiveness of the UCSF Human Rights Protection Program (HRPP) or the University.

*Continuing Noncompliance* is defined as: a pattern of noncompliance that continues to occur after a report of noncompliance and a corrective action plan have been reviewed and approved by the IRB.

## Background

The DSMC is required to receive the Serious Noncompliance and Continuing Noncompliance reports from the PI in order to determine if this issue requires the need for retraining of the PI and/or the study team or the need for an accrual hold for the PI while a corrective action plan is developed and implemented. Additionally, as these Serious or Continuing Noncompliance Reports could possibly lead to a "for Cause" FDA inspection as the FDA receives these reports from the UCSF IRB, this will ensure that the DSMC is notified in order to discuss whether or not the study team should be prepared for a potential for cause inspection as a result of this determination. The DSMC will also review the CAPA plan from the PI to ensure that it adequately addresses the serious noncompliance issue.

## Procedure

The PI contacts the HDFCCC DSMC Chair (or DSMC Vice Chair), DSMC Director, and the Associate Director, Clinical Research Programs via e-mail within 2 weeks after the UCSF IRB has provided the PI with a Serious or Continuing Noncompliance determination report in order to review the CAPA plan for this violation.

The DSMC Chair (or DSMC Vice Chair) and DSMC Director will review this notification report to determine if any immediate corrective action is required. The report will also be reviewed by the DSMC membership at the next scheduled DSMC meeting. This review will include discussion of the potential need for retraining of the PI and/or the study team or the need for an accrual hold for the PI while a corrective action plan is developed and implemented. Additionally, the DSMC will review the CAPA plan for this violation to ensure that it adequately addresses the serious noncompliance issue.

## Policy Exemptions

None

## References

https://irb.ucsf.edu/protocol-violation-or-incident#definitions

## Appendices

None

**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**

Summary of changes must include high-level edits to the policy, the rational for change, and indicate the section of the policy where the edit can be found (see table below). High-level edits include additions or deletions of tasks and workflows; new references or regulations that are applicable to the policy; new forms or appendices; and any other relevant information that would change the reader's ability to adhere to the policy. Administrative edits do not need to be included in the summary of changes but must be identified in the track-changes version.

A full track changes version of the policy (detailing all changes from one version to another) must be prepared by the Responsible Office and submitted to the Policy Coordinator. The Policy Coordinator will keep the track changes version in a shared file, and available for review if required.

**Policy Title**: Requirement for the PI to Notify the DSMC of Serious or Continuing Noncompliance Notifications from the IRB
**Version Date**: 10/7/2024
**Version Number**: 3.0

| | **Section(s)**: |
|---|---|
| **Summary of Change** | Updated the language throughout this policy to match the current version of the Data and Safety Monitoring Plan (DSMP) (version March 2024). |
| **Revised Text** | See revisions in policy in the Purpose, Definition, Background, Policy Exemptions, and signatories for this policy. |
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