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 PIs in the UCSF HDFCCC notify the DSMC Chair (or Vice Chair), DSMC Director, and the designated Associate Director, Clinical Research Programs 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) a significant risk to enrolled or potential participants or others, or b) 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 or Site Committee 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 inspection as a result of this determination.

Procedure

The PI notifies the HDFCCC DSMC Chair (or 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 ensure timely receipt of this notification for DSMC review.

The DSMC Chair (or 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 or Site Committee while a corrective action plan is developed and implemented.

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:	10/14/2021
Version Number:	2.0

	Section(s):
Summary of Change	Updating this policy with the HDFCC Policy on Clinical Research Policies formatting and language.
Revised Text	Revised the entire policy.