

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

**Policy on Minimum Standards for Partnerships with International Clinical
Research Organizations (CROs)**

Guidelines for how CROs for International sites are approved for Multicenter and Consortium
trials

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Purpose

This policy defines the process whereby the Data and Safety Monitoring Committee (DSMC) and the Cancer Center Clinical Research Oversight Committee (CCCROC) approve the process for the use of auditing/monitoring entities for auditing/monitoring services for international sites for multicenter and consortium Helen Diller Family Comprehensive Cancer Center (HDFCCC) Investigator-initiated trials (IITs).

Scope

This policy applies to all staff and faculty involved with HDFCCC multicenter and consortium trials with International participating sites.

Definitions

Clinical Research Organization (CRO) - a contracted entity that provides clinical research auditing/monitoring services for a clinical research team. References to “CRO” refer to any contracted monitoring/auditing entity in this policy.

Consortium - a network of children's hospitals that perform clinical trials of therapies that are specific to the molecular profiles of a patient's tumor.

Study Chair – overall Principal Investigator of the Multicenter or Consortium trial.

Background

All HDFCCC multicenter and consortium IITs in which the Study Chair (UCSF PI) is proposing to open international participating sites must utilize an international CRO or monitoring entity that is approved by the HDFCCC DSMC and CCCROC for the auditing/monitoring services of these participating sites. The HDFCCC DSMC will not be responsible for providing auditing/monitoring services for non-US participating sites; however, the DSMC will act as the overall Data and Safety Monitoring Board (DSMB) for the trial and these sites (i.e., will provide annual DSMB reports, review SAEs, etc.). The contracted international CRO will be required to submit all Monitoring Visit Reports (MVRs) to the HDFCCC DSMC for safety review, dose escalation approvals, and DSMB Reports.

Procedures

Effective October 12, 2018, the HDFCCC DSMC is not required to provide auditing/monitoring services for international participating sites for multicenter and consortium IITs conducted at the HDFCCC.

The HDFCCC PI (Study Chair) will be required to contract with an international CRO in order to conduct the auditing/monitoring of each of the international participating sites for HDFCCC multicenter or consortium trials. The HDFCCC DSMC must be able to review the proposed international CRO's Monitoring/Auditing Standard Operating Procedures (SOPs) and conduct a brief teleconference with the CRO/monitoring entity and study team in order to determine if the CRO will be able to comply with the DSMC's safety and data integrity requirements as per the

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Data and Safety Monitoring Plan (DSMP) template in the protocol. The requirements for a CRO to be able to be selected as the auditing/monitoring entity for the trial include the following:

- Must have SOPs that are in alignment with the DSMP template in the protocol (i.e., must provide auditing/monitoring of participant and regulatory files at a frequency at least in equivalence and scope with the protocol template, must provide the auditing/monitoring reports to the HDFCCC DSMC for review, communicate non-compliance from the site(s) to the HDFCCC DSMC, etc.).
 - Must comply with the DSMP template in the protocol.
- Must provide auditing/monitoring of all enrolled participants in a dosing cohort and provide monitoring visit reports (MVRs) to the HDFCCC DSMC prior to review and approval of the dose escalation request by the PI/UCSF Study Chair for the trial.
- Must provide the HDFCCC DSMC with the MVRs and the follow-up of any action items within three business days after completion of the monitoring visits for Phase I/high-risk trials and within five business days for Phase II/III/moderate risk trials.
- Must follow the communication plan of the protocol and DSMP, which requires that noncompliance issues of the international participating sites are communicated to the PI/Study Chair and the HDFCCC DSMC within two business day of awareness of this issue.

Once the CRO has been approved, the HDFCCC DSMC Director and Chair, and the CCCROC Chair and Co-Chair will sign the Minimum Standards for Partnerships with International Clinical Research Organizations (CROs) document. The final signed document will be submitted to the PI (Study Chair) and the contracted CRO to signify that the CRO has the appropriate policies and resources to comply with protocol requirements. The PI will facilitate the contracting process, with the selected CRO, through UCSF procurement as required.

Policy Exemptions

HDFCCC trials with international sites that don't have adequate funding for hiring a CRO will be reviewed by the DSMC. An auditing/monitoring of these sites will be considered on a case-by-case basis.

References

- Helen Diller Family Comprehensive Cancer Center Data and Safety Monitoring Plan (DSMP), version 07Apr2021
- 21 CFR 312.50
- 21 CFR 812.40

Appendices

Appendix 1 - [DSMC and CCCROC CRO International Approval Form \(version 27Aug2021\).docx](#)

Policy Approval

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

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Helen Diller Family Comprehensive Cancer Center**

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Policy Revision Summary of Changes

Policy Title: Policy on Minimum Standards for Partnerships with International Clinical Research organizations (CROs)
Version Date: 08Sep2021
Version Number: 2.0

	Section(s): Added the Scope and Definitions sections: updated the Purpose, Background, Procedures, Policy Exemptions, and References sections. Updated the titles for the signatories for this policy.
Summary of Change	Updated the language throughout this policy to match the current version of the Data and Safety Monitoring Plan (DSMP) (version March 2021).
Revised Text	See revisions in policy in the Purpose, Scope, Definition, Background, Policy Exemptions, References, and signatories for this policy.