

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

**Policy for Centralized IND/IDE Management**

Data capture, monitoring, and record keeping of all institutional investigator-held oncologic Investigational New Drug applications (INDs) and Investigational Device Exemptions (IDEs).

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**Purpose**

The purpose of this policy is to outline how the Clinical Research Support Office (CRSO) centrally manages and monitors all Investigational New Drug applications (INDs) and Investigational Device Exemptions (IDEs) in oncology filed by University of California, San Francisco (UCSF) investigators in the Helen Diller Comprehensive Cancer Center (HDFCCC).

**Scope**

This policy applies to all oncologic INDs and IDEs sponsored by HDFCC investigators and is relevant to faculty and staff who manage these IND and IDE filings.

**Definitions**

*Investigational New Drug applications (IND)* - A request from a clinical study sponsor to obtain authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.

*Investigational Device Exemption (IDE)* - Permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.

## **Background**

The HDFCCC CRSO provides centralized regulatory management and oversight for clinical trials conducted at the center and serves as the Office of Record for all Food and Drug Administration (FDA) INDs and IDEs held by HDFCCC investigators, regardless of program affiliation.

## **Procedures**

The procedures described below are performed to centrally manage and monitor HDFCCC INDs and IDEs.

### **1.0 Data Capture for New INDs/IDEs**

Data for centralized IND/IDE oversight and management are stored in OnCore, the HDFCCC secure electronic clinical trial management system. New IND/IDEs held by HDFCCC investigators are captured at the point of submission to the center's centralized scientific review committee, the Protocol Review and Monitoring Committee (PRMC). PRMC submission is required for all clinical trials conducted at the HDFCCC and must be completed in OnCore with the required IND/IDE information. The CRSO ensures that IND/IDE information is completed and updated in OnCore for the life of the trial to include the IND/IDE number, status, responsible FDA division, holder, submission date, and approval date.

### **2.0 Monitoring Annual Progress Reports**

The CRSO monitors IND/IDE anniversary dates and ensures annual progress reports are filed within 60 days of the anniversary date. Submissions within 60 days on either side of the anniversary date are considered acceptable based on FDA guidelines. Annual progress reports will be considered late if filed greater than 60 days following the anniversary date. Late annual progress reports identified by the CRSO are escalated to HDFCCC leadership, including the CRSO Medical Director, CRSO Director, HDFCCC Deputy Director, and the Data Safety and Monitoring Chair. If an annual or progress report will be late due to extenuating circumstances, the responsible party must obtain approval from the Deputy Director and CRSO Director.

### **3.0 Record Keeping**

The CRSO ensures that all information and submissions for INDs/IDEs held by UCSF HDFCCC investigators are recorded in OnCore, so that the IND/IDE record in OnCore is complete, accurate, and up to date. All FDA communication dated from October 1, 2010 to present date is housed electronically in the HDFCCC's secure OnCore system. All FDA communication dated prior to October 1, 2010 is housed in paper form in a secure HDFCCC location.

### **Policy Exemptions**

None.

### **References**

[21 CFR 312.33](#)

**21 CFR 812.1**

### **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**

**Policy Title:** Policy for Centralized IND/IDE Management  
**Version Date:** 03/29/2022  
**Version Number:** Revision #3

<b>Section(s)</b>	<b>Summary of Change</b>	<b>Rationale</b>
1.0 Data Capture for New INDs/IDEs	Removed reference to monthly OnCore reports to identify new INDs/IDEs.	New IND/IDEs are identified in new PRMC submissions, as described in the policy.
Throughout	Added Scope, Definitions, References, Policy contact	Revised to HDFCCC Clinical Research Policy formatting and content.