Policy for Centralized IND/IDE Management

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).

Background

The 2007 National Cancer Institute (NCI) Cancer Center Service Grant (CCSG) competing renewal requires that the UCSF HDFCCC centrally manage all Food and Drug Administration (FDA) IND/IDE submissions. This responsibility is performed by the CRSO housed within the HDFCCC. The CRSO provides centralized regulatory management and oversight for clinical trials conducted at the center and serves as the Office of Record for all INDs and IDEs held by HDFCCC investigators, regardless of program affiliation.

Procedures

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 Committee (PRC). PRC 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 runs monthly OnCore reports to identify new trials with INDs/IDEs held by UCSF investigators. 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.

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, Director of Regulatory Affairs and Protocols, 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.

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 secure HDFCCC location.

Alternate Procedure

None.

Policy Approval

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

Charalambos Andreadis, MD  Date
Clinical Research Support Office Medical Director, Helen Diller Family Comprehensive Cancer Center

Eric Small, MD Date
Chief Scientific Officer, Helen Diller Family Comprehensive Cancer Center

Kate Shumate, MPA, CCRP Date
Chief of Staff, Director, Administration and Planning, Helen Diller Family Comprehensive Cancer Center
### Policy for Summary of Changes

**Policy Title:** Policy for Centralized IND/IDE Management  
**Version Date:** September 7, 2018  
**Version Number:** Revision 2

<table>
<thead>
<tr>
<th>Page No.: 1</th>
<th>Section: Purpose</th>
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<tbody>
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<td>Removed Investigational Trials Resource (ITR); Created a Background header and moved text from former Purpose section here.</td>
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<tr>
<th>Page No.: 1 - 2</th>
<th>Section: Procedures/ Initial Data Capture</th>
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<td>Moved some verbiage to appropriate subsections under procedures; Moved detailed processes to process guideline document.</td>
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New Text

Initial Data Capture
Initial data on INDs and IDEs is managed electronically in a secure electronic web-based database. The HDFCCC's centralized scientific review committee, Protocol Review Committee (PRC), uses an online application and review process housed in this database. The application process to the PRC requires applicants to enter IND/IDE details in the system. This system captures all clinical research studies pertaining to cancer or subjects at risk for cancer. See the OnCore PRC (ePRMS) User Manual, the UCSF OnCore Wiki and the ITR CRSO Procedure for Central IND & IDE Management document for details on what data is required and how data is entered. The ITR CRSO identifies new trials requiring INDs/IDEs by regularly running a report on new data entered by all PRC applicants, using the secure electronic web-based database. All new trials identified are added to a tracking spreadsheet entitled IND & IDE Tracking (stored on the CRSO server under CRSO\Reports\INDs & IDEs\IND & IDE Tracking), and the initial FDA correspondence is collected as outlined below under Record Keeping.

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 Committee (PRC). PRC 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 runs monthly OnCore reports to identify new trials with INDs/IDEs held by UCSF investigators. 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.

Reason for Change
Removed Investigational Trials Resource (ITR); Updated wording.

Page No.: 2
Section: Procedures/ Effect Date & Anniversary (Renewal) Date Calculation

Original Text
Effect Date & Anniversary (Renewal) Date Calculation
If an IND application is exempted, there will be no effect date calculated. For approved IND applications, the effect date is calculated as one of the following, whichever is applicable:

• if no communication is received from the FDA for greater than 30 days following FDA receipt of an application (documented in the FDA’s receipt letter), then the effect date is 30 days from the FDA’s receipt date (or the effect date is the date indicated by the FDA in the FDA receipt letter)
• if a Clinical Hold was in place, the effect date is the date the Clinical Hold was lifted
• if a Safe to Proceed communication is issued by the FDA, the effect date is the date the FDA issues the Safe to Proceed communication. The anniversary date (known at the HDFCCC as the renewal date) is calculated as one year following the effect date, and annually thereafter until the application is withdrawn.

New Text
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| Reason for Change | FDA Guideline detailed in guideline process document; General summary information moved to Monitoring section. |

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Reason for Change
Removed Investigational Trials Resource (ITR); Update process; Reword.

Page No.: 3  |  Section: Procedures/ Record Keeping
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Once new INDs/IDEs are identified, the ITR CRSO collects the available FDA correspondence from the applicant for centralized storage in the Office of Record. Likewise, for all annual/progress reports, protocol amendments, addition of investigators, adding protocols, etc., the ITR CRSO collects all relevant FDA correspondence from the appropriate personnel for centralized storage in the Office of Record. All FDA communication dated prior to October 1, 2010 is housed in paper form in the paper Office of Record files. All FDA communication dated from October 1, 2010 forward is housed electronically in the HDFCCC’s secure electronic web-based database. Once the relevant correspondence is centrally housed in the Office of Record, the ITR CRSO ensures consistent data entry within the HDFCCC’s secure electronic web-based database. Detailed instructions on how new INDs and IDEs are identified, how data is entered in the database, and how documents are stored in the database
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