

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

**Guidance Document for the Requirement of the Approval of OnCore Electronic  
Case Report Forms Prior to the Start of Enrollment in Investigator-Initiated Trials**

**Purpose**

This guidance document defines the requirement for the approval of the Study Calendar and electronic Case Report Forms (eCRFs) in OnCore by the Protocol Project Manager (PPM) or Lead Clinical Research Coordinator (CRC) prior to the start of enrollment in all Investigator-Initiated Trials (IITs). This requirement is essential in ensuring that subject data entry in OnCore will be ready to be entered once enrollment in the trial has commenced. This will allow the DSMC Monitors to review the subject data for safety issues, especially prior to dose escalations in Phase 1 IITs.

**Background**

As per the UCSF Data and Safety Monitoring Plan (DSMP) (current version), all subject data must be entered into the OnCore modules prior to monitoring by the DSMC Monitors. Hence, it is imperative that the Subject Calendar and eCRFs modules completed by the CRC in OnCore are approved and signed off by the PPM or Lead CRC so that data can be entered into OnCore for the DSMC monitors to review.

**References**

- UCSF HDFCCC Data and Safety Monitoring Plan (current version).
- Policy for Data and Safety Monitoring of Phase 1 Studies (current version).
- Policy for Data and Safety Monitoring of Phase 2 or 3 Studies (current version).

**Process**

In general, the Subject Calendar and eCRFs for subject data collection in OnCore are approved by the PPM or Lead CRC via an electronic approval in OnCore after the Study Calendar and eCRFs are entered in a collaborative process between the CRC and the OnCore Clinical Trials Management System (CTMS) Analyst. The approval of this Study Calendar and eCRFs for the trial then enables the subject data to be entered in OnCore. Due to the critical requirement for the PI and the DSMC to evaluate this subject data in OnCore for safety, as well as data integrity, this guidance document requires that the approval of the Subject Calendar and eCRFs in OnCore must occur prior to the start of enrollment in all Investigator-Initiated trials. This requirement is especially important for the Investigator-initiated Phase 1 trials which require DSMC monitoring and approval prior to dose escalations in the cohorts of these trials.

**Alternate Procedures**

There are no alternate procedures to this policy. FOR IRB POLICIES ALWAYS CHECK THE UCSF HRPP WEBSITE FOR FORMS AND GUIDANCE.


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<http://www.research.ucsf.edu/chr>

**Policy Approval**


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

  
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10/7/13  
Date

  
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