

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

**Policy for External Monitoring Visits conducted at the Helen Diller Family  
Comprehensive Cancer Center**

**Purpose**

The purpose of this policy is to describe the requirements for external monitors requesting and conducting monitoring visits at the Helen Diller Family Comprehensive Cancer Center (HDFCCC). Externally sponsored clinical trials conducted at the HDFCCC are subject to periodic review by the Sponsor or designated representative, known as a study monitor or Clinical Research Associate (CRA).

**Background**

The Sponsor is responsible for assuring throughout the clinical investigation that the Investigator's obligations are being fulfilled, the facilities used in the clinical investigation are acceptable, regulatory requirements are fulfilled, and complete and accurate data are being reported. The study monitor provides verification of compliance by conducting on-site monitoring visits.

This policy provides guidelines to assist with monitoring visits and site performance expectations. The procedures outlined within the policy were written in accordance with the Code of Federal Regulations (CFR) / International Conference of Harmonisation (ICH) - Good Clinical Practice (GCP) guidelines.

**Scope**

This scope of this policy is to describe the requirements set forth by HDFCCC for monitors requesting and conducting visits at the HDFCCC. It is expected that UCSF staff, guests, and visitors conduct themselves in a manner that embraces values outlined in UCSF's PRIDE Values.

**Process for Scheduling Monitoring Visits**

Visits should be scheduled at least 4-8 weeks in advance. At least two weeks prior to the monitor's visit but ideally when the visit is first being scheduled, the monitor will inform the Clinical Research Coordinator (CRC) via a Monitoring Visit Confirmation letter of the following logistical information:

- Dates that the monitor will be on site for monitoring visit
- Estimated arrival time (refer to section 6.0)
- Number of study monitors attending visit and contact information for each monitor
- Priorities for the visit
- A list of patient charts to be reviewed
- If IND safety reports will be reviewed

- If a meeting with the Principal Investigator is required
- If a Pharmacy visit is required
- If a Cell Therapy Lab visit is required
- If a meeting with the Regulatory Personnel is required

If this letter or email documenting the information above is not received at least two weeks prior to the monitor's visit, the monitoring visit may be rescheduled.

Available monitoring rooms fill-up quickly and requests cannot always be accommodated. The CRC will reserve a room as soon as a date is confirmed to ensure space for the visit. If the visit is cancelled, the CRC will release the space as soon as notification is given as space is limited. Due to space constraints, we are unable to accommodate more than 2 study monitors per visit.

### **Monitoring Visits**

It is the responsibility of the monitor to schedule his/her/their monitoring visits with the CRC assigned to the protocol. A monitor may visit a maximum of 3 days per visit for each protocol they wish to review. The study monitor must inform the study team as to the number of days required to conduct the monitoring visit. Monitoring visits for each study must be scheduled (at a minimum) 8 weeks apart unless greater frequency is outlined in the signed Clinical Trial Agreement (CTA), monitoring plan or protocol.

Monitors may work directly with the CRC for up to 1 hour per day during a visit. If the monitor requires additional time with the CRC, this must be scheduled in advance of their visit with Clinical Research Manager (CRM) approval for adequate coverage of studies and patient safety. Should the monitor request to meet with the CRC, the CRC will meet the monitor in the space reserved for the visit. Non-UCSF personnel are not permitted to meet at the CRC's desk, workspace or areas where PHI is located.

Exceptions may be made for high risk studies, pending availability of the study team. If an exception is needed, the monitor must submit a request to the assigned CRC, CRM, and Associate Director of Clinical Research Programs. Any requests outside of the criteria outlined above must be approved by the CRM and appropriate Associate Director of Clinical Research Programs.

### **Post Monitoring Visits**

The study monitor should provide a brief summary of their review at the conclusion of the monitoring visit. This review should include a list of which subjects/subject visits and regulatory documents were monitored during the visit. This summary should be discussed in an exit meeting with the Principal Investigator (PI) and/or all study staff. When necessary, the exit meeting may occur via phone with the PI after the visit has ended.

All monitoring reports should be sent within 15 business days of the visit to PI, CRC, CRM, and Protocol Project Manager (PPM) for review to ensure all outstanding action items are resolved, unless otherwise agreed upon. Any corrections to the monitoring report should be requested by study team within 10 business days of receipt. Should the monitoring report be sent more than 15 business days after the monitoring visit, the

study team reserves the right to reschedule the following monitoring visit and reschedule once the monitoring letter is received. Action items on the monitoring visit report will be closed out 2 weeks prior to the next monitoring visit, unless otherwise agreed upon.

### **Monitor Personnel Changes**

Any changes to the assigned monitor must be communicated to the study team (PI, CRC, CRM, PPM) as soon as possible. The newly assigned monitor must send an updated monitoring letter documenting the change and items they plan to address during the next monitoring visits (as outlined above).

### **Hours of Operation**

The monitor may arrive on site at 9 AM and must conclude the visit no later than 4:45PM. Should the monitor need to arrive prior to 9 AM or stay later than 4:45 PM, this must be confirmed with the CRC in advance of their visit. The monitor should return all study documents to the CRC at the end of each day of their visit and should not leave anything study-related in the room after their visit.

### **CHECKING IN**

The monitor should be instructed to check-in at the security desk upon arrival (photo ID is required). The monitor should be instructed to ask security to call the CRC (or designated staff member) after receiving their temporary badge (for new monitors, see section 9.0 for instructions). The monitor must remain in the lobby until the CRC arrives. The CRC will meet the monitor in the lobby and escort the monitor to the space that the CRC reserved for the visit. The monitor and the CRC should sign the study's Monitoring Log for each day of monitoring. Monitoring Logs are provided by either the study sponsor or created by the CRC.

New monitors to the Parnassus campus are required to bring the following items to 505 Parnassus Avenue, Room M192 in Moffitt Hospital prior to the first monitoring visit.

- Driver's License or Photo ID
- Company Business Card
- Company Name Badge

The above information will assist in completing the registration of new visiting monitors into the UCSF Security System and will not be repeated at future visits. New monitors should be informed that this process will take roughly 1-2 hours.

Subsequently, monitors are required to check-in each time at the start of their visit at the security desk to obtain a temporary UCSF badge; the monitor should wear this badge for the duration of the visit.

### **HIPAA Compliance**

The UCSF HDFCCC is committed to protecting the privacy of its patients. The monitor should secure all documents if they must step away from their space to ensure that our patients' health information and other study documents are secure. The monitor may

also secure their personal belongings in the room while away. Study monitor should return all study documents prior to leaving campus. Monitors are not permitted to take source documents containing PHI offsite, this includes photographs of source documents or photo copies of source documents.

The UCSF Office of Ethics and Compliance lists 18 patient identifiers, as defined by HIPAA, including patients' names and "full face photographic images and any comparable images." Even if written PHI is not stored in patient care areas, patient names and faces are readily accessible audibly and visually to visitors during normal business hours. To protect the privacy of patients and to comply with UCSF Office of Ethics and Compliance policies, the UCSF HDFCCC does not allow external pharma monitors or sponsors to visit patient care areas while patients are present.

### **Remove Access of Regulatory Documents**

Trials activated after 01JUL2018 may use Complion, an electronic regulatory document management system. For any trials using Complion, remote monitoring may be allowed. Study Monitors may receive remote access of regulatory documents via Complion up to a week prior to the monitoring visit, at the study team's discretion. Access to Complion should generally be limited around monitoring visit dates. Monitors will contact the assigned CRC to request Complion access.

### **Electronic Medical Records**

Requests for over the shoulder and view-only access to our Electronic Medical Record (EMR) from monitoring and auditing entities will not be granted for any industry-sponsored, cooperative group sponsored, consortia and multicenter investigator-initiated clinical trials conducted at the HDFCCC. For additional information, please refer to our UCSF HDFCCC Policy on Monitor, Auditor, and Inspector Requests for View-Only Access to Electronic Medical Records.

### **Internet**

Monitors should connect to the "UCSFguest" WiFi network. No password is required.

### **Printing Requests**

Requests requiring copying, scanning, and faxing should be directed to the study team. The monitor should be instructed to limit their requests to those necessary for their visit. The monitor is not allowed to leave the premises with PHI.

**Policy Approval**

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

DocuSigned by:  
*Charalambos Andreadis*  
6F7C7E82042E47D  
9/23/2019

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

Date

DocuSigned by:  
*Eric Small*  
7FCB32D327E3438...  
9/23/2019

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

Date

DocuSigned by:  
*Kate Shumate*  
80D38159E89D41B...  
9/25/2019

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Kate Shumate, MPA, CCRP  
Chief of Staff,  
Director, Administration and Planning,  
Helen Diller Family Comprehensive Cancer Center

Date

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

**Summary of Changes**

**Policy Title:** Policy for External Monitoring Visits conducted at the Helen Diller  
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