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

Policy for External Study Related Visits conducted at the Helen Diller Family Comprehensive Cancer Center

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Purpose

The purpose of this policy is to describe the requirements for external study related visits at the Helen Diller Family Comprehensive Cancer Center (HDFCCC). Externally sponsored studies 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).

Scope

The scope of this policy is to describe the requirements set forth by the HDFCCC for sponsors and designated representatives when requesting and conducting visits at the HDFCCC. This policy applies to all study related visits, including but not limited to, pre-site qualification visits (PSV), site initiation visits (SIV), monitoring visits, database lock preparation visits, sponsor audits and closeout visits (COV). It is expected that UCSF staff, guests, and visitors conduct themselves in a manner that embraces UCSF's PRIDE Values.

Definitions

MD Link – MD Link is a secure private electronic platform for study monitors to access the UCSF electronic medical record in order to complete required source document reviews as part of the study related visits. MD Link is the UCSF version of EpicCare Link.

Background

Throughout the clinical investigation, the Sponsor is responsible for assuring 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 or remote monitoring visits.

This policy provides guidelines to assist with study related visits and site performance expectations. The procedures outlined within the policy were written in accordance with UCSF guidelines and policies, along with the Code of Federal Regulations (CFR) and International Conference of Harmonization (ICH) - Good Clinical Practice (GCP) guidelines.
The information in the sections below applies to all study related visits. These visits should all be conducted remotely and if an on-site visit is needed, approval is required by the program Clinical Research Manager (CRM).

Procedures

1.0 Process for Scheduling Remote and On-site Study Related Visits

All study related 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 scheduled, the monitor will inform the Clinical Research Coordinator (CRC) via a Study Visit Confirmation letter of the following logistical information:

- Dates that the monitor will conduct the visit

- Estimated arrival time if on-site
- Number of study monitors (up to 2) and contact information for each monitor
- Priorities for the visit
- A list of participant charts to be reviewed
- If a meeting with the Principal Investigator (PI) is required
- If a Pharmacy visit is required and rationale for on-site necessity if a remote visit cannot accommodate the needs (requires IDS (Investigational Drug Services) pharmacy approval).
- 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 visit, the monitoring visit may be rescheduled. All database locks and/or deadlines must be communicated to the study team at least 4 weeks prior to the deadline.

2.0 Study Related Visit Conduct

It is the responsibility of the study monitor to schedule their study related visits with the CRC assigned to the protocol and indicate the number of days they need for the visit. The maximum length of a monitoring visit is 3 days per protocol. Study related 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) or protocol. Exceptions may be made pending availability of the study team and nature of the request. If an exception is needed, the monitor must submit a request to the study team for approval.

During a study related visit, all meetings between the study monitor and CRC should be planned ahead of time so that there is adequate time to plan and prepare for the discussion.
Study documents, including patient source and regulatory documents, will only be provided for sponsor review in the context of a scheduled study related visit. Regulatory documents can be sent outside of scheduled visits to inform sponsors of new personnel listed on the Delegation of Authority log. Any additional source documentation requests outside of a routine monitoring visit will require prior approval from the PI, CRM, and AD CRP. Once approval is obtained, source documents will be uploaded into Complion and access will be provided to the Sponsor or CRO for verification. In an effort to reduce PHI breaches, source documents will not be emailed to Sponsor or CRO except as outlined in the protocol.

It is recommended that electronic review of source documents be conducted remotely and not while on-site at UCSF. On-site review should be limited to those tasks that cannot be conducted remotely.

3.0 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. The 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, downloads, or photocopies of source documents.

The California Department of Healthcare Services 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 monitors or sponsors to visit patient care areas while patients are present.

4.0 Remote Study Related Visits

4.1 Hours of Operation

Remote monitoring visits may occur at any point during the up to 3-day window that the monitor is provided with access to the participant's EMR or electronic study chart. However, the initial meeting and check-ins with the study team must occur between 9am and 4:45 PM Pacific Time. Remote monitors should email the study staff to inform them that the monitor has logged in and begun monitoring. Extensions to the monitoring visit window will not be granted unless approved by the PI and program CRM for exceptional circumstances.

4.2 Meetings

Remote monitors must schedule a meeting via video conference (CRCs can arrange a Zoom meeting if the monitor does not have a video conference system to use) with the study staff at least once during the visit. The study monitor may work directly with the CRC for up to 1 hour each day (at agreed upon times). The IDS pharmacy is also available via video conference, and this is the preferred method of monitoring for pharmacy.

On the first day of the remote monitoring visit, the CRC will meet via video conference with the monitor to review the program-specific Monitoring Guide and help orient the study monitor to MD Link or Complion. The program-specific Monitoring Guide will be provided to the monitor in lieu of any sponsor or CRO source data location logs.

4.3 Provisioning Access to MD Link

To proceed with access to the EMR, the MD Link Participation Agreement must be signed by the sponsor before provisioning access to one of their monitors. Sponsors can reach out to the appropriate CRC and CRM to obtain the MD Link Participation Agreement. Requests for "over the shoulder" viewing of the EMR will not be allowed.

This agreement will allow all of the Sponsor's active and future studies at UCSF to be monitored remotely via MD Link; signing authority on the MD Link Participation Agreement cannot be delegated to Clinical Research Organizations (CROs). In the case of a co-

sponsored trial, a co-signed agreement is required even if existing agreements exist with the individual sponsors.

Individual monitors must sign the UCSF MD Link Confidentiality Agreement when they register for access to MD Link. Access to MD Link will be requested by the study monitor and the CRC once the study is open to accrual.

If the sponsor is unable to sign the MD Link Participation Agreement, study monitors will complete remote visits via Complion or equivalent electronic storage system. Participant shadow e-charts are assembled for each participant to include all protocol-defined source documentation and represent the original source documents extracted directly from the EMR by the study personnel. Shadow charts are reviewed by the PI and study team for accuracy and relevance to the specific trial. Paper shadow charts may be created in exceptional circumstances and require approval from the CRSO Director.

4.4 Monitoring via MD Link

Study monitors for sponsors with MD Link Participation Agreements will have read-only access to the subject's UCSF Electronic Medical Records (EMR) via MD Link. UCSF uses the EPIC platform as the EMR – commonly known as APeX at UCSF. The secure private folder located in MD Link contains electronic records from APeX, divided into small sections for easy navigation and auditability. The subject's entire UCSF medical record is available for viewing in MD Link.

For additional information on how to navigate patient charts in the MD Link system, the monitor can access the "MD Link Quick Start Guide," which can be accessed on the home screen of MD Link. If additional assistance is needed, the study monitor can contact the MD Link Service Desk at (415) 514-8790, option 1.

4.5 Remote Access of Regulatory Documents

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

5.0 On-site Study Related Visits

Studies where all source and regulatory documents are available electronically are permitted to have one on-site visit per year and require prior approval from the study team. If more than one on-site visit is needed, exceptions may be made pending availability of the study team and nature of the request. If an exception is needed, the monitor must submit a request to the study for approval. For any on-site monitoring involving pharmacy, contact the IDS pharmacy directly.

5.1 Planning

Available on-site 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.

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 with CRM approval to ensure adequate coverage of studies and patient safety.
Should the on-site 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 protected health information (PHI) is located.

5.2 Hours of Operation

For on-site visits, the monitor may arrive at 9 AM and must conclude the visit no later than 4:45 PM. Should the monitor need to arrive prior to 9 AM or stay later than 4:45 PM, they must confirm 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.

5.3 Checking In

The on-site 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. 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 may 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.

5.4 Internet

On-site monitors should connect to the “UCSFguest” WiFi network. No password is required.

5.5 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.

Downloading, obtaining screenshots, and printing of records from the participant’s EMR is strictly prohibited.

6.0 After Study Related Visits

The study monitor should provide a brief summary of their review at the conclusion of the visit. This review should include a list of which participants/participant visits and regulatory documents were monitored during the visit. This summary should be discussed in an exit meeting with the PI and/or 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 after the visit to the PI, CRC, CRM, and Protocol Project Manager (PPM) for review to ensure all outstanding action items are resolved, unless otherwise agreed upon. Monitors must document outstanding action items in the monitoring report. 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 until 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.

7.0 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). The CRC or PPM should then provide this policy and other relevant SOPs to the new monitor.

Policy Exemptions

If a study does not utilize Complion for document storage, another compliant system may be used for source document verification.

References

None

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 External Study Related Visits conducted at the Helen Diller Family Comprehensive Cancer Center
Version Date:
Version Number: Revision #2 – 09/22/2023

Section(s)	Summary of Change	Rationale
Scope	Added list of visit types	Clarify that policy applies to all external study-related visits
All	Replaced “Monitoring Visit” with “Study Related Visit”, rearranged sections	Align with scope adjustment, improve topic organization
All	Re-ordered sections to group content of in-person vs. remote study visits together	Improve the readability of flow of the policy
Background	Stated visits to be remote unless CRM approves on-site visit	Clarify default and provide method for requesting on-site visits
1.0	Added requirement for rationale for on-site pharmacy visit requests	IDS Pharmacy SOPs do not allow on-site visits; rationale is needed to grant an exception
2.0	Stated study documents are only provided during monitoring visits and added details of approvals required for exceptions. Added that redacted source documents should not be emailed unless stated in the study protocol.	Standardize study communication methods and reduce risk of PHI breaches.
4.2	Added IDS pharmacy preference for video visits	Clarify how pharmacy monitoring is performed
5.0	Added allowance of one on-site monitoring visit per year; instructed to contact pharmacy directly with on-site requests	Provide standard frequency of on-site visits, encourage direct communication with IDS Pharmacy for pharmacy exceptions
Policy Exemptions	Added alternative to Complion	Complion is mentioned throughout the policy, and not all studies use Complion

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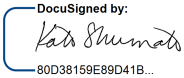
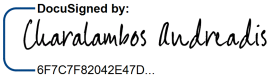
Katherine Shumate kate.shumate@ucsf.edu Chief of Staff, Director of Administration University of California, San Francisco Security Level: Email, Account Authentication (Optional) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DocuSigned by:  80D38159E89D41B... Signature Adoption: Uploaded Signature Image Using IP Address: 198.27.250.129 Signed using mobile	Sent: 9/22/2023 3:41:46 PM Viewed: 9/25/2023 12:31:31 PM Signed: 9/25/2023 12:31:55 PM
Charalambos Andreadis charalambos.andreadis@ucsf.edu 5:05pm University of California, San Francisco Security Level: Email, Account Authentication (Optional) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DocuSigned by:  6F7C7F82042E47D... Signature Adoption: Pre-selected Style Using IP Address: 157.131.170.30	Sent: 9/25/2023 12:31:56 PM Viewed: 9/25/2023 2:55:15 PM Signed: 9/25/2023 2:55:26 PM

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Completed	Security Checked	9/25/2023 2:55:26 PM

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