| **STANDARD OPERATING PROCEDURE**<br>**STUDY MONITORS & MONITORING VISITS** | |
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| **SOP#: 6.1** | **Original Approval Date: 3/25/13** |
| **Version#: 9.0** | **Current Revision Date: 3/10/25** |

## 1.0 PURPOSE/BACKGROUND

The purpose of this Standard Operating Procedure (SOP) is to establish a standard for study monitoring visits in the CCCTO and to ensure that the guidelines for the preparation of the monitoring visits and the procedures during monitoring visits are followed.

## 2.0 SCOPE

This SOP applies to all studies that involve a study monitor visit from an outside agency to perform study monitoring.

## 3.0 RESPONSIBILITY

- Study Staff
- Investigational Drug Service
- Study Sponsors and designees
- CCCTO Budget & Contracts staff
- Others as required

## 4.0 DEFINITIONS

Refer to Glossary of Common Terms and Definitions.

Monitoring: the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures, Good Clinical Practice (GCP) and the applicable regulatory requirements.

EpicCare Link (or "Link"): a secure, web-based service that provides authorized individuals view-only access to patient electronic medical records.

## 5.0 ROLES AND PROCEDURES

### 5.1 Scheduling & Notification

5.1.1 Monitoring visits must be arranged in advance. Study coordinator must notify the required participants of the monitoring visit and confirm availability. Availability of monitoring space must also be confirmed if an in-person visit will be conducted. After the date is agreed upon, the site must

receive notice in writing of the visit at least two weeks prior to the visit, unless an exception is granted by the Research Manager. This applies to on-site and remote monitoring visits. The notice of the monitoring visit must also include the focus of the visit, any special preparations/documents requested, and a list of required participants during the visit (study coordinator, PI, sub-I, Pharmacy, Regulatory, clinical research assistant, etc.).

5.1.2 Monitoring visits will be conducted at the frequency specified in the clinical trial agreement. If the agreed upon frequency is not adhered to, the CCCTO may seek additional financial compensation and the CCCTO Budget and Contracts Office will invoice the sponsor accordingly. On-Site monitoring visits may occur once per year per study. Additional on-site visits will only be granted with management or leadership approval.

5.1.3 If a monitor requests individual access to Epic Care Link ("Link"), access must be requested at least two weeks prior to each visit and will require monitors to fill out an electronic form and set up security questions prior to their first visit. A delay in submitting these forms to Froedtert's Health Information Management team may result in a delay in Link Access. When access is granted, a secure username and password will be emailed directly to the requesting monitor. Access will be granted for the dates of the monitoring visit only. Access for subsequent monitoring visits will be requested by the study coordinator.

5.1.4 Access to Florence eBinders must also be requested at least two weeks prior to individual monitor's first visit and access will be granted through the MCW Office of Research. When access is granted, a secure username and password will be provided to the requesting monitor via email. Access to Florence eBinders will be available to the study monitor continuously throughout their participation in the study.

5.1.5 All documents that are not maintained in Link will be uploaded to Florence eBinders. These would include documents that are not part of the legal medical record (e.g.,regulatory documents, patient questionnaires, drug diaries, adverse event logs, emails, screening and enrollment logs, etc.). Copies of the signed consent forms are located in the Media tab in Link.

5.1.6 Investigational drug service records will be contained in the Vestigo system and monitor access will be granted through the Investigational Drug Service at Froedtert Hospital. A member of the study team will request access for the monitor to receive vestigo access by emailing the IDS shared email address.

### 5.2 Preparation

5.2.1 For on-site monitoring, study staff will make arrangements to reserve an appropriate monitoring area. The area should be equipped with (or in close proximity to) a copier, data portal, and fax machine.

5.2.2 Study staff will prepare for visits by ensuring that all the relevant documents in the regulatory files and the subject files are available and appropriately updated and any outstanding action items have been addressed.

5.3 **During the On-site Monitoring Visit**

5.3.1 Monitors must wear a name badge during their visit identifying them and the organization that they represent.

5.3.2 The study monitor must comply with the MCW/FH dress code while on site. (i.e. business casual attire and no strong-smelling perfumes or colognes.)

5.3.3 No food/meals will be provided to monitors; however, they will be directed to an area where food may be purchased. Monitors are not permitted to buy meals for the study staff.

5.3.4 Monitors must meet with staff in an area where confidentiality can be maintained. Confidential study information should not be discussed in the presence of other study monitors. If necessary, a space can be arranged for private discussions.

5.4 **All Monitoring Visits (On-site and Remote)**

5.4.1 A time for the monitor and the study staff to meet for debriefing should be identified, and applicable study staff should be notified if their presence is requested (i.e. study coordinator, regulatory staff, research manager, clinical research assistant, etc.).

5.4.2 Study coordinators will meet with study monitors during agreed upon intervals throughout the day and action items should be addressed at those times and/or at the debriefing.

5.4.3 Monitors must present the study coordinator with a written or typed list of findings during the debriefing (Any sticky notes or flags in the patient charts should be referenced on the list).

5.4.4 Every effort will be made to schedule time with the Principal Investigator. If a meeting cannot be arranged, an alternative form of contact may be arranged upon request (e.g. phone call).

5.4.5 If the monitor previously requested access to Link, the study coordinator will arrange this with Health Information Management (HIM) in advance. The records available in Link are considered certified copies of the patient medical record.

5.4.6 Study monitoring visits may only be conducted during CCCTO business hours. Any exception must be approved by the Research Manager or CTO leadership.

5.4.7 Study monitors are asked to send a follow-up letter within two weeks following the visit to ensure adequate time to address items requiring action. Study staff may request corrections to the letter if applicable.

5.4.8 The study staff will work to resolve all outstanding issues prior to the next scheduled visit.

## 6.0 REFERENCES

Froedtert Hospital Policy #RI-016 "Case Management Inspector Release"

Froedtert Health Policy #CPM.0116 "Observer Policy"

Froedtert Health Policy #FCH-HR.002 "Dress Code – Personal Appearance"

Medical College of Wisconsin Policy #HR.EE.150 "Personal Appearance for Employees and Volunteers"

## 7.0 APPENDICES

N/A

Authorized by:

Signed Electronically by:
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CCCTO Administrative Director

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