STANDARD OPERATING PROCEDURE
STUDY MONITORS & MONITORING VISITS

SOP#: 6.1	**Original Approval Date: 3/25/13**
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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 Pharmacy
- Study Sponsors and their designees
- CCCTO Budget 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 study 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 requirement(s).

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

5.0 ROLES AND RESPONSIBILITIES

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 staff must also be confirmed if an in-person visit will be conducted. After the date is agreed upon

receive notice in writing of the visit at least two w[illegible] 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
etc.).

5.1.2 Monitor visits will be conducted at a 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 Office will invoice the sponsor accordingly. [illegible] visits may be granted by the PI per year per study. Additional visits may be granted by the PI approval.

5.1.3 If a m[illegible] must be requested [illegible] and will require m[illegible] its to fill out an [illegible] their first visit. A delay in submitting the [illegible] Information Management te[illegible] access [illegible] 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 Copies of the signed consent forms are located in the Medasys in Link.

5.1.5 Access to [illegible] eBinders must also be requested [illegible] to individual m[illegible] or's first visit and access will [illegible] Office of Research Wri[illegible] access is gra[illegible] will be provided to [illegible] e requesting i[illegible] Florence eBinders will be available to the study monitor continuously throughout their participation in the study.

5.1.6 All documents that are not found in Link will be uploaded to Florence eBinders. [illegible] medical record. (Regulatory documents, patient questionnaires, drug diaries, adverse [illegible] ent logs, emails, screening and enr[illegible] ms, etc.

5.1.7 Inves[illegible] system [illegible] and monitor access will be granted through the Investigation[illegible] Drug Service at Froedtert Hospital.

5.2 **Preparation**

5.2.1 For on-site monitoring, study staff must 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 must prepare for visits by ensuring that all the relevant documents in the regulatory files and the subject files are gathered 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 or an MCW CCCTO Visitor Badge, which will be provided.

5.3.2 The study monitor [illegible] (i.e. business casual attire and no strong smelling perfumes or colognes.)

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

5.3.4 Monitors must meet with the staff in an area where confidentiality can be maintained appropriately. 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 [illegible] 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 The study staff will work to resolve all outstanding issues prior to the next scheduled visit.

5.4.5 Every effort will be made [illegible] upon request (i.e. phone call, repeat visit).

5.4.6 If the monitor previou [illegible] requested ac [illegible] arrange this with H [illegible] the records available in Link are considered certified copies of the patient medical record.

5.4.7 Study monitoring visits may only be conducted during the CCCTO study coordinator's normal w [illegible] hours. Any exception must be a [illegible] research manager.

5.4.8 [illegible] following the visit [illegible] re adequate tim [illegible] action. Study staff may request corrections to [illegible] letter [illegible] able.

6.0 References

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

Froedtert Health Policy #CPM.0116 "Observer Policy"

Froedt [illegible] "[illegible] Appearance"

Medical College of Wisconsin Policy #HR.EE.150 "Per [redacted] Volunteers"

7.0 Appendices

N/A

[redacted]

Authorized by: Signed: Stacey Zindars - szindars@mcw.edu
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