ON-SITE CLINICAL TRIAL MONITOR GUIDELINES

The purpose of SCC-CTO monitor guidelines is to provide an overview of how our site operates to make your monitoring visit as productive as possible. Please note that all guidelines will be strictly enforced, and SCC reserves the right to refuse on-site monitor visits as applicable.

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1. Please provide a visit confirmation letter at least two weeks before the visit, including:
   - A prioritized list of up to 10 patient research charts to be reviewed on site.
     - Requests for 'all patients' will not be accepted.
   - All pharmacy visits will be done remotely and requested on the RedCap visit form. Vestigo pharmacy access will be provided for 24 hours.
2. Only 1 monitor per visit is allowed unless otherwise approved in advance by appropriate CTO leadership. No more than five monitors will be allowed anytime in the monitoring room.
3. On-site visits will be limited to a maximum of 2-day (unless approved by leadership) with research chart /source documentation review only. EMR access will not be provided while on site as this time is utilized for chart review only. However, Co-Monitors working remotely will have EMR access as needed.
   - EMR access will be provided prior to or after the on-site visit, if applicable
4. All communication will be done virtually with site staff
   - Zoom meetings will continue for all PI, Data Specialist, Lab, etc.
   - No pharmacy visits or building tours allowed
5. Monitors must adhere to the University parking policy and may not park in the Stephenson Cancer Center garage or utilize the valet. *(See website for details.)*
6. Upon arrival each day, monitors will proceed to the 6th-floor lobby and email data specialist contact. The data specialist will walk you to your assigned monitoring location, where you will receive a monitoring badge and sign in.
7. Monitoring Hours: **Firmly 9:00 AM to 4:00 PM.** For COVID-19 sanitation and security purposes, these hours are strictly enforced. In addition, all study materials must be locked in the room cabinets by 4:00 PM daily.
8. All monitors must respect others and refrain from discussing patient or study issues in the monitoring room, surrounding hallways, and elevators.
9. Food is allowed in the monitoring room, including small snacks and drinks with lids.

10. Monitors may not go outside the monitoring room to research staff offices, patient care areas, labs, or staff work areas. In addition, monitors will be allowed to utilize 6th-floor restrooms and the first-floor lobby for lunch or business purposes.
11. Monitors are not allowed to schedule meetings with the PI, clinic, lab, or pharmacy staff without Data Specialist involvement.
12. Monitors shall provide the site with a visit follow-up letter within 2 weeks of the visit outlining what was accomplished and any outstanding issues. Subsequent visits will not be scheduled less than 4 weeks from the previous visit unless needed by circumstance.
13. Monitors are not allowed to write in or dismantle research charts. Post-it notes may not be placed in subject charts. Making copies of source documents with Patient Health Information (PHI) is prohibited. Please be aware our primary purpose is patient care, and clinic needs take priority; research charts may be requested for return at any time.

We value our relationship and look forward to working with you. Thank you for your attention to and adherence to these Guidelines, which will help ensure a successful and productive visit.

Sarah A. Wilson, MBA
Digitally signed by Sarah A. Wilson, MBA
Date: 2022.12.13 16:24:17 -06'00'

Sarah Wilson, MBA
Executive Director
Clinical Trials Office
Stephenson Cancer Center

Juanita Ortiz
Digitally signed by Juanita Ortiz
Date: 2023.02.07 14:42:19 -06'00'

Juanita Ortiz, MBA
Assistant Director – Data Operations
Clincial Trials Office
Stephenson Cancer Center

By signing below, you agree to adhere to the Clinical Trials Office Monitor Guidelines.

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Monitor Signature