Document Number: SOP-49-v5	Title: External Monitoring Visits
Effective Date: 4/1/2022	

1. 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 (SOPs), GCP, and the applicable regulatory requirement(s).
Source Documents	Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial or research study).
Source Data	All information in the original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.
Sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.
Study Team	The team that prepares for external monitoring, responds to monitor(s) inquiries, and participates in meetings and follow-up as needed.

2. BACKGROUND

This SOP supports Sponsor monitoring as indicated in the Code of Federal Regulations (CFR) (21 CFR 312.50 & 60) and the International Conference for Harmonisation Good Clinical Practice (ICH-GCP) Guidelines E6 (4.1.4 & 5.18).

3. PURPOSE

The purpose of this SOP is to document procedures for scheduling, conducting, and responding to monitoring and close-out visits for clinical research studies managed by Lineberger Comprehensive Cancer Center (LCCC) Clinical Protocol Office (CPO).

4. SCOPE

This SOP applies to all externally sponsored clinical trials managed by the LCCC CPO.

5. RESPONSIBLE PARTIES

The Principal Investigator (PI) and CPO Management and study staff.

6. PROCEDURES

6.1. Scheduling/Preparation

6.1.1. Monitoring visits may occur in person per the following frequency: after first subject enrolled, annually, and at close out. Otherwise, all external monitoring visits will be conducted remotely.

6.1.2. Monitor visits are scheduled between the hours of 8:30am and 4:30pm, Monday through Friday. Monitor visits will not extend beyond 4:30 pm. Exceptions may be granted with manager approval.

6.1.3. Regular monitoring visits will be scheduled at intervals specified in the contract, regardless of being in person or remote. If unspecified in the contract, monitor visits should occur no earlier than every 4-6 weeks. Exceptions may be granted after review of previous follow-up monitoring letters by Management. Verification of the reason for the exception will be requested.

6.1.4. Monitors must confirm the visit and the agenda at least four weeks prior to the visit whenever feasible. Monitors must specify their needs for review such as appointments with the Principal Investigator (PI), Investigational Drug Services (IDS), Clinical Trials Unit (CTU) Laboratory, and Regulatory when scheduling the visit. If a monitor is not explicit about their needs, the coordinator will confirm the needs of the monitor.

6.1.5. Monitors must disclose the number of monitors planning to attend at the time the visit is scheduled. Additional monitors may attend if space permits; however, access to the electronic medical record is not guaranteed if the request is received with less than two weeks' notice.

6.1.6. Future monitoring visits may be scheduled in advance; however, they are contingent on timely receipt of the follow-up letter from the previous visit. See 6.3.1 below.

6.2. Monitoring Visit

6.2.1. Visits not started in a timely manner (within 15 minutes of scheduled time) may result in the missed portion of the visit being rescheduled. Exceptions are only granted through Management.

6.2.2. When monitoring on site, monitors are required to be checked in and out each visit day and wear a guest ID badge at all times. In areas intended for authorized personnel only (IDS, CTU lab, PI offices, etc.), monitors must be accompanied by a study team member. Monitors are required to sign a study-specific monitoring log upon arrival.

6.2.3. When monitoring remotely, monitors are required to check in with the site staff at the beginning of their review.

6.2.4. Epic access is offered to all monitors. Requests for Epic access made less than two weeks from the visit date are not guaranteed. As of 8/26/2016, medical records are no longer printed and added to the research chart; therefore, Epic access will be required for source documentation review.

6.2.5. Access to Vestigo, Lineberger's Investigational Product management system, is required for all monitors to limit the time spent at IDS.

6.2.6. Access to Florence e-Regulatory binders will be granted for remote review. Electronic copies of paper files will be otherwise provided.

6.2.7. Monitors are not permitted access to individual CPO staff workstations due to HIPAA regulations and our obligation of confidentiality to all study participants and additional sponsors.

6.2.8. Monitors are expected to maintain confidentiality and respect Protected Health Information (PHI) in accordance with HIPAA, GCP, and ICH guidelines. Sponsor representatives are expected to respect shared spaces and limit conversations to study-related topics conducted at respectful volumes when on site. Sponsor representatives will not be disruptive to other sponsor representatives. Any deviations outside these expectations are reported to Management.

6.2.9. Monitors may not make copies of any documents with PHI unless they are redacted per the LCCC CPO SOP-52 Redaction of Subject Identifiers. Microsoft Teams is an acceptable platform to share source documentation not available in Epic.

6.2.10. As applicable to the type of monitoring visit (remote or in person), the Coordinator and/or Data Coordinator (DC) meets in person/communicates remotely with the monitor at each visit in which research charts or drug accountability is reviewed. The Regulatory Associate and/or Regulatory Assistant meets in person/communicates remotely with the monitor at each visit during which regulatory documents are reviewed. The PI meets with the monitor as scheduled.

6.2.11. Investigational Drug Services and Tissue Procurement Facility appointments are made at the request of the monitor.

6.3. Follow-Up

6.3.1. A written summary of all study monitoring and close out visits conducted by the monitor is expected within two (2) weeks of the last day of a visit. This summary should include details of study title, visit activities, timeliness of data entry, number and details of queries outstanding, deviations occurring during the period reviewed, and any items requiring follow up by LCCC CPO or the sponsor. All written or electronic summaries should be addressed to the Principal Investigator, Coordinator, DC (if applicable), Regulatory Associate, and Regulatory Assistant. If a written summary is not received at least 2 weeks prior to the next scheduled visit, the visit may be cancelled or postponed until the summary is received.

6.3.2. Upon receipt of the monitoring follow-up letter, the Regulatory Assistant will upload the letter to the respective folder on a secure shared drive as well as to the Florence eReg study binder.

6.3.3. The Regulatory Assistant will ensure that the PI has received a copy of the follow-up letter.

6.3.4. Action items will be addressed, and a response sent to the monitor. Monitors are expected to remove completed action items and/or correct errors noted by study staff.

7. REFERENCES

7.1. ICH GCP Guidelines: https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

7.2. Food and Drugs: Title 21 CFR 312: http://www.ecfr.gov/cgi-bin/text-idx?SID=a6f3107138b82ce04efc4a2c62f60287&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_160

8. APPROVALS

CPO Director Approval:

Theresa Cummings

Tess Cummings, RN, DBA, CCRP

3/17/2022

Date

9. REVISION HISTORY

Version No.	Date	Author	Reason for Change
1	UNK	UNK	Initial Document
2	09/16/2019	Regulatory Management	Clarify and streamline personnel activity
3	10/10/2019 12/18/2019	Clinical Team	Clarify procedures based on current practices
4	2/9/2021	Janine Bennett	Revised role and procedure for handling and distribution of follow-up letters, added reference to Florence eReg binders for new regulatory documents handling. Added information specific to remote monitoring capabilities and procedures.
5	3/1/2022	S. Ladd	Instituted limit on in person monitoring due to shift in work locations post COVID-19 pandemic. Referenced e-Regulatory files.