***TITLE: Monitor Visits***

***SOP*** CL XX.XX

***Author(s):***

 ***Approved by Date***

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1. **SCOPE/PURPOSE**

The purpose of this SOP is to insure compliance with the sponsor/CRO and the site requirements for monitoring of a study and ensure accurate data and to ensure that all relevant information from the monitoring visit is addressed. This is SOP is intended to meet FDA Federal Regulations and Good Clinical Practice Guidelines.

**II. ALLOWABLE EXCEPTIONS**

**III. RELEVANT REGULATIONS/GCPS**

• 21 CFR 50

• Guidelines for Investigators (UAB IRB)

• FDA (Food and Drug Administration) Requirements

**IV. DEFINITIONS/ACRONYMS**

**V. RESPONSIBLE PERSONNEL**

This SOP applies to the following – Study Investigators, Study Coordinators, Regulatory Affairs, and Sponsors.

**VI. DETAILS**

1. **Scheduling**
	1. Monitors should be given the Monitor Informational Letter prior to any monitoring visit. This letter is to assist them during and in planning for their monitoring visit. The regulatory coordinator will send the letter to the monitor and notify the coordinator when the letter has been sent.
	2. Monitoring visits are pre-arranged and conducted on working days between 8:30 am and 4:00 pm. The coordinator and the monitor are responsible for scheduling the visit. If the monitor requests additional appointments with the PI, pharmacy or other areas the coordinator is responsible for arranging the appointment times in advance of the visit.
	3. Monitoring visits are scheduled on the shared research calendar. When a date is scheduled, the coordinator emails the site manager and the regulatory coordinator with the date. The regulatory coordinator adds the date to the shared research calendar. No more than one monitor visit is scheduled in the same day. If it is necessary to schedule more than one monitor visit on the same day, the site manager must approve the additional visits.
	4. A working location will be provided for the monitor with access to appropriate research staff.
	5. During the monitoring visit the study coordinator and all appropriate documents will be available to the monitor.
	6. The Site Manager must review the results of the monitoring visit. Study coordinators are responsible for seeing that the monitors allocate time towards the end of their visit for an exit interview. The exit interview will be conducted after all CRFs and regulatory documents have been reviewed by the monitor. For this interview the monitor must prepare a written summary of findings regarding all aspects of the monitoring visit. A copy of this summary will be given to the Site Manager conducting the exit interview in order to clarify and/or resolve issues.
2. **Regulatory documents**
	1. The regulatory coordinator is responsible for resolving any regulatory issues of the monitoring visit.
	2. The regulatory coordinator keeps the regulatory documents up to date and ready for the monitor visit. The regulatory coordinator will place the regulatory binders in the conference room prior to the monitor visit so they are ready for the monitor. During the visit the regulatory coordinator will meet with the monitor to discuss any issues or concerns and address as many as possible prior to the completion of the visit. The monitor may not remove any regulatory documents or study documents from the research offices.
3. **Participant documents**
	1. The study coordinator is responsible for the resolution of the monitoring issues concerning clinical aspects of the study. The coordinator must notify and review issues with the Site Manager.
	2. The study coordinator maintains the participant source documents and case report forms up to date. The coordinator prepares for the visit by making sure that all study paperwork is complete and ready for the monitor to review. Prior to the monitor visit the study coordinator places all the necessary documents requested by the monitor in the conference room
4. **Conclusion**
	1. Upon conclusion of the monitoring visit and exit interview, the monitor will confirm that a written summary of all clinical and regulatory findings will be sent to the Site Manager and Principle Investigator within two weeks of the visit.
	2. When the visit is concluded. The regulatory coordinator returns all regulatory documents to the proper location. The study coordinator returns all study paperwork to the proper location.
	3. The study coordinator and regulatory coordinator make sure the room used for the monitor visit is left clean and in order.
	4. A summary of the monitor’s visit, exit interview, and resolution of findings will be presented at staff meetings by the Site Manager and required actions, if any, will be noted.
	5. The monitor’s follow up letter must be reviewed and signed by the Principle Investigator, Site Manager and study coordinator. The letter is then given to the regulatory coordinator with the corrective action items for IRB submission.

**VII. QA**

NA

**VIII. APPENDICES/RESOURCES**

NA

**IX. RELATED SOPS**

NA