**PURPOSE:** This describes the process followed by members of the research team when the

monitor, assigned by the Sponsor/CRO, conducts a monitoring visit.

**SCOPE:** Members of the research team who assist the Principal Investigator when hosting a monitoring visit pertaining to clinical studies subject to all regulations for drugs and biologics during all investigational phrases of development.

**PERSONNEL RESPONSIBLE:**  Principal Investigator and when delegated by the Principal Investigator---- Sub-Investigators, Study Coordinator and/or other pertinent staff.

**PROCEDURES:**

**Scheduling the site monitoring visit**

* Schedule a mutually agreeable date/time between the research team or designee(s) and the monitor to accommodate the visit.
* Reserve a work space for the monitor.
* If applicable, arrange for subject medical records to be available for review.
* Notify all members of the research team (e.g. Regulatory Coordinator, Pharmacy, Lab, etc.) with the confirmed visit date, time and location.

**Washington University School of Medicine Visitor Policy**

* Per Washington University School of Medicine Visitor Policy; if a monitor visit is scheduled between October 1st and March 31st, the research team member scheduling this visit will request that the monitor present documentation of an influenza vaccine for that current season. This documentation should be forwarded to the research team member prior to the scheduled monitor visit. Monitor must have had the influenza vaccine completed prior to coming on the medical campus.
* The monitor must complete the Washington University questionnaire and forward the completed form to the research team member.
* If the monitor states that there is a religious reason why they cannot receive the influenza vaccine, they need to complete the WU Request for Religious Exemption from Influenza Vaccination form.
* If the monitor states that there is a medical reason why they cannot receive the influenza vaccine, they need to complete the WU Request for Medical Exemption from Influenza Vaccination form.
* Upon completion and receipt of the monitor’s completed form(s), the research team member will fax form(s) and influenza documentation to WUSM Occupational Health (#362-0058). If the visitor answers “yes” to any questions on the form, he/she may not interact with patients or visit a patient care area until evaluation by Occupational Health is completed.

**Preparing for the monitoring visit**

* Ensure that all regulatory documents, CRFs, and drug/device accountability records are available for review.
* Ensure that all data queries and corrections received to date have been resolved to the extent possible.

**Managing the monitoring visit**

* Ensure that the monitor signs the visit monitoring log.

**Following up after the monitoring visit**

* Ensure that all issues identified for resolution or follow up are addressed within the specified time frame provided by the sponsor.