**WHAT is the Monitoring Log?**

The Monitoring Log is a means to track and document any review of the study, such as outside monitoring visits from sponsor and FDA site visits/audits.

Includes the following information Optional information as deemed helpful (*not inclusive*)

▪ Name of Monitor ▪ Signature of Monitor

▪ Date of Review/Monitoring ▪ PI Initials – acknowledgement of visit

▪ Reason for Review/Monitoring ▪ Final Monitoring Report/Letter sent to IRB

**WHEN is a Monitoring Log required?**

Sponsored-studies may require investigators to maintain a Monitoring Log, in which case sponsors should specify what information to capture, or provide the log prior to study start.

It is recommended for all studies to consider if a Monitoring Log will help them conduct the study in a more efficient and organized manner.

**WHY would you need a Monitoring Log?**

A Monitoring Log documents all reviews conducted on the study, usually initiated by the sponsor and is especially recommended for multi-center studies involving site visits, or studies requiring regular reviews. Please note that a monitoring log is required for FDA-sponsored studies.

This can offer a record of all monitoring visits, and can be used as a reference to any corresponding letters, reports and changes resulting from the visit. The Monitoring Log also offers documentation of all outside persons who have had access to confidential study materials and when. Finally, the log may also serve as a checklist to ensure all outside monitoring/FDA reports have been submitted to the IRB as required by VCU/VCUHS policy.

**HOW do you use it?**

Create a log that includes all the information that the research staff agrees will be useful throughout the study. Complete the log prior to the start of the study, including only information deemed useful, and adding any other information as necessary.

**WHERE do you put it?**

If a sponsor provides the Monitoring Log, file as instructed. Otherwise, it is recommended to file the log in a location easily accessible for all research staff to reference and update (*e.g.* separate section in Study Binder or files). It is further recommended to file any corresponding reports from monitoring visits, and all correspondence relating to any reviews behind the Monitoring Log in chronological order.

Applicable References for Consideration:

FDA: Food and Drug Administration, 812.40: Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, enduring proper monitoring of the investigation.

FDA: Food and Drug Administration, 812.43: A sponsor shall select monitors qualified by training and experience to monitor the investigational study in accordance with this part and other applicable FDA regulation.

ICH Guidelines for Good Clinical Practice 8.3.10: To document site visits by, and finding of, the monitor; 8.3.19: Interim or Annual Reports to IRB and authorities – interim or annual reports provided to IRB