**WHAT is a Document Log?**

The Document Log provides a system that lists all study documents used during the protocol and to track where these documents are located if they are stored somewhere other than the study regulatory binder.

Includes the following information

▪ Document Name

▪ Document Description

▪ Date filed/revised

▪ Location of Document

▪ Duration Document used (if terminated prior to study close, provide reason document is no longer used)

**WHEN is a Document Log Required?**

More and more, research teams are storing study documents *electronically*. With larger research staffs that are not always centrally located and often with minimal office and storage space, electronic storage may be advantageous as it can provide a simple and effective way to allow all research staff to access necessary study documents as needed.

Some study documents may be stored in *different locations* (e.g. signed consents in PIs office, and individual subject data in research coordinator’s office), however, there should be a single, central location to serve as the reference point listing all study documents and where they are located. The Document Log can serve as the central reference to track and locate all study documents.

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

A Document Log is a good way to track all study documents. If the research staff has determined that it is appropriate for some of the study documents to be stored either electronically or in multiple locations, a document log will serve to provide a simple way to reference, track and locate the study document quickly. Additionally, outside monitors and auditors should be able to know where all study documents are stored.

**HOW do you use it?**

Complete a log that includes the document name, a brief description, the date the document was last updated and where the document is stored.

**WHERE do you put it?**

If a sponsor provides Document Log, file as instructed. Otherwise, the log should be filed in a location easily accessible and available for the research staff to reference and update as needed (i.e. Regulatory Binder).

Applicable References for Consideration: