| WI #: | TITLE | VERSION DATE |
|---|---|---|
| WI-PM-3009 | Developing and Maintaining an Essential Document Checklist for use with ShareFile eTMF/eISF | 21-DEC-2017 |
| | | VERSION # |
| | | V1.0 |

## 1. PURPOSE

These instructions are to be followed to develop and maintain the Essential Document Checklist that will track the documents in the eTMF and eISF when using manual eTMF/eISF ShareFile..

The Essential Document Checklist is a living document and should be updated as changes in the study occur. The Essential documents are based on the ICH GCP guidelines and 21 CFR Part 11

## 2. APPLICABLE ROLES

Clinical Trial Assistant

Site Monitor

Project Manager

## 3. PROCESS

| Step | Responsible Role | Activities | Timing |
|---|---|---|---|
| 1 | Project Manager or designee | Develop the Essential Document Checklist at Study Start using the Essential Document Checklist Template and agreeing on format with the Sponsor. | Upon study award |
| 2 | CTA or designee | Update and maintain the Essential Document Checklist as documents are added or modified to the eTMF and/or eISF. Follow instructions tab of Essential Document Checklist for completion guidelines. | When documents are added to the eTMF or eISF |
| 3 | CTA or designee | Check documents:<br>• If documents are correct file, appropriately based on the DIA Reference Model. If not correct, follow process in *WI-PM-3005 Using the eTMF and eISF with ShareFile* to request revisions by the site.<br>• Update and add the link to the document in the Essential Document Checklist | When documents are added to the eTMF or eISF |
| 4 | CTA or designee | Maintain a list of the expiration dates for all appropriate documents or pull reports from applicable systems (i.e. STAR, Medrio, etc.) Assure that current documents are obtained filed prior to expiration. | When documents with expiration dates are uploaded to eTMF or eISF |
| 5 | CTA or designee | At the study completion, assure that all archives are completed by the technology vendor and that the documents are complete and correct for each site and Sponsor. | When all signatures are complete |
| 6 | CTA or designee | Sponsor does not receive any documents with subject's personal identifying information (e.g.<br>Informed Consents, Subject Logs or Subject Identification Lists)<br>Site will receive all documents from the central eTMF needed to complete their study files. | When all signatures complete |

| | | | |
|---|---|---|---|
| | | • Expiration Date, if any<br>• Molecule | |
| | PM or designee | Use the Sharefile Document Storage report to verify that documents listed the Essential Document Checklist has been uploaded in filed in Sharefile. Any missing documents should be file by the end of the study. Documentation in the form of a Note-to-File should be created explaining why the document is missing. The<br>• Note-to-File must be filed appropriate in the eTMF/eISF. | As defined in the DDRG |

## 4. ABBREVIATION LIST

| ABBREVIATION | DEFINITION |
|---|---|
| CFR | Code of Federal Regulations |
| CMP | Clinical Monitoring Plan |
| CTA | Clinical Trial Assistant |
| DIA | Drug Information Association |
| eISF | Electronic Investigator Site File |
| eTMF | Electronic Trial Master File |
| GCP | Good Clinical Practice |
| ICH | International Council for Harmonisation |
| PM | Project Management |
| RBM | Risk Based Monitoring |
| SOP | Standard Operating Procedures |
| STAR | Site Tracking Analyzing Risk |
| TPL | Template |
| WI | Work Instruction |