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| WI #: | TITLE | VERSION DATE |
| WI-PM-3005 | Using the eISF and eTMF with ShareFile | 21-DEC-2017 |
| | | VERSION # |
| | | V1.0 |

1. PURPOSE

This SOP describes the MANA RBM Procedure for using Electronic Signatures. MANA RBM allows electronic signatures for all corporate documents and all documents used in the conduct of clinical trials.

2. APPLICABLE ROLES

Project Management Department

3. Applicable Departments

ALL

4. PROCESS

| Step | Responsible Role | Activities | Timing |
|------|--|--|--|
| 1 | All MANA RBM, Contractors, and study team members | May use electronic signatures for all documents including, but not limited to, time sheets, contracts, training documentation, etc. | At all times |
| 2 | Project Manager or designee in studies run for Sponsors | Send notification to the FDA that the Sponsor will use electronic signatures, if no letter has been sent to the FDA that Sponsor is using electronic signatures. | Within 14 days of Study Start (First Patient, First Visit) |
| 3 | Project Manager or designee in studies run for Sponsors | File copy of letter in Sponsor Trial Master Files or provide to Project Manager if electronic Trial Master Files not available. | Within 5 days of sending notification to FDA. |
| 4 | For all study team members that will be using eSignature | Sign a document attesting to their understanding of that an electronic signature is the same as a "wet ink" signature and that they will not share their passwords. | Prior to completing electronic signatures |
| 5 | Clinical Trial Associate or Designee | <ol style="list-style-type: none"> Files the signed documents in the eTMF or eISF as appropriate. For all MANA RBM contractors, a copy of the signed document is also stored in the Staff folders. | Upon receipt of signed eSignature Attestation |

5. ABBREVIATION LIST

| ABBREVIATION | DEFINITION |
|--------------|---------------------------------|
| DM | Data Manager |
| eCRF | Electronic Case Report Form |
| eFile | Electronic File |
| eISF | Electronic Individual Site File |
| eSource | Electronic Source Document |



WORK INSTRUCTIONS

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|------|------------------------------|
| eTMF | Electronic Trial Master File |
| PM | Project Manager |
| PMP | Project Management Plan |
| SOP | Standard Operating Procedure |
| TEC | Technology |
| TPL | Template |
| TS | Technology Specialist |
| WI | Work Instruction |

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