WI #:	TITLE	VERSION DATE
WI-PM-3008	Sending a Document for Electronic Signature	21-DEC-2017
		VERSION #
		V1.0

1. PURPOSE

These instructions are to provide guidance when sending a document for electronic Signature.

2. APPLICABLE ROLES

Clinical Trial Assistant
Project Manager

3. PROCESS

Step	Responsible Role	Activities	Timing
1	CTA or designee	Review document, PDF, and file in the appropriate folder in the eTMF or eISF as applicable.	Within the appropriate timeline as defined in Data and Document Review Guidelines
2	CTA or designee	1. Right Click on the document. 2. Select “Send for Signature” from Sub Menu	After document is filed as defined in the Essential Document Checklist
3	CTA or designee	Add names and emails for those that need to sign or receive copies of the document	Prior to sending document for signature
4	CTA or designee	Add tags to the document as follows: • Name of document (from Essential Document • Checklist, e.g. FDA Form 1572 v 1.0) • Site • Protocol • Name of Signatory(s)	Prior to using electronic signatures
5	CTA or designee	Delete the unsigned version of the document from the folder in the eTMF or eISF as applicable after document has been signed by the party(s).	When all signatures are complete
6	CTA or designee	For each signed version, add details to each document name: • Name of document • Site • Protocol • Version • Expiration Date, if any • Molecule	When all signatures complete
7	CTA or designee	Notes: • Follow steps 3 through 6 if sending document through electronic signature instead of through eTMF/eISF. (Click upload document or template at the top of the page in the electronic system first) • Collect an Electronic Signature Attestation for each person that signs a document electronically (required for 21 CFR Part 11).	Prior to sending document for signature

4. ABBREVIATION LIST

ABBREVIATION	DEFINITION
CFR	Code of Federal Regulations
CTA	Clinical Trial Assistant
eISF	Electronic Investigator Site File
eTMF	Electronic Trial Master File
FDA	U.S. Food and Drug Administration
PDF	Portable Document Format
PM	Project Management
RBM	Risk Based Monitoring
SOP	Standard Operating Procedures
TPL	Template
WI	Work Instructions