WI #:	TITLE	VERSION DATE
WI-PM-3007	Generating and Using Certified Electronic Copies	21-DEC-2017
		VERSION #
		V1.0

1. PURPOSE

These instructions are to be used for generating and using certified electronic copies.

2. APPLICABLE ROLES

Data Manager
Site Monitor
Central Monitor
Clinical Trial Assistant
Project Manager
Technology Specialist

3. PROCESS

Step	Responsible Role	Activities	Timing
1	PM, SM or designee	Confirm with Sponsor which documents will be collected and maintained as certified electronic copies.	During Study Set Up
2	Tech Specialist or designee	Assure electronic system is available that can: • Convert a document from paper to electronic form. • Enable electronic signature of the document certifying the electronic copy is an exact replica of the paper version of the document.	During Study Set Up
3	SM, CTA or designee	Obtain signed Electronic Signature Certification for every person that will be completing electronic signatures and: • File signed documents in the eTMF/eISF as appropriate. • Note if the electronic signature system collects this information within the system; this form is not needed.	Prior to using electronic signatures
4	CTA or designee	Provide documentation sheet to all users to include with any document scanned from paper, which will include the eSignature certification if system does not include this as a feature.	Prior to using electronic signatures

4. ABBREVIATION LIST

ABBREVIATION	DEFINITION
CFR	Code of Federal Regulations
CM	Central Monitor
CTA	Clinical Trial Assistant
DM	Clinical Data Management

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PM	Project Manager
RBM	Risk Base Management
SM	Site Monitor
SOP	Standard Operating Procedures
TPL	Template
UAT	User Acceptance Testing
WI	Work Instructions

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