eSignatures and Digital Signatures

to assist their use in clinical trials by researchers.

What is the difference between eSignature and Digital signatures?

A digital signature and eSignature are not the same. Digital signatures are a secure type of electronic signing.

eSignatures:

- Equivalent of a handwritten signature online
- A signature that may be scanned, copied, or pasted

Digital Signatures:

- The most secure and valid version of an eSignature
- A type of signature that validates the signature is being done by the person signing e.g. includes a two-step authentication process/pre-set pin is required
- Time and date stamped with contact information link to signature and/or system account for systems where the system owner knows the identity of all signatories

Other key requirements for digital signatures

Digital signatures do not require a handwritten signature, or a photo uploaded when used electronically. Digital signatures do have to have to be able to authenticate the signer's identity, uniquely link the signatory, link the signature to the document and ensure that any changes following a signature are detectable (EFGCP).

There are a few different systems/software's available at the MCRI for executing eSignatures and digital signatures.

These platforms are:

- Florence HC
- Adobe Sign (supported by MCRI IT)
- DocuSign
- REDCap

Digital Signatures in Clinical Trials?

Digital signatures are required by clinical trial regulations GCP ICH section 5.5.3, FDA 21 CFR part 11 and EU No 910/2014.

For clinical trials, digital signatures must be used for all trial-related documents signed electronically.

Digital signatures must authenticate the signatory, ensure non-repudiation, ensure an unbreakable link between signature and the document signed as well as provide timestamps.

To meet these requirements, completed copies of signed documents must be made available to signees and the software used to sign must invalidate any signatures on documents edited or altered after the time of signing.

When to use eSignatures?

eSignatures are appropriate for non-trial documents such as administrative documents e.g., timesheets, and legal documents such as contracts and indemnities. They cannot be used for other trial documents such as Participant Information & Consent Forms (PICFs) (refer to MCTC165 Consent SOP) or Delegation and Training logs.

System/ Software	Signature Type Available	Compliance with FDA 21 CFR 11
Florence HC	Digital signature (with two step-authentication) can be stamped or provided as signature page to any document type e.g. logs, protocols etc.	System is compliant.
Adobe Sign	Digital signatures available with a paid account/corporate license to Adobe Sign ($500 p.a.).	Must have an account set up for validated digital signatures, but not compliant.
DocuSign	Sign envelope for a document available.	Only compliant if purchased license is used. Recommended for use in contracts only.
REDCap	Signature via ticked box acknowledgment.	Not compliant.

Find Out More

Review the GCP ICH section 5.5.3, FDA 21 CFR part 11, EU No 910/2014 and EMA/INS/GCP/112288/2023

Please contact crdo.info@mcri.edu.au if you have any questions. MCTC178