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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to outline the use of Electronic Signatures on Regulatory Documents provided by NACHO Clinical Trial sites participating in FDA regulated clinical trials.

POLICY

The use of electronic signatures on Regulatory Documentation for clinical trials is becoming more widespread throughout the research community, including NACHO Clinical Trial Sites. Sites will be required to submit local processes for utilizing electronic signatures on these documents. Documents to which this policy applies include:

- Delegation of Responsibility Log
- Study Financial Disclosure Form
- FDA Form 1572
- Serious Adverse Event Reporting Form
- IND Application Documents

PROCEDURES

1. Signatures on regulatory documents may be obtained through a wet-ink signature process or an electronic signature process as outlined below.
2. If a Wet-Ink process is utilized, the original signed document must be kept on-file at the site and made available for monitoring or auditing purposes.
3. If electronic signatures will be utilized, the site should provide NACHO Ops one or more of the following as part of the study activation process:
   a. Site specific SOP that outlines use of electronic signatures on trial documents
   b. System documentation (I.e., VEEVA or Florence) outlining compliance with 21 CFR Part 11 compliance
4. The electronic signature must be obtained through a means that allows for compliance to 21 CFR Part 11. This would include signatures obtained through systems that:
   a. State the printed name of the signer
   b. State the date/time the signature was applied
   c. State the meaning of the electronic signature (i.e., “approved” or “reviewed” or “verified”).
   d. Must be a part of the record that was signed (i.e., the signature is not separable from the record).
   e. Unique to a single user (User ID and password)
   f. Allows for an audit trail
5. Signatures that are obtained through one of the following methods will be considered acceptable:
   a. Use of a Clinical Trial Document System, such as VEEVA Vault or Florence, with a Part 11 signature process enabled, or
   b. Use of DocuSign or Adobe Sign which provides a Part 11 signature process (Digital Signature). (Of note, signatures obtained thru the Adobe “Fill and Sign” method will not be accepted).

MAINTENANCE RESPONSIBILITY

The NACHO SOP Ad Hoc Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the NACHO Executive Committee.

AUTHORIZATION

This SOP was developed by the SOP Ad Hoc Committee and reviewed and approved by the NACHO Executive Committee.

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
07/27/2022	V 1.0	Original documentation/publication.