

## **SIGNATURE REQUIREMENT GUIDANCE**

The purpose of this guidance document is to outline signature requirements for the following documentation submitted to the DAIDS Protocol Registration Office (PRO):

- Form FDA 1572s
- DAIDS IoR Forms
- Investigator Curriculum Vitae (CVs)

The DAIDS PRO accepts hand-written and electronic signatures. For hand-written signatures, the date associated with the signature must also be handwritten. Documents with a hand-written signature and typed date will not be accepted. If an electronic signature is used, the typed date must match the electronic date stamp.

An Electronic Signature is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature (21 CFR 11.3(b)(7)).

Adobe Acrobat Self-Sign plug-in can be utilized to insert your signature on fillable FDA Forms (e.g., Form FDA 1572). Alternatively, for U.S. Sites, any part 11 compliant method to utilize an electronic signature will be accepted. For international Sites, some countries may have defined additional requirements which should also be considered when applying electronic signatures. Use of methods to electronically sign documents that do not minimally meet part 11 compliance requirements will not be accepted.

Signed electronic records shall contain information associated with the signing that clearly indicates all the following:

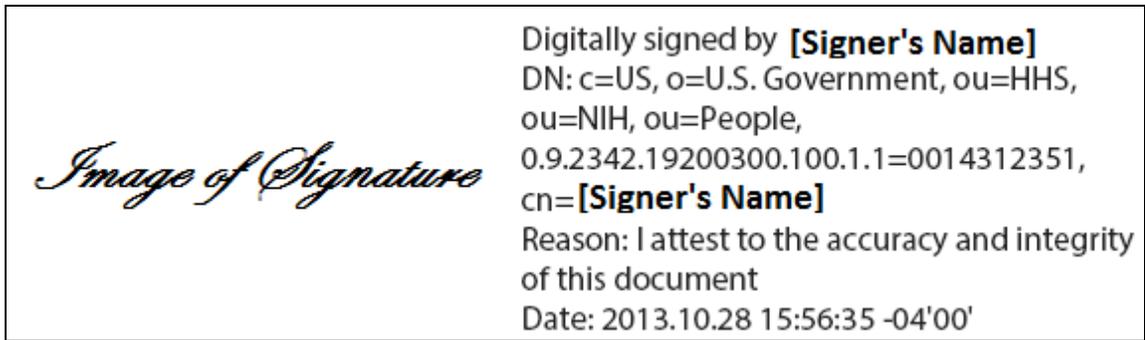
- The printed name of the signer;
- The date and time when the signature was executed; and
- The meaning (such as review, approval, responsibility, or authorship) associated with the signature. For the purposes of Form FDA 1572/DAIDS IoR Forms, the placement of the signature in the signature section provides the meaning of the signature in agreeing to the commitments identified on the form.

The items identified in 1-3 above shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

Accepted signature include the following:

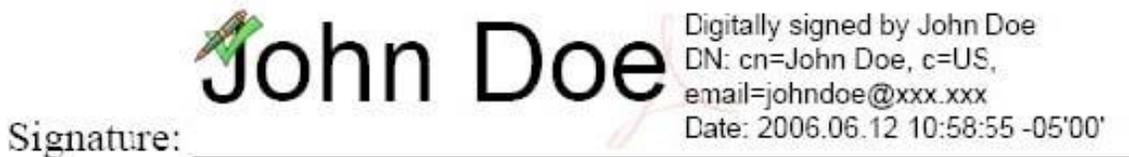
- Scanned signatures

Figure 1: Example of Approvable Scanned Signature



- Digital signatures: A Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

Figure 2: Example of Approvable Digital Signature



- Flattened digital signatures. A Flattened signature occurs when flattening pushes the appearance of the signature annotation into the page content, effectively deleting interactive elements, but retaining the visual appearance of those elements.

Figure 3: Example of Flattened Digital Signature



**References:**

21 CFR Part 11; Electronic Records - <https://www.ecfr.gov/cgi-bin/text-idx?SID=43b330dced7e1abf7b7beadf067055e7&mc=true&node=pt21.1.11&rgn=div5>

Guidance for Industry Part 11, Electronic Records; Electronic Signatures - <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm563785.pdf>

Adobe Sign and 21 CFR Part 11 White Paper - <https://www.adobe.com/content/dam/acom/en/security/pdfs/adobe-sign-compliance-21CFRpt11-wp-ue.pdf>