

FAQ:

Can I use Adobe Self-Sign Digital ID e-signature for e-consent?

No. This e-signature process does not apply to the informed consent process. As per the HSRO's SOP HRP-093, Investigators must obtain IRB approval to document consent in an electronic format. This process is not intended to obtain e-signatures from research participants. E-consent must be obtained via REDCap.

Can anyone use this e-signature process?

Yes, the Adobe Self-Sign Digital ID e-signature process is available for use by anyone at the University who has Adobe Acrobat installed on their computer.

Can I sign a study protocol, Delegation of Authority Log (DOAL) or even an FDA Form 1572 using the Adobe Self-Sign Digital ID e-signature?

For FDA-regulated studies, it is preferable to be consistent and to continue to e-sign documents using Complion. Additional documents such as a note to file or progress note that cannot be e-signed within Complion, should either be signed on paper or e-signed using Adobe Self-Sign Digital ID e-signature.

I have been using a different Adobe e-signature process. Do I have to switch to this Adobe Self-Sign Digital ID e-signature process?

Yes. For FDA-regulated studies, users must adopt the Adobe Self-Sign Digital ID e-signature which requires a password entry and will show the reason or meaning of your signature. These are required per FDA's Part 11 regulation.

For research not regulated by the FDA, or for e-signatures used outside of research, users may choose another e-signature process.

Can I use Adobe Fill and Sign instead of Adobe Self-Sign Digital ID?

No. Adobe Fill and Sign has not been validated for 21 CFR Part 11 and should not be used in FDA-regulated studies.

For any questions please email the ovprshelpdesk@miami.edu.