

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** use of DocuSign for research consent form  
**Date:** Wednesday, March 25, 2020 11:12:45 AM  
**Attachments:** [REDACTED]

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Good morning –

Thank you for your email. I found a previous query that is similar to your query. Please see below.

QUESTION -

*Our institution is planning to utilize a 21 CFR part 11 compliant version of DocuSign for electronic signatures on regulatory documents for clinical trials. We've completed an internal review of compliance with our IT and information security teams and are currently working on the FDA notification letter. I was wondering if other groups have started utilizing e-signatures for regulatory documentation. Have any institutions utilizing e-signatures for regulatory been audited by the FDA? Are there specific pitfalls that we should be aware of before we begin implementation?*

ANSWER -

*Other groups have started using e-signatures for regulatory documentation and have been audited by the FDA. The specific pitfalls that you should be aware of before implementation of electronic signatures on regulatory documents for clinical trials are:*

- Not having a secure process to authenticate signers*
- Not programming timeouts and log-outs necessitating the re-entry of a password to gain access to the system*
- Not linking electronic signatures to the document signed*
- Not implementing safeguards to immediately detect and report unauthorized attempts to use signatures*
- Not having a process for an emergency to allow a person to “authorize” another person to use his/her signature*
- Not having an audit trail to track when the document was signed and who signed it*
- Not having the ability to have multiple signers for a document*

Additionally, electronic signatures can be used for informed consent but would need to comply with FDA's regulations on electronic signatures and electronic records. Following are links to the regulations and also to several guidance documents:

21 CFR Part 11 is FDA's regulation addressing electronic records and signatures  
[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)

Guidance for Industry: Part 11, Electronic Records; Electronic Signatures - Scope and Application  
<https://www.fda.gov/media/75414/download>

Guidance for Industry: Computerized Systems Used in Clinical Investigations  
<https://www.fda.gov/media/70970/download>

Guidance for Industry and FDA Staff: General Principles of Software Validation  
[www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf)

Draft Guidance for Industry: Electronic Source Data in Clinical Investigations  
<https://www.fda.gov/media/85183/download>

You may also contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at [CDEROMP@fda.hhs.gov](mailto:CDEROMP@fda.hhs.gov) as they are the experts on electronic documents in clinical trials if I have not adequately answered your question. I believe that the previous query mentioned above came from CDER/OMP.

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
Office of Clinical Policy and Programs  
Office of Good Clinical Practice (OGCP)  
U.S. Food and Drug Administration



This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [REDACTED]  
**Sent:** Tuesday, March 24, 2020 11:24 AM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** use of DocuSign for research consent form

Dear FDA,  
Would you consider a research consent form using docuSign as a 'signed consent' for regulatory purposes?  
Sincerely,

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]