

From: OC GCP Questions
To: [REDACTED]
Subject: Questions on the use of electronic signature for internal documents
Date: Monday, May 15, 2017 10:06:00 AM
Attachments: [REDACTED]

Good morning –

Your first paragraph does not appear to be in violation with FDA regulations.

It is acceptable for CI sites to certify to FDA their e-signatures are compliant with 21 CFR Part 11, or the sponsor may choose to certify that all CI sites participating in the trial are implementing e-signatures which are compliant with 21 CFR Part 11. Since either process is acceptable, this is an area where there needs to be discussions with the sponsor on how this will be handled for the trial in question.

The information below was a question answered by a colleague in OGCP a few years ago. Please see below. FDA has a guidance that addresses electronic signatures. Please see the link below.

<https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm125125.pdf>

The regulation found at 21 CFR 11.100(c) simply requires that persons using electronic signatures certify to FDA that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures. The preamble to this regulation explains more about who needs to submit the certification. We recently posted the Federal Register publication of 21 CFR Part 11 to our Good Clinical Practice Program's web page (see "Miscellaneous" at www.fda.gov/oc/gcp/preambles/default.htm). This posting includes the preamble and the codified for the Part 11 final rule. I mention this because this publication contains the agency's comments on electronic signature certification procedures. I've copied (immediately below) comment #120 because I believe it best answers your questions.

"120. Several comments questioned the procedures necessary for submitting the certification to FDA, including: (1) The scheduling of the certification; (2) whether to submit certificates for each individual or for each electronic signature; (3) the meaning of "territory" in the context of wide area networks; (4) whether such certificates could be submitted electronically; and (5) whether organizations, after submitting a certificate, had to wait for a response from FDA before implementing their electronic signature systems. Two comments suggested revising proposed Sec. 11.100(c) to require that all certifications be submitted to FDA only upon agency request. One comment suggested changing "should" to "shall" in the last sentence of Sec. 11.100(c) if the agency's intent is to require certificates to be submitted to the respective FDA district office. The agency intends that certificates be submitted once, in the form of a paper letter, bearing a traditional handwritten signature, at the time an organization first establishes an electronic signature system after the effective date of part 11, or, where such systems have been used before the effective date, upon continued use of the electronic signature system.

A separate certification is not needed for each electronic signature, although certification of a particular electronic signature is to be submitted if the agency requests it. The agency does not intend to establish certification as a review and approval function. In addition, organizations need not await FDA's response before putting electronic signature systems into effect, or before continuing to use an existing system.

A single certification may be stated in broad terms that encompass electronic signatures of all current and future employees, thus obviating the need for subsequent certifications submitted on a pre-established schedule.

To further simplify the process and to minimize the number of certifications that persons would have to provide, the agency has revised Sec. 11.100(c) to permit submission of a single certification that covers all electronic signatures used by an organization. The revised rule also simplifies the process by providing a single agency receiving unit. The final rule instructs persons to send certifications to FDA's Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857. Persons outside the United States may send their certifications to the same office.

The agency offers, as guidance, an example of an acceptable Sec. 11.100(c) certification: Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that [name of organization] intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures.

The agency has revised Sec. 11.100 to clarify where and when certificates are to be submitted.

The agency does not agree that the initial certification be provided only upon agency request because FDA believes it is vital to have such certificates, as a matter of record, in advance of any possible litigation. This would clearly establish the intent of organizations to equate the legally binding nature of electronic signatures with traditional handwritten signatures. In addition, the agency believes that having the certification on file ahead of time will have the beneficial effect of reinforcing the gravity of electronic signatures by putting an organization's employees on notice that the organization has gone on record with FDA as equating electronic signatures with handwritten signatures."

As you can see, the regulation leaves the decision as to who submits the certification entirely up to the affected parties. Whether you, the CRO/sponsor plan to submit certification is something your firm should clarify with and, ideally, obtain in writing from the CRO/sponsor so there is no later misunderstanding about this regulatory responsibility.

You may also wish to review FDA's guidance on Computer Systems Used in Clinical Investigations.

<https://www.fda.gov/ohrms/dockets/98fr/04d-0440-gdl0002.pdf>

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



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.

From: [REDACTED]
Sent: Friday, May 12, 2017 1:08 PM
To: OC GCP Questions
Subject: Questions on the use of electronic signature for internal documents

Good Day,

I am working in clinical research and working remotely from home. The use of an electronic signature facilitates the work of internal documents management such as monitoring report, training logs,... that would be signed by hand (and scanned and filed electronically). Adobe Acrobat allows to create a secure electronic signature that is unique and secured with an identification and password only accessible to the individual creating it's electronic signature. The use of the electronic signature and the identity of the individual who created the electronic signature is also validated within the organization. Thus, the Adobe Acrobat signature seems to comply to those requirements of the FDA for an electronic signature. Are those requirements sufficient for the use of an electronic signature.

The FDA also mentions the following:

- Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.
- The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.
- Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

I am not certain of the 3 statement above. Does every individual using an electronic signature needs to communicate with the FDA to attest the above.

Thank you for your assistance on this matter

