

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Certification statements for electronic signatures
Date: Wednesday, January 22, 2020 6:53:22 AM
Attachments: [REDACTED]

Good morning –

Thank you for your email. 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.

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.

Sec. 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

(c) 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.

(1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the [ORA, 12420 Parklawn Dr., Element Bldg., rm. 2133, Rockville, MD 20857](#):

(2) 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. Please see the FDA link below.

Electronic Records: Electronic Signature Certification | FDA

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.

As far as I know, there is no template for these types of letters.

If I have not adequately answered your question, please contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov They are the experts on electronic records in clinical trials.

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: Tuesday, January 21, 2020 9:48 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Certification statements for electronic signatures

Dear FDA

Title 21 - Food and Drugs Chapter I – Food and Drug Administration Department of Health and Human Services. Subchapter A – General. Part 11 Electronic Records; Electronic Signatures

Subpart C--Electronic Signatures

Sec. 11.100 General requirements.

- (a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
- (b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.
- (c) 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.

Per point (c) of the above referenced document, please can you clarify if we should submit a certification statement to the FDA for every employee/user, current and future, that makes use of an electronic signature, or if we can submit a broad statement advising of such.

Many thanks

Best regards

