

From: [Donnelly, Janet](#)
To: [REDACTED]
Subject: RE: Request for Assistance with 21 CFR 11
Date: Friday, May 29, 2020 1:07:00 PM
Attachments: [REDACTED]

Dear [REDACTED] -

Thank you for your question. I'm in FDA's Office of Good Clinical Practice (OGCP) and want to share with you that our office has a public mailbox where you can send GCP questions in to us and we will do our best to get back to you as quickly as we can. You can send future GCP questions to gcp.questions@fda.hhs.gov. This public mailbox is the best place to send GCP questions as the central mailbox is monitored daily Monday-Friday, so if I'm out of the office, you won't have to wait for me to get back! I also wanted to mention that OGCP redacts and posts previous GCP queries, along with our responses in a central location at <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice>. Many find this to be a helpful resource.

Regarding your question about how to complete the certification process, I consulted a few of my OGCP colleagues. Our office typically confers with staff from FDA's Center for Drug Evaluation and Research (CDER) on part 11 questions, and we have collectively answered similar questions in the past. I am providing some thoughts here for you based on what we have said in the past about this topic in hopes that this will be helpful to you.

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. These regulations permit submission of a single certification that covers all electronic signatures used by an organization. A single certification may be stated in broad terms that encompass electronic signatures of all current and future employees.

Regarding 21 CFR 11.100(c), you may submit a general letter of certification on behalf of your entire organization for employees, agents or representatives to the FDA to indicate all electronic signatures are equivalent to traditional hand-written signatures. Please see some sample text below. In addition, please note that the appropriate mailing address to send the letter of certification is:

FDA (OHAFO – DHAF0B)
ELEM RM2133 HFC-1
12420 Parklawn Drive
Rockville, MD 20857

SAMPLE TEXT:

Re: Electronic Signature Certificate Statement

To Whom It May Concern:

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that [Company Name], intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of the traditional hand-written signatures of individuals whose identity [Company Name] has verified.

Sincerely yours,
[Hand-written signature]
[Name of Company Representative]
[Company Representative Title]

I hope this information is helpful to you. Should you need additional assistance or have additional questions, please let me know and I can put you in touch with a contact at CDER.

Have a wonderful day and stay safe!

Best Regards,

Janet

Janet Donnelly, RAC

Policy Analyst

**Office of Good Clinical Practice
Office of Clinical Policy & Programs**



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: Wednesday, May 27, 2020 4:35 PM
To: Donnelly, Janet <Janet.Donnelly@fda.hhs.gov>
Subject: Request for Assistance with 21 CFR 11

Dear Ms. Donnelly,

Good afternoon. I hope you are healthy and safe. I received your name from [REDACTED]

[REDACTED] and I am hoping you can assist me in navigating 21 CFR Part 11. Given the current health environment, we here at [REDACTED] are looking into how to continue research in compliant manners including electronic consent. We are looking into the use of Adobe Sign; however, we are hitting a snag as to how to complete the certification process as per 21 CFR 11.100(c) and (c)(1).

(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 Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.

I would greatly appreciate it if you could you please provide assistance as to how to proceed and where I can find additional information.

Kindest regards,

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

[REDACTED]
[REDACTED]

[REDACTED]