From: OC GCP Questions
To: [redacted]
Subject: RE: 21CFR part 11
Date: Thursday, March 28, 2019 2:40:00 PM
Attachments: [redacted]

Dear [redacted]-

Thank you for your question. 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.

The regulations at 21 CFR 11.100(c) 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.

I am not aware of a template, but 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.

I confirmed with a colleague that instead of using the address provided in the regulation, it is best to send your certification letter to the following address:

> U.S. Food and Drug Administration
> Office of Regulatory Affairs (ORA)
> 12420 Parklawn Dr.
> Element Bldg., rm. 2133
> Rockville, MD 20857 U.S.A.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

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: Thursday, March 21, 2019 7:48 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 21CFR part 11

Hello Sir/Madam,

My name's [redacted]. I am very happy to contact to you.
I have some questions need your assistance. Could you please help me?

To meet 21 CFR 11. 100(c), we are preparing the single certificate to submit to agency.

- Do you have the template of certificate? Or please tell me what information we need to mention in certificate?
  Do we list out the employee who use E-signatures. And then, each employee signs their handwritten signature on certificate?
  Please share me an example or a template of certificate.
- Please confirm the address where we will summit the certificate? It is:
  Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857, US.

  Thank you very much for your support.
  Best regards,
  [redacted]