From: CDER DRUG INFO
To: [redacted]
Subject: FW: Query regarding specific date format for FDA Form 1572
Date: Friday, February 01, 2019 1:37:54 PM

Hi Doreen,

I checked in with the forms team. Typically they should format the date according to the form's requirement (mm/dd/yyyy). Because of a field restriction, namely it was coded to take only the amount of characters that was asked for, this field will reformat the date from 01/Feb to 02/01 if it is done electronically. We are aware that this form is allowed to be filled out by hand in which case there may be a 'wet' signature instead of electronic. Although the sponsor is required to collect the 1572 from the investigator, FDA does not require the form to be submitted to the agency.

In the cases where they are filling out the form with the research date format, we are assuming they are signing these with a pen, a wet signature. Could you confirm this is the case.

Thanks.

Holli Tierno
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From: [redacted]
Sent: Tuesday, January 29, 2019 2:43 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: Query regarding specific date format for FDA Form 1572
Importance: High

Dear FDA Representative,
Is it imperative that the PI's dating of the 1572 be in US Date Format as indicated in the form legend?

We work so hard getting our Pi's to use Research Date Format on all other Research Documents that they occasionally date a 1572 the same way. Generally this is accepted by all Sponsors with either format. Every now and then, we get a CRO who insists on getting the PI to re-sign the document in US Date Format. Is this really necessary, or is it acceptable to respond indicating that the FDA does not mandate US Date Format?

In reviewing the FDA Guidance Instructions on completion of a FDA Form 1572. The only sentence referring to the PI's dating of the form states:

"***18. How should the 1572 be completed?***
The 1572 on FDA's website may be completed by typing the information directly into the fillable form and printing the completed form. Alternatively, it is acceptable to print the blank form from FDA's website and hand-write or type the information onto the form. Typed forms are preferable because they are usually more legible. The completed form must be signed and dated by the investigator (either by hand or using an acceptable electronic method)."

Please provide me with an answer to my query so that I may better communicate with Sponsors/CRO's regarding this issue.

Respectfully,

[redacted]

[redacted]

[redacted]