

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question Regarding Part 11 Compliance for Clinical Trial Agreements
Date: Monday, June 08, 2020 2:33:00 PM
Attachments: [REDACTED]

Good afternoon –

Thank you for your inquiry. FDA would generally not review clinical trial agreements or contracts during an inspection. FDA investigators will expect to see investigator agreements and signed 1572 forms. CTAs are not required by FDA but are often used.

That said, we have had similar questions in the past and our IT specialists in CDER (Center for Drugs) have said the following --

There are no restrictions on which documents are maintained electronically or signed with e-signatures. If the record or signature is required by FDA regulations, and not subject to the enforcement discretion exceptions in the Scope and Application guidance, Part 11 controls are necessary.

Please see:

Part 11, Electronic Records; Electronic Signatures — Scope and Application
<https://www.fda.gov/media/75414/download>

For general information on the use of computer systems in clinical trials in FDA regulated clinical trials, please reference the following guidance:
<https://www.fda.gov/media/70970/download>

Or draft e-Source Guidance:
<https://www.fda.gov/media/70970/download>

For the outside US questions with not using/signing a 1572 as well as the Part 11 questions, please contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as this office are the experts on 1572 forms/foreign studies and Part 11 compliance.

Kind regards,

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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: Monday, June 08, 2020 1:36 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question Regarding Part 11 Compliance for Clinical Trial Agreements

Good afternoon,

In the course of managing clinical trials we, as the CRO, may sign clinical trial agreements (CTAs) with Investigators and/or clinical sites. In the US, we also may collect the FDA Form 1572, signed by the Investigator.

Where both a CTA and Form 1572 are signed for a particular trial, does FDA consider the CTA to be an agreement that is required to be maintained under FDA guidance/regulations, such that the CTA must be 21 CFR Part 11 compliant with regard to use of an electronic signature?

Further, in instances (e.g., ex-US) where no Form 1572 is collected, does FDA consider the CTA to be an agreement that is required to be maintained under FDA guidance/regulations, such that the CTA must be 21 CFR Part 11 compliant with regard to use of an electronic signature?

I appreciate your time and consideration.

Kind regards,

[REDACTED]

