

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Paper Copies of the CRF and Guidelines in the ISF
Date: Tuesday, October 27, 2020 11:27:00 AM
Attachments: [REDACTED]

Good morning –

Thank you for your enquiry. There is no need to print the information (pages) from the EDC. The EDC would be considered your source.

You may wish to review the guidance documents below for information about FDA's expectations related to electronic records in clinical trials:

Computerized Systems Used in Clinical Investigations: <https://www.fda.gov/media/70970/download>

This guidance document allows for direct entry of data electronically onto a PC or laptop. It is something we expect to see more frequently with electronic data capture (EDC) becoming more common. We would expect an FDA investigator during a BIMO inspection to be able to review such electronic CRFs, though would request that someone at the site access the data and provide paper copies for any page(s) requested rather than have the FDA investigator navigate the site's computer system

Additionally states It is important to keep track of all changes made to information in the electronic records that document activities related to the conduct of the trial (audit trails). The use of audit trails or other security measures helps to ensure that only authorized additions, deletions, or alterations of information in the electronic record have occurred and allows a means to reconstruct significant details about study conduct and source data collection necessary to verify the quality and integrity of data. Computer-generated, time-stamped audit trails or other security measures can also capture information related to the creation, modification, or deletion of electronic records and may be useful to ensure compliance with the appropriate regulation.

The need for audit trails should be determined based on a justified and documented risk assessment that takes into consideration circumstances surrounding system use, the likelihood that information might be compromised, and any system vulnerabilities. Should it be decided that audit trails or other appropriate security measures are needed to ensure electronic record integrity, personnel who create, modify, or delete electronic records should not be able to modify the documents or security measures used to track electronic record changes. Computer-generated, time-stamped electronic audits trails are the preferred method for tracking changes to electronic source documentation.

Audit trails or other security methods used to capture electronic record activities should describe when, by whom, and the reason changes were made to the electronic record. Original information should not be obscured though the use of audit trails or other security measures used to capture electronic record activities.

If you are going to create a Note-To-File, a standard operating procedure should be created so that

all study staff are consistent with implementing your internal processes/procedures.

Please see FDA's guidance on Part 11, Electronic Records; Electronic Signatures--Scope and Application: <https://www.fda.gov/media/75414/download>

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 considered the experts on electronic documents and systems in FDA-regulated clinical trials.

Kind regards,

Doreen M. Kezer, MSN
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Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration



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, October 26, 2020 2:44 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Paper Copies of the CRF and Guidelines in the ISF

Hi,

I believe it is acceptable per GCP, to simply place a Note To File stating the CRF copy has not been printed as it can be viewed on the EDC and provide that information instead of printing off many pages of a CRF (which is in EDC). The same for CRF Completion Guidelines. It seems wasteful to print all those pages off or even minimize the size of the print to simply keep a hard copy in the ISF.

Please advise.

Many thanks.

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