

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: CRF Archival and Submission Requirements
Date: Friday, February 28, 2020 10:28:11 AM

Good morning –

Thank you for your email. Your question is very broad. It is permissible to transfer archival records to an electronic medium. However, if you intend for these copies to substitute for the paper copies (i.e. destroy or dispose of the originals) then 21 CFR 11 applies <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>. This regulation covers the use of electronic records and signatures used to meet an FDA record-keeping requirement. If you propose to maintain electronic copies of study records in lieu of the paper copy, your system for doing so would have to comply with the requirements of Part 11. For example, your process for copying and retrieval would have to meet expectations for availability and being able to generate electronic copies suitable for FDA review and further copying. There are a couple of points to consider. First, Part 11 applies only to the records that are required to be maintained by regulations. For FDA clinical trials in general, sponsor record keeping and retention requirements are found in 21 CFR 312.57 and clinical investigator record keeping requirements are found in 21 CFR 312.62. Second, please note that retention periods are specified in the regulations. Records only have to be retained for the period of time indicated. You are free to decide how records are to be copied, stored or otherwise disposed of, if the records you propose to copy and archive are no longer required by FDA to be retained. You do not have to keep the paper copies if your electronic system complies with Part 11..

There are several references that you may find useful. You can find our guidance on Computers in Clinical Trials at <https://www.fda.gov/media/70970/download>. I would especially direct your attention to the definitions of "certified copy" and "source documents" found in section I . You also may be interested in section 8 of the Consolidated Guide for Good Clinical Practice (ICH E6 (R2)), which gives guidance on what records should be retained and by whom. <https://www.fda.gov/media/93884/download>

Additionally, burning a CD at the end of the study is an acceptable method to archive study related documents. (FDA does not have any regulatory requirements as to the type of CD or DVD that might be used to preserve information (presumably to meet the regulatory requirements concerning clinical data/records). A company just needs to make certain that whatever media it uses does so in a manner that preserves the integrity of the original data/information. If a certified copy will serve as a substitute for the original, it would be desirable that they have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. This procedure should be developed and approved by the sponsor.

You may also wish to review FDA's guidance on Part 11 -

<https://www.fda.gov/media/75414/download>

For submission requirements under an IND, please consult the Center for Drugs (CDER) at druginfo@fda.hhs.gov

For electronic records and systems in clinical investigations, please consult the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN

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Office of Clinical Policy and Programs

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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: Friday, February 28, 2020 3:39 AM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>

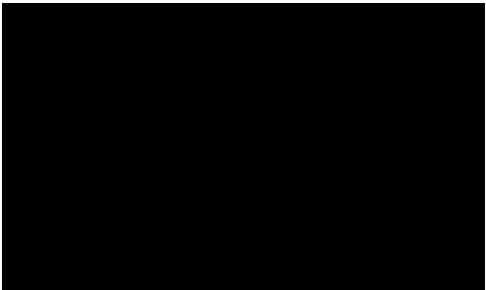
Subject: CRF Archival and Submission Requirements

Dear FDA Team

Would you have a guideline which outlines the requirements for archival and submission CRFs?

We would like to ensure that EDC vendors can provide archival media to meet the specific requirements exactly.

Many Thanks



Thank You,

