

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** email archiving in TMF  
**Date:** Thursday, April 23, 2020 11:46:25 AM

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Good morning –

Thank you for your email. This office generally does not comment on specific SOPs. However, I can offer you the following general information.

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 (812 as you cite) 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.

The guidance documents listed below might be helpful to you.

Part 11 -Electronic Records -

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

Computerized Systems Used in Clinical Investigations -

<https://www.fda.gov/media/70970/download>

Electronic Source Data in Clinical Investigations -

<https://www.fda.gov/media/85183/download>

If I have not adequately answered your question (emails archiving), you may contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at [CDEROMP@fda.hhs.gov](mailto:CDEROMP@fda.hhs.gov) as they are the experts on electronic records in clinical investigations.

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
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.

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**From:** [REDACTED]  
**Sent:** Wednesday, April 22, 2020 5:42 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** email archiving in TMF

Good afternoon,

I am aware of the requirements in § 812.140 Records for device studies pertaining to correspondence:

*(a) Investigator records. A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:*

*(1) All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.*

*(b) Sponsor records. A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:*

*(1) All correspondence with another sponsor, a monitor, an investigator, an IRB, or FDA, including required reports.*

I would appreciate your opinion on whether the following would be acceptable good clinical practice and/or if you have suggestions for improvements:

1. The Sponsor of a device trial maintains a secure email server capable of meeting (communication) record retention requirements for clinical trials.
2. Within this server, the Sponsor created a “central email address” and repository for each clinical study.
3. SOPs define “relevant” communications and require all such communications via email are copied to the central email address. The emails on the server can be made available for FDA review during an inspection.
4. The Sponsor, Investigative Sites, CROs and Monitors are all trained to copy the address on all relevant communications.
5. The Sponsor is the Administrator of a Part 11 and HIPAA compliant “shared platform” eTMF with separate sponsor and site-specific sections. Appropriate Security and Access controls are in place. An FDA auditor can be granted read-only privileges during an audit.
  - a. The Investigative Site uses a hybrid approach to its “complete” TMF; some required records are in the shared eTMF (i.e. protocol versions, IRB approvals) and some are paper records maintained at the site (i.e. wet ink documents, case histories, ICFs)

Because all relevant communications are copied to and maintained on the Sponsor email server indefinitely, is there a need to also place a copy of the emails in the site-specific section of the TMF for archiving?

Thank you in advance,

[REDACTED]