

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Moving to eTMF - Request for Guidance on 1572 Originals  
**Date:** Tuesday, August 04, 2015 1:20:45 PM

---

Good afternoon –

Yes the original 1572 can be converted to the electronic record if the below information is followed. If you have an electronic certified copy of the 1572, the original does not have to be maintained in paper format. Please see the information below.

The Form FDA 1572 (the 1572), while an official FDA form, is meant to provide full information about a study site to the study sponsor and to serve as a commitment to compliance with the investigational plan and pertinent regulations by the clinical investigator signing it. There is no requirement that the form be submitted to FDA, though most study sponsors do so, as it is a quick way to provide much of the information required for an IND. As an official agreement between the clinical investigator and the sponsor, as with most such agreements, the sponsor should keep the original form since once signed it represents a contract between the clinical investigator and the sponsor to adhere to the investigational plan and pertinent regulations.

You might find FDA's 1572 form guidance helpful. Please see the link below.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

The sponsor should obtain the original signed document for the 1572. Per the instructions on the 1572 form, the clinical investigator is instructed to:

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

Additionally, if it is decided to have a certified copy substitute for the original, it would be desirable to have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information should be the same person who actually made the copy from the original. Certification should be accomplished by having the person who makes the copy, sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bulk. Whichever method is used the SOP should describe the procedure. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA

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:** Tuesday, August 04, 2015 12:18 PM  
**To:** OC GCP Questions  
**Cc:** [REDACTED]  
**Subject:** Moving to eTMF - Request for Guidance on 1572 Originals

Dear Office of Good Clinical Practice,

Our company is moving towards the use of electronic Trial Master Files, and would like to kindly inquire regarding original 1572s. In reviewing available regulations and guidance documents, we could not find anything that states whether original 1572s must be maintained when using an electronic TMF. Please provide the current FDA opinion regarding whether original 1572s must be maintained along with electronic copies in eTMF.

Thank you,

[REDACTED]