Mass General Brigham

HUMAN RESEARCH AFFAIRS

ELECTRONIC STORAGE OF RESEARCH DOCUMENTS

This guidance presents an acceptable process for creation of electronic copies of source documentation (including consent documents). This guidance is applicable to Investigator-initiated research, including NIH funded and FDA regulated research. Industry and other Sponsors generally have specific requirements for electronic records to comply with 21 CFR Part 11, when applicable. Investigators should seek the written permission of the Sponsor and follow the Sponsor's requirements for electronic storage of source documents prior to creation of electronic source document storage. Documentation of Sponsor permission should be filed with study documents.

In order to convert existing paper source documentation to electronic source documentation, the site must create a ***certified copy***. A ***certified copy*** is "a copy of original information that has been verified, as indicated by a dated signature, as an exact copy, having all of the same attributes and information as the original."

As with all research activities, the principal investigator (PI) is responsible for maintaining adequate records. The PI should, therefore, ensure that this guidance is followed when implementing electronic storage of source documents. It is recommended that Investigators create an SOP describing how source documents will be scanned, certified, and stored.

See also Mass General Brigham policy Guidelines on *Retention of Research Data, Materials and Records for guidance*.

Recommended Procedures

(1) Creation of electronic files

Source documents/consent forms should be scanned individually and converted to an Adobe Acrobat PDF file. The PDF file name should be labeled with:

- The study's IRB-assigned protocol number
- The study's assigned subject ID
- The date the source document was obtained or completed
- A word identifying the specific source document (e.g. "consent", "HAM-D")
  (For example: 2015P000000_A12345_20150531_consent)

(2) Certification of electronic files

The person who certifies the copy as an accurate and complete representation of the original, having all the same attributes and information as the original, should be the same person who actually created the electronic copy from the original. The person certifying is verifying that they have done all of the following:

- Reviewed all pages of the scanned document and confirmed that they are EXACT copies of the originals.
- Confirmed that each scanned page is legible and facing in the appropriate direction.

- Confirmed that wet ink signatures and dates are legible on the scanned document.

Although the PI does not have to personally certify every document, the PI still bears the responsibility for ensuring that the certification process is being followed.

(3) Methods and storage of electronic files

Different software and applications can be used to create certified copies. For FDA-regulated research documentation, systems and processes should be FDA-compliant (including 21 CFR Part 11). For non-FDA-regulated research documentation, systems must comply with Mass General Brigham policies.

In all cases, the person performing the certification should use their own personal account, identification, key, or unique credentials. Using a shared account or someone else's account, such as a PI's account, does not comply with regulatory requirements or Mass General Brigham policies.

Electronic files of scanned and certified source documents should be stored in a system approved by Mass General Brigham Research Computing for such purposes. More information about storage options is available from RISC: https://rc.partners.org/it-services/storage-backup .

Frequently Asked Questions

1. ***Is IRB approval required when converting paper source documents to electronic storage?***

   No, IRB approval is not required to convert study source documents to electronic documents. An internal SOP for document scanning and certifying should be maintained on-site. Additionally, records of documents scanned and documentation of certification should be maintained on site.

2. ***Once scanned, certified, and placed in an appropriate Mass General Brigham-approved system, can the paper documents be destroyed?***

   Yes, once the document is scanned and certified, the paper copy can be destroyed.

3. ***At what point can source documents be scanned and stored?***

   Anytime, as long as the site has a process/procedure for scanning, certifying, and storing electronic documents.

4. ***Can this be done for an ongoing (still enrolling) study?***

   Yes.

5. ***How long should electronic source documents be maintained?***

   Consistent with record retention requirements for paper source documents, electronic files of source documents should be kept for a minimum of 7 years following study closeout and in accordance with institutional policy. Sponsored studies may have additional requirements, which would need to be met in addition to institutional policy.

6. ***How should Sponsor's permission for electronic storage of source documents be documented?***

   Sponsors should agree to electronic storage of source documents in writing. This can be in the form of an email or letter. This email or letter should specify the person granting permission and their job title. Documentation of sponsor agreement should be kept on file.

7. ***What Mass General Brigham-approved systems can be used to create certified copies of research documents?***
   Veeva SiteVault Free can be used to create certified copies of research documents. It is 21 CFR Part 11 compliant and is available at no cost to Mass General Brigham researchers by contacting the Compliance & Education Office at humanresearchqi@partners.org. Mass General Brigham REDCap is another system that can be used; it has a template for scanning, certifying, and storing research documents. More information is available in the REDCap Resource Center (https://confluence.partners.org/x/mgRVBQ).

   To inquire about the use of other systems or vendors, contact the Research Information Security Office at riso@partners.org.

8. ***Can documents be certified as a group/in bulk?***
   Yes. A group of documents can be scanned together and then the resulting file certified. Keep in mind the overall size of the file so that it can be copied, moved, uploaded, etc., as well as how the file will be named so that the name reflects all the scanned components. Alternatively, several documents can be scanned individually and then one certification attestation created listing all the individual files which have been certified.

9. ***Is REDCap 21 CFR Part 11 compliant?***
   For information about REDCap, review the links below.

   REDCap Resources:

   REDCap Project: https://projectredcap.org/

   REDCap at Mass General Brigham:https://confluence.partners.org/x/mgRVBQ

   Mass General Brigham REDCap 21 CFR Part 11 compliance information: https://confluence.partners.org/x/kntVBQ

   HRA Compliance and Education Office (Pages - Human Research Affairs Compliance and Education Office (sharepoint.com))

10. ***What other tools/technologies can we use to certify copies?***
    In addition to REDCap and Veeva SiteVault Free, technologies that create a signature or certification on a PDF are acceptable as long as they comply with 21 CFR Part 11. Compliance includes, but is not limited to: systems validation, audit trail of the document to ensure no changes or only tracked changes have been made after certification, and access controls. Please contact riso@partners.org with any questions about technologies.

11. ***Do all pages of the informed consent form need to be scanned, or just the signature page(s)?***
    All pages of the informed consent document should be scanned, verified and certified.