National Institute of Allergy and Infectious Diseases

Electronic Storage of Human Research Study Documents for DAIDS Sponsored Research – Digitization of Research Records

NIH defers to local Institutional Review Board (IRB)/Ethics Committee (EC) decisions and the FDA and EMA's guidance regarding acceptance of electronic storage of research documents. DAIDS standards for digitization of research records align with FDA and EMA guidance.

Requirements Before Converting Records from Paper to Electronic Format:

- Approval from DAIDS (as the regulatory sponsor) should be requested, in writing, to convert paper research study documents to electronic files for storage. Please reach out to your DAIDS point of contact (e.g., Program Officer (PO), Contracting Officer Representative (COR)). Documentation of DAIDS approval should be filed with the research study documents.
- Institutional Review Board (IRB)/Ethics Committee (EC) and institutional approval should be requested to convert paper research study documents to electronic files for storage.

Guidance Regarding the Creation and Storage of Electronic Records

The FDA and EMA allow electronic storage of research study documents as long as the electronic copies are certified. As defined by the FDA, 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 (https://www.fda.gov/media/85183/download).

What are best practices for electronic storage?

- Index the documents for ease of retrieval.
- Certify the electronic copies.
    - Review of each page in the electronic document by a research team member to confirm that all pages are present and legible.
    - Complete certification statement and maintain in study files.
    - Use appropriate security measures to protect files from unauthorized access.
- Standard Operating Procedures (SOPs) should outline the steps that will be taken to carry out QC of the certified copies, the percentage of documents to be reviewed to meet this risk-based QC approach, and how this QC will be documented.

Where should electronic files be stored?

- Electronic files of the scanned and certified research study documents must be stored securely.
- There should be an SOP that outlines procedures for electronic storage of research documents, back up procedures, and long-term storage requirements. Consideration should be given to how documents are retrieved if questions arise in the future.

How should electronic files be created?

If scanning research records of all types:

- Research records should be scanned as a 'chart'; that is, all of the records for a single participant should be scanned together and identified as that participant's records (initials; participant ID). Informed consent forms (ICFs) should be included with each participant's file, unless scanning all of the ICF documents for the study as a separate file.
- Bookmarks are recommended, similar to the use of tabs in a paper research record.
- Pertinent e-mail correspondence (relevant communications) should be included in scanned files.
- General study documents (delegation logs, general sponsor correspondence, etc.) should be scanned in a separate file.
- Do not save over previous versions when a document is updated (e.g., if the PI signs a new FDA Form 1572, prior versions should continue to be maintained in line with record retention requirements).
- Scanned research records must be password protected if they are stored in location accessible to anyone outside of the approved research team.

If scanning Informed Consent Form (ICF) documents only:

- ICFs can be scanned individually or as a group of participants.
- If scanning ICFs as a group, it is recommended to keep the number of ICFs per .pdf in mind while considering size and number of ICFs per participant. For example, you may only wish to scan 10 ICFs per .pdf if the ICFs are more than 20 pages each; however, you may wish to scan 50 ICFs per .pdf if the ICFs are only 2 pages each.
    - Naming of files should be consistent - The .pdf file name should be labeled consistently.
- Scanned ICFs must be password protected if they are stored in a location accessible to anyone outside approved research team.
- It is recommended that ICFs be bookmarked by participant name and date signed (**for example:** Smith, Jane signed 7-17-2013).
    - If participants have more than one ICF, each ICF should be labeled to clearly document this (**for example**: Smith, Jane PG ICF signed 7-17-2013).
    - Scanned ICFs should NOT be saved or bookmarked by the participant's ID number.

What should be done during the Certification Process?

Anyone completing the certification form is certifying 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 each scanned ICF is bookmarked (if used) and named appropriately and consistently.
- Confirmed that the scanned document is password protected and saved in a secure location.

Once scanned and certified, can the paper records be destroyed?

Once all of the research records are scanned and certified, the paper copies can be destroyed. See below for additional guidance.

- There is guidance on the destruction of original documents after certified copies have been made. See the EMA GCP Inspectors Working Group (GCP IWG) document, entitled "Guideline on the Content, Management and Archiving of Clinical Trial Master File (paper & electronic)," dated 06DEC2018.
- Section 5.1 states that a process be in place for a risk-based QC of certified copies before destroying the originals. Risk-based QC should look at:
    - congruency of the information contained between original and certified copy;
    - accuracy of the metadata attributed to the document (when applicable);
    - accuracy of file name; including that it is marked as an updated version of an already existing document;
    - quality of the image [(suitable resolution to allow readability as per the original, legibility and reproduction of colour — when the colour gives meaning and legibility of wet-ink signatures or annotations and handwriting in general etc. (when applicable)];
    - approval of the certification process (when applicable)

How long should electronic files of research study documents be kept?

The record retention requirements include national, state, and local laws as well as institutional policies which may extend the record retention requirement. In circumstances where multiple sets of requirements apply, the most stringent applicable retention requirement must be followed.