

# CHICKEN SOUP FOR THE BUSY COORDINATOR

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## Electronic Filing of Essential Documents

### Scenario

A Principal Investigator (PI) had completed his research study. However, the PI is facing the challenge in maintaining hard copies of essential documents due to the space constraints with archiving research documents on-site and high costs of off site archival. Therefore he is considering to convert paper originals to electronic copies. What are some of the important points that the PI must adhere to?

### Requirements to be met before the destruction of original paper essential documents

1. Ensure the electronic copy is a complete and accurate representation of the original (i.e. certified true copy). This process should be documented (e.g. SOPs, Work Instructions) and include details such as how copies are made, verified, destruction of originals (where applicable), who is authorized to check / sign off documents and how the process will be documented (e.g. tracking logs).
2. The electronic copy is placed in a validated electronic document management system
3. A training plan covering the process flow and applicable SOPs / Work Instructions has been created, is available, and users have successfully completed the training (and training is documented).

### Can all original paper essential documents be destroyed after it has been replaced by electronic copies?

Some essential documents must be categorized as legally "protected" to prevent the destruction of those paper documents.

### Examples of documents that have a low risk from destruction include:

1. A paper copy of an electronic original can be destroyed, as long as the original remains in the electronic investigator file. (e.g. a printout of a monitoring visit report placed in an electronic investigator file).
2. Paper documents that do not have legally required wet-ink signatures; the electronic version can serve as a certified copy of the paper original.

### Examples of documents which are considered high risk from destruction:

1. Paper originals with wet-ink signature.
2. These may include protocol signature pages, agreements/contracts, signed informed consent forms, completed case report forms and delegation logs.
3. It is recommended that all original documents with legally required wet-ink signatures should not be destroyed until the retention period is over, even after electronic copies have been created.

### When can original paper essential documents be destroyed after it has been replaced by electronic copies?

1. After creation of electronic copies, paper essential documents should not be destroyed before the end of the retention period. However, creation of certified electronic copies may enable earlier destruction of the original document.
2. Not all copies of essential documents need to be signed as certified copies. Certified copies are necessary when original records are copied to a different media for archiving purposes and the originals are destroyed, or the site wants a copy as a substitute for the original records.
3. Destruction of original essential documents should be documented (e.g. tracking log).

### Maintaining essential documents in an electronic document management system

1. Store single versions centrally to eliminate redundancy and reduce the risk of using outdated copies of documents
2. Leverage shared drives or cloud-based repositories which are compliant to applicable Regulations, SOPs and guidelines (e.g. institutional SOPs, data policies)
3. Establish a standard naming convention so that documents can be easily retrieved
4. Establish role based access to documents to ensure that only authorized individuals have access to sensitive or confidential information
5. Create, manage and demonstrate adherence to SOPs / Work Instructions and guidelines

Currently, PIs may consider the use of SharePoint and local Storage Area Network (SANS) to store electronic essential documents. However, they are encouraged to check with their institutional IT departments or clinical research office / unit for any further requirements.

### REFERENCES

1. Adapted from NHG Guidance 599-006 Document on Electronic Filing of Essential Documents
2. NHG PCR SOP 501-B05 Documentation

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*\*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.*