

CHICKEN SOUP FOR THE BUSY COORDINATOR

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What You Should Know About Documentation & ‘Certified True Copies’

Scenario

Senior clinical research coordinator (CRC) Mary is the mentor for junior CRC Susan, who had been tasked to prepare study documents for archival due to space constraints at the site. Junior CRC Susan sought the advice of CRC Mary who shared some important pointers and principles as follows:

What is “Certified Copy” of the original document? A paper or electronic copy of the original record that has been verified (e.g., by a dated signature) or has been generated through a validated process to produce an exact copy having all of the same attributes and information as the original.

When are ‘Certified True Copies’ used and Who Certifies them? 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. Any transfer or conversion (e.g., electronic or paper copy), which does not fulfil the criteria for a certified copy, is not suitable to replace an original file. Generally, the person who certifies the copy should be the person who created the copy. To certify the copy the person can sign and date the copy to indicate that it meets the requirements of a certified copy.

Who should perform the Quality Checks (QC) of certified copy documents? It is recommended that the QC checks be performed by a different person than the person who created the electronic documents.

When can original paper essential documents be destroyed after it has been replaced by electronic copies? 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. A risk-based approach should be used to determine what may be destroyed. Some essential documents must be categorized as legally “protected” to prevent the destruction of those paper documents. Destruction of original essential documents should be documented (e.g., tracking log).

For electronic copies, how should it be verified to ensure that it is a certified true copy of the original? A process should be in place for risk-based Quality Control (QC) checks of certified copies before the destruction of paper originals. It is recommended that the QC checks include the following quality features:

Quality Features	Examples
Congruency of the information contained between original and certified copy	<ul style="list-style-type: none">• Are all the pages present?• Is all the information in the paper document present on the electronic image, including headers and footers?• If scanner settings are duplex, are true blank pages removed?• Is the document the correct size and orientation?• Are the pages in the correct sequence?
Accuracy of file name; including that it is marked as an update version of an already existing document	<ul style="list-style-type: none">• Does the file name match that of the paper original company, including version number and date?
Quality of the image (suitable resolution to allow readability as per the original, legibility and reproduction of color – when the color gives meaning and legibility of wet-ink signatures or annotations and handwriting in general etc.) (where applicable)	<ul style="list-style-type: none">• Is the image too light or too dark?• Are the pages skewed?• If all content including signatures legible?• Is any content blocked by bent corners of the paper or enclosed material (e.g., post-its)?• Has any content that appears on the original document (e.g., hole punch) been removed from the digital image?
Approval of the certification process (when applicable)	<ul style="list-style-type: none">• The process for certifying a copy must be documented (e.g., SOP/ Work instructions). Each step of a certified copy process should be documented to show that it has been adhered to.• One way of process documentation would be to establish a unique naming convention of electronic documents that reflects the document and the content
The audit trail associated with the document (when applicable)	<ul style="list-style-type: none">• Any audit trail associated with the paper original should also be present on the electronic version.

Reference: NHG Proper Conduct of Research SOP: 501-B05 Documentation, NHG 599-006: Guidance Document on Electronic Filing of Essential Documents

Additional resource: NHG Proper Conduct of Research SOP: 501-B08 Data Collection and Handling

Article Contributed By: Khoo Jin Rong Senior CRC, Caron Tan CRC, NHGP

Edited By: NHG Group Research, OHRPP

***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.**

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