CLINICAL RESEARCH - CREATING CERTIFIED COPIES

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose is to outline the procedure for the creation of certified copies of original records for clinical research, in compliance with NSW Health, SCHN and regulatory requirements.
- The procedure must be followed by all personnel involved in the conduct of clinical research.

CHANGE SUMMARY

- Document due for mandatory review
- References updated

READ ACKNOWLEDGEMENT

- Read/Acknowledge Only – Personnel involved in the creation of certified copies of original records for clinical research.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st October 2021	**Review Period**: 3 years
Team Leader:	Clinical Trials Program Manager	**Area/Dept**: Kids Research Institute

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Purpose/Scope

The purpose is to outline the procedure for the creation of certified copies of original records for clinical research, in compliance with NSW Health, SCHN and regulatory requirements.

This procedure must be followed by all personnel involved in the creation of certified copies of original records for clinical research.

Background

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 4.9, the Investigator should maintain adequate and accurate source documents that are attributable, legible, contemporaneous, original, accurate, and complete.

When a copy is used to replace an original source document, the copy should fulfil the requirements for certified copies.

A certified copy is a copy (irrespective of the type of media used) of the original record that has been verified (i.e. by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original (Section 1.63).

Procedure

- In order to create a certified copy of an original record, the Investigator or Delegate is responsible for:
    - Retrieving the original document;
    - Removing any wallets/staples/binding and/or paperclips;
    - Perform a QC check of the original document to determine whether simplex or duplex scanning settings are required and that all pages are of a quality suitable for scanning;
    - Scanning the original document in colour into Adobe Portable Document File (PDF) electronic format;

- Performing QC checks to verify that the PDF has the same attributes and information as the original document with regard to size and orientation, colour (only required if the use of colour will improve the readability and interpretation of the document(s)), legibility, quality, intact header and footer, and the inclusion of all pages in the correct sequence;
- Note: Pages containing only header and footer information are not to be considered as blank pages, though 'true' blank pages (generated through duplex scanning settings) may be deleted from the file.
- If the scanned document does not meet the requirements of a certified copy (an exact copy having all of the same attributes and information as the original), the original document should be re-scanned and/or retention of the original document should be considered;
- Once verified, naming the file in accordance with the SCHN Procedure 2019-145 – Record Keeping to ensure its clear identification;
- Applying a 'Certified Copy' electronic stamp to the first page of the document detailing the total number of pages, the full name, electronic signature (see SCHN Procedure 2019-149 – Clinical Research - Use of Electronic Signatures) and date that the Investigator or Delegate performed the verification of the certified copy, as well as the following statement:

  "The following [Insert No.] pages are a copy of the original document which has been scanned into the Adobe® PDF format, and verified by me as a true and accurate copy, according to SCHN Procedure – Clinical Research – Certifying Essential Documents ".
- Filing the certified copy in the appropriate location;
- Ensuring secure destruction of the original document(s) in accordance with the terms and provisions of the relevant Disposal Authorities and Guidelines issued by State Records NSW and in compliance with NSW Health, SCHN and regulatory requirements.

Abbreviations and Definitions

Certified Copy	A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.
GCP	Good Clinical Practice
NSW	New South Wales
NTF	Note to File
PD	Policy Directive
QC	Quality Control

SCHN	Sydney Children's Hospitals Network
Source Documents	Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical research);
TGA	Therapeutic Goods Administration

Related Documents

1. SCHN Policy – Clinical Research [DRAFT]
2. SCHN Procedure 2019-149 – Clinical Research – Use of Electronic Signatures - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4712
3. SCHN Procedure – Clinical Research - Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
4. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/5646
5. SCHN Procedure 2019-145 - Clinical Research – Record Keeping - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661
6. NSW Health PD2012_069 - Health Care Records - Documentation and Management - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2012_069.pdf
7. SCHN Policy 2014-9045 – Health Care Records Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3274/download
8. SCHN Policy 2014-9019 – Destruction of Scanned Health Care Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4064/download
9. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf