CLINICAL RESEARCH – CERTIFIED COPIES AND USE OF ELECTRONIC SIGNATURES

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- This procedure outlines the steps for creating certified copies of original clinical research records and the proper use of electronic signatures, in compliance with NSW Health, SCHN, and regulatory requirements.
- The procedure should be followed by all personnel involved in the conduct of clinical research.

CHANGE SUMMARY

- Document updated to combine procedures for both creating certified copies [2019-025] and electronic signatures [2019-149].
- References updated.

READ ACKNOWLEDGEMENT

- Personnel involved in the creation, management and/or certification of records and the use of electronic signatures in clinical research, including agreements are to read and acknowledge (i.e. sign-off after reading) this document.

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Introduction

Purpose/Scope

The purpose is to ensure that certified copies of original records and electronic signatures are created and maintained in accordance with Good Clinical Practice (GCP), NSW Health, SCHN and regulatory requirements. This ensures the integrity, authenticity, and compliance of all records related to clinical research.

Background

Clinical research requires maintaining high standards of documentation to ensure the accuracy, integrity, and compliance of trial data. Regulatory bodies, including the Therapeutic Goods Administration (TGA) and international guidelines such as the ICH-GCP, mandate that original source documents and essential records be handled in a manner that preserves their integrity for audit and inspection purposes.

ICH-GCP mandates that all clinical trial-related information be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification. Additionally, Section 1.63 of ICH-GCP defines a certified copy as a copy of the original document that has been verified through a validated process to contain the same information and attributes as the original.

Certified copies and electronic signatures play a critical role in modern clinical research by facilitating secure and efficient document management. Certified copies allow for the secure destruction of original documents while still maintaining accurate records for regulatory and legal purposes. Proper certification of copies ensures compliance with the requirement that trial documentation remains attributable, legible, contemporaneous, original, accurate, and complete (ALCOAC - Section 4.9.0 of ICH-GCP).

Electronic signatures offer a secure method for signing documents in clinical research settings. They reduce reliance on physical signatures, expedite workflows, and provide an audit trail that enhances transparency. As per ICH-GCP Section 8.1, all essential documents, including those bearing electronic signatures, must permit evaluation of the conduct of the trial and the quality of the data produced. The use of electronic signatures must be validated and comply with institutional, national, and international guidelines to ensure the integrity of trial records.

This procedure aligns with the Sydney Children's Hospitals Network (SCHN) and NSW Health policies, as well as Good Clinical Practice (GCP) guidelines, providing clear and standardised processes for creating certified copies and using electronic signatures. All clinical research personnel involved in documentation management must follow these guidelines to ensure the accuracy, security, and compliance of trial data.

1 Procedure for Creating Certified Copies

Document Preparation and Scanning Process

Retrieve and Prepare Original Documents:

- Remove any wallets, staples, bindings, or paperclips.
- Perform a quality control (QC) check to ensure that all pages are ready for scanning and determine if simplex (single-sided) or duplex (double-sided) scanning is required.

Scan the Document:

- Scan the document in colour using the Adobe PDF format.
- Ensure the scanned document retains the following attributes from the original:
- Size, orientation, legibility, and inclusion of all pages in the correct sequence.
- Colour scanning is required only if it improves the readability or interpretation of the document.

Verify the Certified Copy:

- Conduct a QC check of the scanned PDF to confirm it is an exact match to the original, including:
- Correct header/footer, sequence of pages, and legibility.
- Ensure no blank pages are included (except where intentionally scanned).
- If any discrepancies are found, re-scan the original document until a complete and accurate certified copy is obtained.

Apply the Certified Copy Stamp:

- On the first page of the scanned document, apply an electronic “Certified Copy” stamp containing:
- Number of pages.
- Full name of the individual verifying the document.
- Electronic signature (see Section 2 below) and date.

  The following certification statement:

  “The following [Insert No.] pages are a copy of the original document, which has been scanned into Adobe® PDF format and verified by me as a true and accurate copy”.

File and Store the Certified Copy:

- Name the certified file in a consistent and standardised format.
- Store the certified copy securely in the appropriate clinical trial records system.
- Ensure the secure destruction of the original document(s) per NSW Health and State Records NSW guidelines.

2 Procedure for Use of Electronic Signatures

Requirements for Electronic Signatures:

Authentication:

- All personnel must use an approved electronic signature system that complies with SCHN's electronic records and signatures policies.
- Electronic signatures must be unique, traceable, and associated with the individual who has applied the signature.

Using Electronic Signatures:

- Electronic signatures can be used for:
  - Verifying certified copies.
  - Approving study-related documents.
  - Authorising key clinical trial procedures.
- The electronic signature must be applied directly within the validated system that maintains the clinical trial records.

Signature Format:

- The electronic signature must include:
  - The individual's full name.
  - The date and time the signature was applied.
  - An identifier (such as a user ID or encrypted token) that ensures traceability.

Electronic Signature Security:

- Access to electronic signatures is controlled via secure login credentials and multi-factor authentication where applicable.
- All signed documents must be stored in a validated electronic records system to maintain compliance with regulatory standards.

3 Record Keeping & Compliance

Certified copies and electronically signed documents must be stored in a consistent and standardised manner.

Original records and certified copies should be securely destroyed following the NSW Health Disposal Authority guidelines.

4 Abbreviations and Definitions

Term	Definition
ALCOAC	Attributable, Legible, Contemporaneous, Original, Accurate, Complete
Certified Copy	A copy (irrespective of the type of media used) of the original record that has been verified, either by a dated signature or through a validated process, to have the same information, including the context, content, and structure, as the original.
CFR	Code of Federal Regulations
CTMS	Clinical Trials Management System
GCP	Good Clinical Practice. An international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials that involve human subjects.
Electronic Signature	A legally recognised electronic identifier that is used to authenticate a document in a way that complies with regulatory requirements.
FDA	Food and Drug Administration
ICH	International Conference on Harmonisation
MHRA	Medicines and Health Products Regulatory Agency
NSW	New South Wales
PD	Policy Directive
Record	Any document or other source of information compiled recorded or stored in written form or on film, or by electronic process, or in any other manner or by any other means.
SCHN	Sydney Children's Hospitals Network

5 Related Documents

- SCHN Policy 2014-9045 – Health Care Records Management - https://webapps.schn.health.nsw.gov.au/epolicy/policy/6197
- SCHN Policy 2013-9056 - Electronic Information Security - https://webapps.schn.health.nsw.gov.au/epolicy/policy/6523

Please refer to SCHN Clinical Research Policies and Procedures found on the intranet'

6 References

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