

CLINICAL RESEARCH - USE OF ELECTRONIC SIGNATURES PROCEDURE [®]

DOCUMENT SUMMARY/KEY POINTS

- The purpose is to outline the procedure for the use of electronic signatures on records for clinical research, 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

- Not applicable – New Sydney Children’s Hospitals Network Procedure.

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Personnel involved in the creation, management and/or certification of 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:	1 st August 2019	Review Period: 3 years
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Purpose/Scope

The purpose is to outline the procedure for the use of electronic signatures on records for clinical research, in compliance with NSW Health, SCHN and regulatory requirements.

Adherence to this procedure will ensure appropriate quality control with regard to the use of electronic signatures and improved consistency and efficiencies in workflow processes for clinical research personnel.

This procedure should be followed by all personnel involved in the creation, management and/or certification of electronic file and records management for clinical research.

Background

An electronic signature is a form of electronic identification (bio-metric or non-biometric) that is executed, adopted or authorised by an individual to be the legally binding equivalent of the individual's handwritten signature.

Electronic signatures can come in many forms including, but not limited to, representations that are type-written, scanned, tick-boxes with declarations, images, or a unique digital combination of characters (e.g. hash or checksum).

To be deemed valid, electronic signatures must serve the same essential functions that are expected of records signed by handwritten signature, namely integrity, non-repudiation, authentication and confidentiality.

In the digital context, integrity means ensuring that a communication has not been altered in the course of transmission and as such that it is accurate and complete and able to be relied upon as valid.

In a clinical research context, electronic systems and/or processes including electronic records with electronic signatures, are subject to additional requirements, as per ICH GCP Section 5.5.3 and international best practice guidelines.

Such records must be generated and managed in adherence with ALCOA principles and also be maintained and made accessible to inspecting parties (see SCHN Procedure – Record Keeping).

Given this, it is required that electronic signatures on records for clinical research are requested and/or applied via validated electronic systems using a methodology that is appropriate to the risk inherent in the transaction, in order to assure their authenticity.

Procedure

- Records requiring electronic signatures must be initially generated and/or issued in an electronic format;
- If wet ink signatures are already present on paper records, an electronic format of the record can be created, if desired, in accordance with the SCHN Procedure 2019-025 - Creating Certified Copies and this Procedure;
- Wet ink signatures must not be re-issued as electronic signatures after the creation of an electronic record in the form of a certified copy (e.g. by asking a signatory to add an additional electronic signature to a record);
- Electronic signatures should not be used in transactions where there is a legal requirement for a written signature, for example, in the signing of a deed or other document where the signature is required to be witnessed.
- If SCHN data is being provided to an international regulatory authority (FDA, EMEA etc.), the Investigator may provide a statement to the Sponsor or Delegate attesting that electronic signatures generated by the Site are the legally binding equivalent of handwritten signatures per the requirements of FDA CFR 21 Part 11;
- The method of authentication for electronic signatures used in clinical research should be proportionate to the risk inherent in the transaction with consideration for record keeping outlined by the SCHN Procedure – Clinical Research – Record Keeping;
- The use of Adobe in accordance with the appended 'How-To Guides' is recommended;
- Electronically signed records for clinical research must clearly represent the:
 - Printed name (identity) of the signatory, if not otherwise stated in the context of the record;
 - The date (and time, if significant) on which the signature was executed; and
 - Intent of the signatory (e.g. acknowledgement, reviewed, approved or otherwise notated), if not otherwise stated or evident in the context of the record.
- The electronic signature applied must also be:
 - Under the sole control of the person using it;
 - Linked to the record in such a way that changes to the record invalidates the signature(s) originally applied (as applicable); and
 - Verifiable (i.e.: the identity of the signatory is corroborated *at least* 1 or more authentication method(s) e.g. single-factor authentication).
- The use of an inserted image, footnote or other annotation(s) indicating that a record has been electronically signed, but that does not meet all stated requirements above

would generally not be deemed compliant for clinical research records, unless otherwise agreed with the Sponsor or Delegate.

Abbreviations and Definitions

ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available
CFR	Code of Federal Regulations
CTMS	Clinical Trials Management System
GCP	Good Clinical Practice
FDA	Food and Drug Administration
ICH	International Conference on Harmonisation
MHRA	Medicines and Health Products Regulatory Agency (MHRA)
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

Related Documents

1. Electronic Transactions Act 1999 - C2011C00445 - <https://www.legislation.gov.au/Details/C2011C00445/Html/Text>
2. Electronic Transactions Act 2000 (NSW) No 8, Part 2, Division 2 Section 9 - <https://www.legislation.nsw.gov.au/~/-/view/act/2000/8/full>
3. FDA – CFR 21 Part 11 - https://www.ecfr.gov/cgi-bin/text-idx?SID=36b83f1291e437a297dd6837e77c5d57&mc=true&tpl=/ecfrbrowse/Title21/21cfr11_main_02.tpl
4. Lim , Y. F. (2002). Digital Signature, Certification Authorities and the Law. Murdoch University Electronic Journal of Law, 9(3) - <http://www5.austlii.edu.au/au/journals/MurUEJL/2002/29.html>
5. MHRA (March 2018) - 'GXP' Data Integrity Guidance and Definitions Revision 1 - <https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity>
6. National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 - <https://www.nhmrc.gov.au/guidelines-publications/e72>
7. NSW Health PD2012_069 - Health Care Records - Documentation and Management - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2012_069.pdf
8. NSW Health PD2013_033 - NSW Health Electronic Information Security Policy - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_033.pdf
9. SCHN Policy – Clinical Research [DRAFT]
10. SCHN Policy 2014-9045 – Health Care Records Management - <http://webapps.schn.health.nsw.gov.au/epolicy/policy/3274/download>
11. SCHN Policy 2013-9056 - Electronic Information Security = <http://webapps.schn.health.nsw.gov.au/epolicy/policy/3094>
12. SCHN Procedure 2019-025 – Clinical Research – Creation of Certified Copies - <http://webapps.schn.health.nsw.gov.au/epolicy/policy/4695>

13. SCHN Procedure 2019-027 – Clinical Research- Personnel Qualifications and Training Records - <http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623>
14. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - <http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624>
15. SCHN Procedure – Clinical Research – Record Keeping <http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661>
16. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - <https://www.tga.gov.au/sites/default/files/ich13595an.pdf>

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