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 including agreements 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

- Document due for mandatory review. Minor changes made throughout.
- References updated.

READ ACKNOWLEDGEMENT

- Read/Acknowledge Only – Personnel involved in the creation, management and/or certification of records including agreements for clinical research.

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

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Purpose/Scope

The purpose is to outline the procedure for the use of electronic signatures on records including agreements 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 2019-145 – Clinical Research - 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;
- SCHN is unable to accept e-signing methods initiated by the Sponsor or Delegate that require the release of personal information, such as the mobile phone numbers of signatories.
- 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 – Clinical Research - 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 2019-145 – Clinical Research – Record Keeping;
- The use of Adobe Sign in accordance with the appended ‘How-To Guides’ is required to assure compliance with local and international regulatory requirements, including FDA 21 CFR Part 11;
- 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* 2 authentication method(s) e.g. two-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.

Appendices

How-To Guide – Requesting an Electronic Signature(s) via Adobe Sign (Website)

How-To Guide – Actioning a Request for Electronic Signature via Adobe

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. Adobe - Adobe Sign & Healthcare and Life Sciences Organizations: A Handbook for 21 CFR Part 11 and EudraLex Annex 11 - https://www.adobe.com/content/dam/cc/en/security/pdfs/adobe-sign-handbook-for-fda-regulated-organizations-ue.pdf
2. CT-IQ - Joint Position Statement – Electronic signatures and Clinical Trial Research Agreement execution in Australia - https://ctiq.com.au/wp-content/uploads/Joint-Position-Statement_Electronic-Signatures.pdf
3. Electronic Transactions Act 1999 - C2011C00445 - https://www.legislation.gov.au/Details/C2011C00445/Html/Text
4. Electronic Transactions Act 2000 (NSW) No 8, Part 2, Division 2 Section 9 - https://www.legislation.nsw.gov.au/~/view/act/2000/8/full
5. FDA – CFR 21 Part 11 - https://www.ecfr.gov/cgi-bin/text-idx?SID=36b83f1291e437a297dd6837e77c5d57&mc=true&tpl=/ecfrbrowse/Title21/21cfr11_main_02.tpl
6. 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
7. MHRA (March 2018) - 'GXP' Data Integrity Guidance and Definitions Revision 1 - https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity
8. NSW Health - COVID-19: Guidance on clinical trials for Sponsors, Researchers, Trial Sites, HRECs, and RGOs- https://www.medicalresearch.nsw.gov.au/app/uploads/2020/10/NSW-Health-Guidance-Document-COVID-19-and-Clinical-Trials_Version-2_Sep-2020.pdf
9. NHMRC - National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 - https://www.nhmrc.gov.au/guidelines-publications/e72
10. NSW Health PD2012_069 - Health Care Records - Documentation and Management - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2012_069.pdf
11. NSW Health PD2013_033 - NSW Health Electronic Information Security Policy - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_033.pdf
12. SCHN Policy – Clinical Research [DRAFT]
13. SCHN Policy 2014-9045 – Health Care Records Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3274/download
14. SCHN Policy 2013-9056 - Electronic Information Security = http://webapps.schn.health.nsw.gov.au/epolicy/policy/3094
15. SCHN Procedure 2019-025 – Clinical Research – Creation of Certified Copies - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4695
16. SCHN Procedure 2019-027 – Clinical Research- Personnel Qualifications and Training Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
17. SCHN Procedure 2019-028 - Clinical Research – Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
18. SCHN Procedure 2019-145 – Clinical Research – Record Keeping http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661
19. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf