CLINICAL RESEARCH - RECORD KEEPING

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose is to outline the procedure for record keeping for clinical research, in compliance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the conduct of clinical research.

CHANGE SUMMARY

- Document due for mandatory review. No major changes
- References updated.

READ ACKNOWLEDGEMENT

- Read/Acknowledge Only – Personnel involved in the creation and management of records 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

Purpose/Scope

The purpose is to outline the procedure for the creation and management of records used as part of clinical research, in compliance with NSW Health, SCHN, regulatory and protocol requirements.

Adherence to this procedure will ensure that records for clinical research are:

- Sufficient to enable the reconstruction of clinical research by inspecting parties and assure the quality and integrity of data used for clinical research;
- Evidence of the appropriate delegation of roles and responsibilities including Investigator oversight, interpretation/adjudication and decision making; and
- Appropriately maintained in order to assure their long-term reliability and accessibility.

This procedure must be followed by all personnel involved in the creation and management of records for clinical research.

Background

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 1.51, source data is defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities conducted as part of clinical research.

The maintenance of source data is essential for the reconstruction, evaluation, and validation of findings, observations, and other activities that occur as part of clinical research. Source data is typically found within source documents, defined as the original documents, data and records relating to clinical research, that serve to substantiate the integrity of data, confirm observations that are recorded, and confirm the existence of participants.

It is critical that any source data and documents collected as part of clinical research, regardless of whether in paper and/or electronic formats, are handled and stored in a way that allows or their accurate reporting, interpretation and verification through the maintenance of a complete audit tail.

Documentation by exception (e.g. in the event of a deviation from baseline or an unexpected outcome) as per standard clinical care practices is not deemed to be acceptable for clinical research purposes.

Procedure

The Investigator or Delegate is responsible for ensuring that:

- Original source documents are retained at the Site as part of the TMF in either paper or electronic format;
- That measures are taken to prevent the accidental or premature destruction of source documents during both the conduct and the archival periods;
- Complete records are made available for inspection by representatives of the Sponsor, HREC and/or regulatory authorities on request;
- Source documents adhere to ALCOACEA principles at all times (see Table 1) in being attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available;
- Source documents are annotated by the Investigator or Delegate in accordance with roles and responsibilities delegated per the SCHN Procedure 2019-028 - Personnel Roles and Responsibilities in order to demonstrate oversight of study conduct and decision making in relation to clinical care;
- Source documents are maintained in accordance with the SCHN Procedure 2019-026 – Clinical Research - Trial Master File;
- Research participants are made aware of the requirement for inspection of complete health record(s) by representatives of the Sponsor, HREC and/or regulatory authorities on request as part of the informed consent process for clinical research and assured that the confidentiality of records will be maintained to the extent permitted by the applicable laws and/or regulations;
- The definition of source for a given data point and the location of all source data and documents of relevance to the protocol is clearly indicated and documented in the form of a Source Data Identification Log or equivalent prior to activation of the Site (and amended in the event of a change in procedures and/or practices);
- Note: Adaptation of the Source Data Identification Log (Appendix) is recommended in the absence of protocol-specific instructions and/or templates being provided by the Sponsor or Delegate;
- The research participants identity remains confidential by means of reference only to the participants protocol-specific identification number, initials and/or date of birth on any clinical research records released from the Site including PISCFs and the secure storage of source documentation at Site;
- Notes to File are used on a case-by-case basis to summarise and/or explain issues relating to records for clinical research, including, but not limited to, source documentation discrepancies, in circumstances where annotation of the source data is not feasible;

Note: Adaptation of the Note To File Template (Appendix) is recommended in the absence of protocol-specific instructions and/or templates being provided by the Sponsor or Delegate.

Table 1: ALCOACCEA Principles

Attribute	Description
Attributable	The record must clearly indicate the person who undertook the action(s) (e.g. performed the procedure/assessment and/or recorded the data).
Legible	The record must be readable and interpretable by an independent reviewer, including any signatures or annotations.
Contemporaneous	The record should be generated at the same time that the observation occurred. Where this is not possible, a chronology of events should be documented.
Original	The data must be original (e.g. the first record of an occurrence by the appropriate person), or a certified copy of the original record.
Accurate	The record must be a correct representation of facts. Entries should never be overwritten. Corrections on paper records are to be made by: ▪ Striking through the incorrect entry with a single line; ▪ Ensuring that the original entry is not obliterated or covered up with correction fluid or any other medium; ▪ Recording the correct data and the reason for the error, if applicable; ▪ Ensuring the entry is initialled and dated by the person making the correction.
Complete	The record must enable the full reconstruction of activities performed in order to verify compliance with the Protocol. Any amendments must be traceable.
Consistent	The record must demonstrate the required attributes consistently. There should only be 1 source defined for a given data point at one time.
Enduring	The record is recorded permanently using a durable medium that is protected from premature destruction.
Available	The record is accessible for inspection.

Appendices

Note to File

Source Data Identification Log

Abbreviations and Definitions

ALCOACCEA	Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
NSW	New South Wales
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration
TMF	Trial Master File

Related Documents

1. National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 - https://www.nhmrc.gov.au/guidelines-publications/e72
2. NSW Health PD2015_049 - Code of Conduct - https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2015_049
3. NSW Health PD2012_069 - Health Care Records - Documentation and Management - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2012_069.pdf
4. NSW Health PD2015_036 - Privacy Management Plan - https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2015_036
5. NSW Health PD2009_057 - Records Management - Department of Health - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2009_057.pdf
6. SCHN Policy 2007-8113 - Access to Electronic Healthcare Records for Improvement Activity or Case Study Purposes - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4063
7. SCHN Policy – Clinical Research [DRAFT]
8. SCHN Procedure 2020-153 - Clinical Research - Access to Electronic Healthcare Records for Inspection Purposes - http://webapps.schn.health.nsw.gov.au/epolicy/policy/5062
9. SCHN Policy 2014-9019 – Destruction of Scanned Health Care Records - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4064/download
10. SCHN Policy 2014-9045 – Health Care Records Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3274/download
11. SCHN Procedure 2019-023 – Clinical Research – Close-Out and Archiving - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4688
12. SCHN Procedure 2019-025 – Clinical Research - Creating 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 2018-189 – Clinical Research – Review of Medical Results - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4650
16. SCHN Procedure 2019-026 – Clinical Research - Trial Master File - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4698
17. SCHN Procedure 2019-149 – Clinical Research – Use of Electronic Signatures - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4712
18. SCHN Procedure 2016-9002 - Consent to Participate in Human Research – Participant Information and Consent - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3666
19. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf