CLINICAL RESEARCH - CLOSE-OUT AND ARCHIVING

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that close-out and archiving is performed in accordance with NSW Health, SCHN and regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in conduct of close out and archiving tasks for clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Personnel performing close out and archiving tasks 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 March 2019	**Review Period**: 3 years
Team Leader:	Clinical Trials Program Manager	**Area/Dept**: Kids Research Institute

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Purpose/Scope

The purpose of this procedure is to ensure that close-out and archiving is performed in accordance with NSW Health, SCHN and regulatory and protocol requirements.

This procedure must be followed by all personnel involved in the close-out and archiving of clinical research.

Background

Close-out is defined as the act of ensuring that all clinical research related activities are appropriately reconciled, recorded, and reported at the completion of a clinical research initiative.

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 8.1, final close-out of clinical research can only be performed once the Investigator and Sponsor or Delegate have confirmed that all necessary records are filed and archived, to allow retrieval in the event of future retrieval for inspection or other purposes.

Procedure

Close-Out

- Close-out procedures will be performed as soon as possible after the end of the clinical research;
- The end of the clinical research will generally be defined by the protocol or equivalent, or in the case of early termination, as defined by the Sponsor or Delegate;
- In instances where SCHN is acting as the Site, close-out procedures may be performed as soon as the last clinical research participant has completed all requirements per protocol;
- The method of performing close out will be stipulated by the Sponsor or Delegate and may involve the conduct of on-site visit(s), remote correspondence or a combination of these methods;
- The Sponsor or Delegate is responsible for ensuring all requirements for close-out, as stipulated by the protocol or equivalent (e.g. protocol-specific monitoring plan) are addressed, including, but not limited to:
    - Providing an agenda for the close-out visit outlining the clinical research personnel required to attend and/or facilities to be made available for inspection;
    - Issuing any outstanding data clarification queries;
    - Ensuring all SDV is performed (as applicable);
    - Inspecting the Sponsor and Investigator TMF for completeness;

- Ensuring that arrangements are made for the long-term storage, return or destruction of any bio specimens retained at Site in accordance with informed consent provisions;
- Reconciling any IMP, equipment and/or supplies (as applicable) including confirmation of arrangements for return and/or disposal;
- Reviewing any requirements for reporting, adverse event follow-up, dissemination of results (if applicable) and records retention and retrieval in the event of inspection
- Providing the CSR (or equivalent) once available;
- Ensuring the regulatory authorities are notified of the completion of the clinical research and provided with a summary of the key outcomes;
- Updating the registry on which the clinical research is listed to accurately reflect the research and/or Site's (if applicable) status;
- Providing a copy of the Investigator's data post sign-off of the CRFs (or equivalent) for clinical research participants; and
- Promptly providing a written report (Appendix) detailing an issues and/or resolutions as a result of close-out proceedings for filing in the TMF.

- The Investigator or Delegate must facilitate the performance of close-out activities in accordance with NSW Health, SCHN and regulatory and protocol requirements, including, but not limited to:
  - Notification of any the HREC, RGO as well as any Supporting Departments and third-party vendors (as applicable) are advised regarding the completion of the clinical research;
  - Filing all essential documents in the TMF;
  - Entering any outstanding data, preferably in advance of the close-out visit;
  - Ensuring the attendance/involvement of all required clinical research personnel as part of close-out proceedings;
  - Enabling access to all facilities required to be inspected (if applicable), as per the agenda;
  - Enabling access to all records required for the purposes of SDV;
  - Resolution of any final data clarification queries generated at the close-out visit;
  - Ensuring all financials have been reconciled in accordance with the SCHN Procedure- Clinical Research – Financial Management [DRAFT];
  - Actioning the requests of the Sponsor or Delegate with regard to the return and/or disposal of retained bio specimens, IMP, equipment and/or supplies (as applicable);
  - Authorising the data provided by the Site through sign-off of the CRFs (or equivalent) for clinical research participants;
  - Actioning any requirements for adverse event follow-up and the dissemination of results (if applicable);

- Providing a final report regarding of the outcomes of the clinical research, including the CSR (or equivalent) (once available) and any other supporting documentation (as applicable) to HREC and RGO, in collaboration with the Sponsor or Delegate;
- Communicating plans with regard to records retention and retrieval in the event of an inspection to the Sponsor or Delegate; and
- Informing the Sponsor or Delegate promptly post the close-out visit if notified of an impending inspection by a regulatory body.

Archiving

- Following the actioning any requirements for unblinding, dissemination of results, receipt of the CSR (or equivalent), and receipt of the Investigator's data post sign-off of the CRFs (or equivalent) (as applicable), the TMF must be archived;
- The Investigator or Delegate is responsible for determining whether records will be securely archived in paper, electronic or a mixture of both paper and electronic formats;
- Completed protocol-specific IMP Prescriptions will be archived separately by the Department of Pharmacy, in accordance with NSW Health PD2013_043;
- The storage system used for archiving (irrespective of the type(s) of media used) must enable ease of record identification, version history, search and retrieval;
- Paper records must be sent to the Governance Records Repository (GRR) managed by State Records NSW for long-term storage;
- Any costs associated with archiving must be cost recovered in accordance with the SCHN Procedure – Financial Management [DRAFT];
- Electronic records will be maintained by SCHN on exiting Network servers or copied to electronic media (e.g. CV/DVDs and/or USB drives), and then sent to the GRR for long-term storage;
- Records will be managed in compliance with the provisions of State Records' Standard on the Physical Storage of State Records, the Australian & International Standard on Records Management AS ISO 15489-2004 and The State Records Act 1998;
- Standard barcodes will be affixed to all records sent to the GRR to allow all items in storage to be uniquely identified and to facilitate the tracking of all items in storage including the date and time that each transportation occurred;
- Paper and/or electronic records for each study should ideally be boxed separately i.e. records from different studies should not be mixed;
- An Archive Log (Appendix) must be completed detailing the location and nature of any protocol-specific archived records, including the date of archiving and the minimum period of retention applicable;
- A copy of the Archive Log must be securely retained by the Investigator or Delegate to facilitate retrieval in the event of inspection;

- Once all relevant records have been prepared for archiving, the Investigator or Delegate is responsible for contacting the GRR to request pick-up and transfer of the boxes to be GRR facility.

Retention

- Records for clinical research will be stored for the minimum period required by State Records NSW Health Services, Public: Patient/Client records (GDA17);
- Where records for a clinical research initiative fall into more than one class of record type, the most conservative retention schedule must be applied;
- In accordance with the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 4.9.5, records should be retained until "at least 2 years after the last approval of a marketing application in an ICH region and until there is no pending or contemplated marketing applications in an ICH region or at least 2-years have elapsed since the formal discontinuation of clinical development of the investigational product";
- The records should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the Sponsor or Delegate;
- Clinical trials will be maintained for a minimum period of 15 years, or until the youngest participant recruited from the site turns 25 years of age, whichever is longer;
- Records may be stored for a longer period of time or indefinitely, if required by the applicable regulations, or at the request and prior agreement of the Investigator, Sponsor or Delegate.

Retrieval

- Sponsor or Delegate requests for the retrieval of paper or electronic records must be made via written request to the Investigator or Delegate;
- Requests will be actioned promptly with consideration of their urgency;
- Retrieval of the records must be authorised and actioned by the Investigator or Delegate;
- The Investigator or Delegate is responsible for returning the records to the GRR once they are ready to be re-archived.

Destruction

- Records must only be destroyed after the minimum period of retention has lapsed and the written approval of the Sponsor or Delegate has been obtained;
- It is the responsibility of the Sponsor or Delegate to advise the Investigator or Delegate when destruction of the records may occur. However, if this does not happen routinely, the Investigator or Delegate may initiate contact with the Sponsor or Delegate for confirmation of destruction date(s);
- SCHN reserves the right to act with regard to the destruction if the Sponsor or Delegate are not responsive to reasonable attempts to seek confirmation of the destruction date(s) after the expiry of the originally agreed retention period;

- The destruction of any records must comply with the terms and provisions of the relevant Disposal Authorities and Guidelines issued by State Records NSW with consideration of the type of record(s);
- For records stored in the GRR authorised for destruction, a written Disposal Authorisation with specific reference to the instrument under which the records are being destroyed must be signed by the Investigator or Delegate;
- Records being destroyed by the GRR will be pulped under supervision and all resulting waste recycled. Magnetic media and other formats will be destroyed by incineration in a suitable third-party facility under the direction of State Records NSW;
- Destruction certificate(s) must be provided for all actions taken by the GRR, and a copy of the certificate(s) also issued to the Sponsor or Delegate.

Appendices

Archive Log

Close-Out Report incl. Checklist

Abbreviations and Definitions

CRF	Case Report Form
CSR	Clinical Study Report
ICH	International Conference on Harmonisation
GCP	Good Clinical Practice
GDA	General Retention and Disposal Authority
GRR	Government Records Repository
NSW	New South Wales
PD	Policy Directive
SCHN	Sydney Children's Hospitals Network
SDV	Source Document Verification
TGA	Therapeutic Goods Administration
TMF	Trial Master File

Related Documents

1. National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 -
2. NSW Health PD2013_043 - Medication Handling in NSW Public Health Facilities - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_043.pdf

3. NSW Health Practitioner Regulation (NSW) Regulation 2016 http://www.legislation.nsw.gov.au/regulations/2016-543.pdf
4. SCHN Policy – Clinical Research [DRAFT]
5. SCHN Policy 2014-9027 – Medication Handling in NSW Public Health Facilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3263/
6. SCHN Procedure – Clinical Research – IMP Accountability [DRAFT]
7. SCHN Procedure- Clinical Research – Creating Certified Copies [DRAFT]
8. SCHN Procedure – Clinical Research – Equipment and/or Supplies – Maintenance and Calibration [DRAFT]
9. SCHN Procedure – Clinical Research - Financial Management [DRAFT]
10. SCHN Procedure – Clinical Research – IMP Destruction [DRAFT]
11. SCHN Procedure- Clinical Research – IMP Transit and Transfer [DRAFT]
12. SCHN Procedure – Clinical Research - Personnel Qualifications and Training Records [DRAFT]
13. SCHN Procedure - Clinical Research – Personnel Roles and Responsibilities [DRAFT]
14. SCHN Procedure – Clinical Research - Record Keeping [DRAFT]
15. SCHN Procedure – Clinical Research – Trial Master File [DRAFT]
16. SCHN Procedure - Clinical Research – Use of Electronic Signatures [DRAFT]
17. State Records NSW – Disposal Authorities and Guidelines (GDA17) - https://www.records.nsw.gov.au/recordkeeping/rules/gdas/gda17
18. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf