CLINICAL RESEARCH - ACCESS TO ELECTRONIC HEALTHCARE RECORDS FOR INSPECTION PURPOSES

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to outline the process by which clinical research monitors, auditors and other authorised parties are provided with view only access to the SCHN eMR for inspection purposes in accordance with NSW Health, SCHN and regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in conduct of clinical research involving the use of the SCHN electronic Medical Record (eMR).

CHANGE SUMMARY

- Document due for mandatory review with minor changes made throughout.

READ ACKNOWLEDGEMENT

- Read/Acknowledge Only – Personnel involved in the conduct of clinical research involving the use of the SCHN electronic Medical Record (eMR).

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st May 2022	**Review Period**: 3 years
Team Leader:	Clinical Research Manager	**Area/Dept**: Kids Research

Purpose/Scope

The purpose of this procedure is to outline the process by which clinical research monitors, auditors and other authorised parties are provided with view only access to the SCHN eMR for inspection purposes in accordance with NSW Health, SCHN and regulatory and protocol requirements.

This procedure must be followed by all personnel involved in the conduct of clinical research involving the use of the SCHN eMR.

Background

In a clinical research context, inspection involves clinical research records being made available to authorised parties for the purpose of overseeing the progress of clinical research and verifying compliance with the protocol and all applicable regulatory requirements.

As per the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Section 4.1.4, the Investigator/Institution must allow inspecting parties to have direct access to clinical research records, including electronic health records.

The written informed consent of each clinical research participant for the issuing of direct access to health records, to the extent permitted by the applicable laws and regulations, must be obtained prior to access being granted to inspecting parties.

Procedure

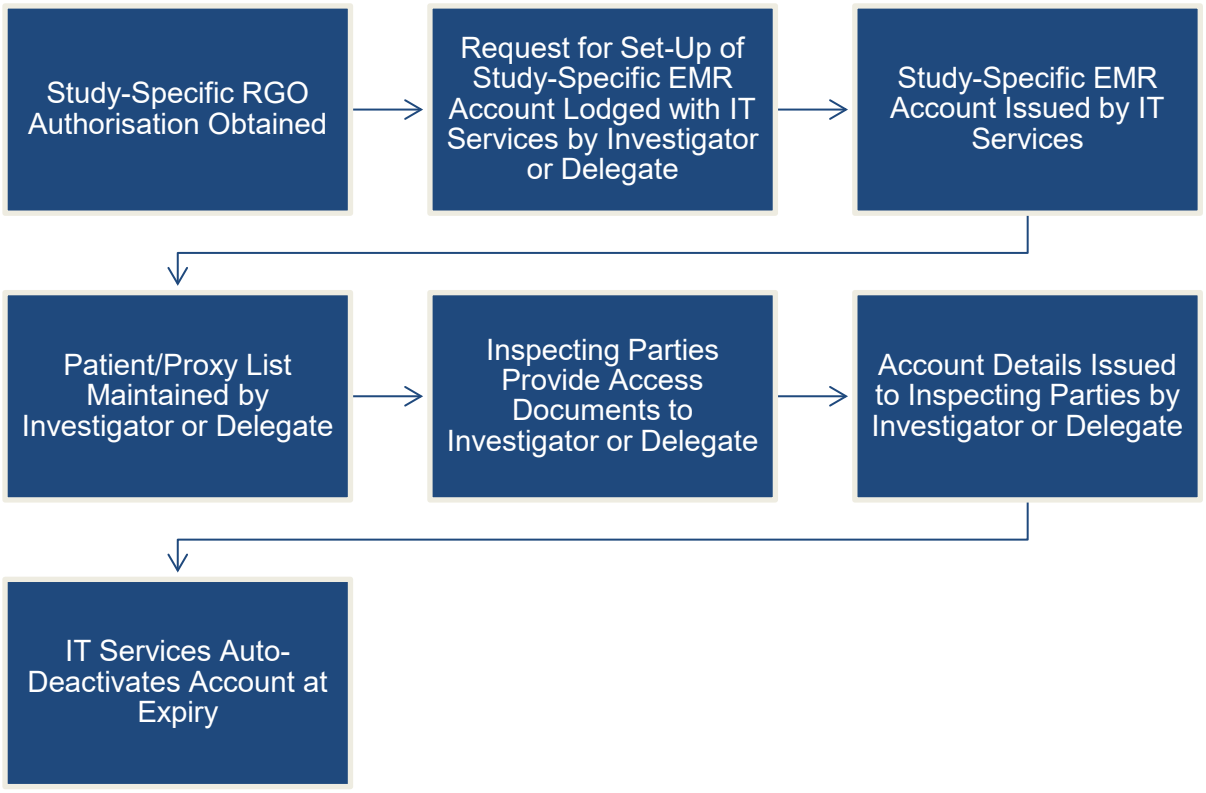
Establishment

- A study-specific eMR account(s) for the purpose of inspection by authorised parties may be requested by the Investigator or Delegate via IT Services;
- To establish a study-specific eMR account(s) the following details must be provided to IT Services:
  - Protocol Number
  - Protocol Full Title
  - Estimated Expiry Date (i.e.: 3 Months Post COV)
  - Copy of the Initial RGO Authorisation Letter
- IT Services will establish the study-specific, restricted access, eMR account(s) with a unique username (e.g. Protocol Number), password and expiry date;
- IT Services will provide the Investigator or Delegate with the details of the study-specific eMR account(s);
- The details of the study-specific eMR account(s), as well as any corresponding documentation must be filed centrally in a secure location by the Investigator or Delegate.

Management

- The Investigator or Delegate is responsible for ensuring that the study-specific eMR account patient/proxy list is maintained through the:
  - Addition of clinical research participants once written informed consent has been provided;
  - Removal of participants who have withdrawn consent for access (if/as permitted in accordance with the Participant Information Sheet and Consent Form(s));
- Inspecting Parties requiring access must complete and return the SCHN IT Access Form and NSW Health Code of Conduct prior to being provided with the details of any study-specific eMR account(s) by the Investigator or Delegate;
- The signed SCHN IT Access Form and NSW Health Code of Conduct, as well as any corresponding documentation must be filed centrally in a secure location by the Investigator or Delegate;
- In the event of a change to the estimated end date for the Protocol, the Investigator or Delegate is responsible for ensuring that IT Services is notified in order to update the expiry date on the account;
- IT Services need to be contacted to will ensure that the account is deactivated in accordance with the nominated expiry date.

Flow Chart



Abbreviations and Definitions

COV	Close-Out Visit
eMR	Electronic Medical Record
ICH	International Conference on Harmonisation
IT	Information Technology
GCP	Good Clinical Practice
HIU	Health Information Unit
NSW	New South Wales
PD	Policy Directive
RGO	Research Governance Office
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration

Related Documents

1. National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 - https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018
2. NSW Health PD2015_049 – NSW Health Code of Conduct - https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2015_049
3. SCHN –Learning.Kids - Sharing Patient List via Proxy - https://learning.schn.health.nsw.gov.au/sharing-patient-list-proxy
4. SCHN Policy – Clinical Research [DRAFT]
5. SCHN Policy 2014-9045 – Healthcare Records Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3274
6. SCHN Policy 2013-9048 – Healthcare Records – Documentation and Management – http://webapps.schn.health.nsw.gov.au/epolicy/policy/3004/
7. SCHN Procedure 2019-145 – Clinical Research - Record Keeping - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661
8. SCHN Procedure 2019-026 – Clinical Research – Trial Master File - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4698
9. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf