CLINICAL RESEARCH - REVIEW OF MEDICAL RESULTS

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that all medical results for clinical research are reviewed by the Investigator to ensure the safety of clinical research participants, adherence with the protocol and compliance with applicable NSW Health, SCHN and regulatory regulations.
- The procedure must be followed by all personnel involved in the conduct of clinical research involving medical results.

CHANGE SUMMARY

- Document due for mandatory review

READ ACKNOWLEDGEMENT

- Read/Acknowledge Only –Personnel involved in the conduct of clinical research involving medical results.

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

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Purpose/Scope

The purpose of this procedure is to ensure that all medical tests conducted for clinical research purposes are reviewed by the Investigator to ensure the safety of clinical research participants, adherence with the protocol and compliance with applicable NSW Health, SCHN and regulatory regulations.

This procedure applies to all clinical research conducted within SCHN where the Investigator is responsible for reviewing medical test results to ensure clinical research participant safety and care, as per the protocol.

This procedure applies regardless of whether such tests are performed at SCHN or by external agencies, such as central laboratories.

Adherence to this procedure will ensure that:

- Investigators promptly receive and review medical test results for clinical research participants under their care;
- Investigators promptly act to review, escalate, respond and document any decisions made or actions taken, as a result of the review of medical tests to ensure the safety of clinical research participant under their care (as appropriate); and
- Investigators respond in compliance with the requirements of the protocol (as applicable) and regulatory approvals, except when necessary to eliminate immediate hazards to the participant as per ICH GCP Section 3.3.7.

The procedure must be followed by all personnel involved in the conduct of clinical research involving medical results.

Background

As per the TGA Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6(R2) Section 4.3 ‘Medical Care of Subjects’, the Investigator retains responsibility at all times for:

- All clinical research related medical decisions;
- Ensuring that adequate medical care is provided for any adverse event, including clinically significant laboratory values;
- Ensuring the clinical research participant is made aware of any intercurrent illness(es) of which the Investigator becomes cognisant of during the course of participation (if appropriate);
- Ensuring the clinical research participants general practitioner or equivalent is aware of the participants involvement in the study to ensure prompt notification of adverse events (as appropriate);

The Investigator must not delegate responsibility for any of the above tasks, at any time, to personnel who are not duly qualified and trained physicians performing the role of an Investigator for the clinical research.

Procedure

- The Investigator will remain aware of all medical tests required to be performed per protocol, as well as those necessary to be performed to eliminate immediate hazards to the participant under ICH GCP Section 3.3.7;
- Medical test results will be made available to the Investigator as per the means specified in the protocol by the Sponsor or Delegate or equivalent (e.g. Source document agreement);
- All medical tests results must be promptly reviewed by the Investigator or a duly qualified and trained physician performing the role of Sub-Investigator;
- The Investigator will initial and date all medical test results as evidence of their review and annotate any test results outside of the clinically acceptable range (as per protocol or the documented lab reference ranges) as 'Not Clinically Significant' (NCS) or 'Clinically Significant' (CS);
- If the Investigator identifies an immediate hazard to the participant through review of medical test results, they must act immediately to ensure the safety of the clinical research participant, but otherwise should respond in accordance with the requirements of the protocol (as applicable);
- The Investigator is responsible for escalating any clinical scenarios dictated by the protocol as reportable to the Sponsor or Delegate's nominated medical representative (e.g. Medical Monitor or equivalent) within the required timeframes (as applicable);
- The Investigator is responsible for advising clinical research personnel of any decision, action and follow-up to be taken in response to the review of medical test results;
- The Investigator is responsible for reporting any Significant Safety Issue (SSI) or Urgent Safety Measure (USM) to the Sponsor, as per the protocol, and other relevant Parties as per current guidelines, including the NSW Health PD2017_039 - Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations;
- Any 'Clinical Significant' (CS) medical test results which occur should be considered as a possible Adverse Event (AE) and followed up until resolution, or for the period of time specified by the protocol;
- Any additional medical tests performed (e.g. as part of follow-up) must be filed as part of the Investigator Site File for the clinical research. The Sponsor or Delegate will determine whether such results will be included in the reportable data set for the clinical research.

Abbreviations and Definitions

AE	Adverse event
CS	Clinically significant
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
Medical Test	A medical assessment or procedure performed to detect, diagnose, or monitor diseases, disease processes, susceptibility, and determine a course of treatment.
NCS	Not clinically significant
NSW	New South Wales
OHMR	Office of Health and Medical Research
SCHN	Sydney Children's Hospitals Network
SSI	Significant Safety Issue
TGA	Therapeutic Goods Administration
USM	Urgent Safety Measure

Related Documents

1. NSW Health PD2017_039 - Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_039.pdf
2. Office of Health and Medical Research - Clinical Trial Monitoring and Safety - https://www.medicalresearch.nsw.gov.au/clinical-trial-safety-monitoring/
3. SCHN Policy – Clinical Research [DRAFT]
4. SCHN Procedure 2019-027 – Clinical Research - Personnel Qualifications and Training Records – http://webapps.schn.health.nsw.gov.au/epolicy/policy/4623
5. SCHN Procedure 2019-028 - Clinical Research - Personnel Roles and Responsibilities - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4624
6. SCHN Procedure 2019-145– Clinical Research - Record Keeping - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661
7. SCHN Procedure 2012-9061 - Safety Reporting For Clinical Trials - http://webapps.schn.health.nsw.gov.au/epolicy/policy/1543
8. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf