CLINICAL RESEARCH - USE OF LABORATORY FACILITIES

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this policy is to ensure that best practices are applied in any use of laboratory facilities for clinical research.
- The policy must be followed by all personnel involved in the use of laboratory facilities for clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Personnel involved in the use of laboratory facilities 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 policy is to ensure that laboratory facilities are used in compliance with best practice guidelines, NSW Health, SCHN, regulatory and protocol requirements.

This policy does not apply to the use of NATA-accredited pathology laboratories, whether for research or standard clinical care purposes.

Adherence to this policy will ensure that:

- Investigators or Delegates use laboratory facilities that are fit for purpose with consideration of protocol-specific requirements dictated by the Sponsor or Delegate, and in accordance with local risk-assessments;
- Laboratory facilities and equipment are used in a safe, equitable and compliant manner; and
- Any data garnered from the performance of pre-analytical laboratory tasks is reliable and credible.

The policy must be followed by all personnel involved in the use of laboratory facilities for clinical research.

Background

Clinical research often requires the use of laboratory facilities for the performance of a variety of tasks. The improper use of laboratory facilities can pose a risk to the user, others and the surroundings, as well as impact on the integrity and validity of data obtained.

In accordance with the TGA Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95):

- Systems with procedures that assure the quality of every aspect of clinical research should be implemented (Section 2.13);
- Essential documents must be maintained to demonstrate the competence of facilities used to perform required test(s) and support the reliability of data (Section 8.2.12 and 8.3.7).

The following topics are outside the scope of this policy and associated procedures:

- Blood and blood products for transfusion;

- Transport of medical waste; and
- Requirements for the handling genetically modified organisms (GMOs).

Policy

The Investigator or Delegate remains responsible for ensuring:

- All instructions or other guidance related to the use of laboratory facilities for clinical research are clearly defined and agreed with the Sponsor or Delegate prior to the commencement of the clinical research;
- The instructions and processes for key activities pertinent to the use of laboratory facilities (including bio specimen handling) are detailed in either the protocol or a standalone document such as a laboratory manual;
- The appropriate type of laboratory facility is used to ensure a high standard of safety and compliance, with consideration of requirements for access to specialised equipment, accreditation status, physical containment and /or proximity to patient care and/or processing areas;
- Any use of laboratory facilities for clinical research purposes must be discussed with and approved by the responsible Head of Department or Delegate prior to commencement;
- Any duties or tasks for clinical research are performed in compliance with all NSW Health, SCHN, regulatory and protocol requirements, as well as any local work instructions or procedures applicable to the laboratory facility being accessed;
- All personnel delegated to perform laboratory tasks or duties have received orientation and training, and operate under their supervision in accordance with the SCHN Procedure – Personnel Qualifications and Training Records and SCHN Procedure - Personnel Roles and Responsibilities [DRAFT];
- All clinical research personnel operating under their supervision have received orientation, as applicable, via the responsible Head of Department or Delegate, in relation to:
    - The appropriate use of PPE;
    - Procedure for evacuation;
    - Location of emergency exits, fire extinguishers, eye wash stations and showers;
    - Waste management; and
    - The management and reporting of incidents (including spills).

Abbreviations and Definitions

ICH	International Conference on Harmonisation
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
NATA	National Association of Testing Authorities
NSW	New South Wales
PD	Policy Directive
PPE	Personal Protective Equipment
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration

Related Documents

1. NSW Health PD2017_026 - Clinical and Related Waste Management for Health Services - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_026.pdf
2. NSW Health PD2014_004 - Incident Management Policy - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2014_004.pdf
3. NSW Health PD2017_013 - Infection Prevention and Control Policy - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_013.pdf
4. NSW Health PD2007_052 - Sharps Injuries - Prevention in the NSW Public Health System - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2007_052.pdf
5. SCHN Practice Guideline 2016-9029 - Personal Protective Equipment for Infection Control - http://webapps.schn.health.nsw.gov.au/epolicy/policy/2609
6. SCHN Policy – Clinical Research [DRAFT]
7. SCHN Policy 2013-9044 - Incident Management Policy - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3033
8. SCHN Policy 2014-9061 - Sharps Injuries - Prevention in the NSW Public Health System - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3295
9. SCHN Policy 2015-9070 – Waste Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3649/download
10. SCHN Procedure – Clinical Research - Bio Specimen Collection, Processing and Shipment [DRAFT]
11. SCHN Procedure – Clinical Research - Equipment and Supplies – Maintenance and Calibration [DRAFT]
12. SCHN Procedure – Clinical Research - Equipment and Supplies - Receipt and Storage [DRAFT]
13. SCHN Procedure - Clinical Research - Personnel Qualifications and Training Records [DRAFT]
14. SCHN Procedure - Clinical Research - Personnel Roles and Responsibilities [DRAFT]
15. SCHN Procedure - Clinical Research - Record Keeping [DRAFT]
16. SCHN Procedure – Clinical Research - Storage of Chemicals [DRAFT]]
17. SCHN Procedure – Clinical Research - Use of Biological Safety Cabinet [DRAFT]
18. SCHN Procedure – Clinical Research - Use of Centrifuge) [DRAFT]
19. SCHN Procedure – Clinical Research - Use of Dry Ice [DRAFT]
20. SCHN Procedure – Clinical Research - Use of Fridges and Freezer [DRAFT]
21. SCHN Procedure – Clinical Research - Use of Fume Hood
22. SCHN Procedure – Clinical Research - Use of Liquid Nitrogen [DRAFT]
23. SCHN Procedure – Clinical Research - Use of Mass Spectrometer [DRAFT]
24. SCHN Procedure 2006-8324 – Incident Management - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3795

25. TGA - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) - https://www.tga.gov.au/sites/default/files/ich13595an.pdf