CLINICAL RESEARCH - BIO SPECIMEN COLLECTION, PROCESSING AND SHIPPING

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to ensure that bio specimens for clinical research are collected, processed and shipped in compliance with NSW Health, SCHN, regulatory and protocol requirements.
- The procedure must be followed by all personnel involved in the collection, processing and shipping of bio specimens for clinical research.

CHANGE SUMMARY

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

READ ACKNOWLEDGEMENT

- Training/Assessment Required – Personnel involved in the collection, processing and shipping of bio specimens 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 bio specimens for clinical research are collected, processed and shipped in compliance with NSW Health, SCHN, regulatory and protocol requirements.

This procedure does not apply to the processing and shipment of bio specimens, whether for research or standard clinical care purposes via NATA-accredited pathology laboratories. These laboratories will use their own local policies/procedures for performing any delegated tasks.

Adherence to this procedure will ensure that:

- Bio specimens are collected, processed and shipped in a safe and compliant manner;
- All samples are maintained under suitable conditions during processing and shipment; and
- Appropriate records detailing the chain of custody for bio specimens are maintained at all times.

The procedure must be followed by all personnel involved in the collection, processing and shipping of bio specimens for clinical research.

Background

This procedure provides the requirements for the collection, processing and shipping of bio specimens from the point of first collection to the laboratory where analysis is performed.

The use of the appropriate collection, processing and shipping methodologies is critical to ensuring the clinical care and participant safety risks associated with clinical procedures are reduced, the integrity of bio specimens are maintained and the safety of clinical research personnel is preserved.

The overall classification scheme for hazards associated with the shipment of bio specimens referenced in this procedure is derived from the IATA DGRs. The DGRs detail the specific packaging requirements for the surface transport of infectious substances deemed to be Category A, Category B and/or Dangerous Goods.

The Investigator or Delegate' must apply their professional judgement and also consult with clinical research personnel holding Safe Transport of Dangerous Goods certification in relation to the appropriate methodology for the shipment of bio specimens or associated substances, to ensure compliance with the DGRs, where necessary.

It is recommended that the Investigator assigns some or all duties relating to the collection, processing and shipment of bio specimens for clinical research to appropriately qualified and trained personnel operating under their supervision, in accordance with the SCHN Procedure – Clinical Research – Personnel Roles and Responsibilities [DRAFT].

Procedure

- A chain of custody that enables bio specimens to be tracked from the point of collection to analysis, storage or disposal (as applicable) must be maintained by the Investigator or Delegate at all times;
- Such records are to be completed in accordance with the protocol-specific instructions provided by the Sponsor or Delegate and in compliance with the SCHN Procedure – Clinical Research - Record Keeping [DRAFT];
- The Bio Specimen Log (Appendix) is recommended for adaptation in the absence of protocol-specific instructions being provided by the Sponsor or Delegate;
- Original records related to the chain of custody for bio specimens, including supporting documentation such as requisitions and packaging slips, must be filed in the ISF.

Collection

- Procedures for bio specimen collection must be performed in accordance with the SCHN Policy 2016-9052 – Clinical Procedure Safety and in compliance with the protocol or equivalent (e.g. Lab manual) provided by the Sponsor or Delegate;
- Significant deviations to standard practices for bio specimen collection mandated by the protocol, must be approved by the responsible NUM or Delegate (as applicable) prior to commencement of clinical research;
- Where the collection of bio specimens for clinical research purposes occurs in parallel with collection for standard clinical care purposes, the Investigator or Delegate is responsible for ensuring safe practices are upheld at all times (e.g. limits on the cumulative volume of blood to be drawn, and/or the order of blood draws);
- Procedures to enable bio specimen collection for clinical research purposes must only be performed after valid, informed consent has been provided in accordance with the SCHN Procedure 2016-9002 - Consent to Participate in Human Research – Participant Information and Consent;
- The Investigator or Delegate must ensure the participant is also fully informed of any specific requirements with regard to fasting, diet and/or medication restrictions, in advance of the collection occasion;
- Bio specimen collection vessels (e.g. tubes, receptacles) should be individually labelled immediately after the bio specimen collection procedure(s) at the point of collection e.g. bedside.
- The person labelling the collection vessels must be physically present during the bio specimen collection and the labelling must occur in the presence of the clinical research participant;
- Labels should follow the protocol-specific requirements and if these are not defined are recommended to include the protocol reference, participant ID, visit, date of collection, time of collection, collector’s initials, and test(s) and/or laboratory requisition reference;

- No identifiable information, including name or MRN, should be recorded on the label for any bio specimen vessels intended to be stored and/or shipped to a central (non-SCHN) laboratory for analysis for clinical research purposes unless the Sponsor or Delegate has obtained HREC approval and RGO authorisation to do so;
- Where clinical research participants are required to collect their own bio specimens, clear instructions and/or guidance must be provided by the Investigator or Delegate, and appropriate collection containers and packaging provided to reduce the risk of exposure and/or contamination;
- Any waste generated during collection must be discarded in the clinical waste receptacle and/or sharps bin provided (as appropriate);

Processing

- Bio specimens must be processed (e.g. centrifugation, aliquoting, preparation of slides, storage) according to the instructions detailed in the protocol or equivalent (e.g. Lab manual);
- If it is not possible for bio specimens to be processed immediately after collection, samples must be held in a secure location under appropriate conditions;
- Bio specimens that have undergone centrifugation must be placed in a suitable tube rack (or on ice, as required);
- After centrifugation, bio specimens should be transferred to an appropriately labelled aliquot or transfer tubes, as per protocol. Care should be taken to ensure that only one specimen is labelled and aliquoted at a time before moving on to the next. Care should also be taken to ensure that the label on the aliquot or transfer tube exactly matches that of the original collection vessel.
- An appropriate pipette must be used for the transfer of any bio specimen components into the aliquot(s), noting that if a Gilson pipette or similar system is used, the dial should be set to the correct amount of fluid to be pipetted and a fresh pastette (or pipette tip) used for each sample. Mouth pipetting is not permitted;
- If any deviation to the instructions detailed in the protocol or equivalent (e.g. Lab manual) occurs, the Investigator or Delegate must ensure that the nature of the deviations are appropriately documented and/or reported to the Sponsor or Delegate, as required;
- Any waste generated during processing must be discarded in the Clinical waste receptacle and/or sharps bin provided (as appropriate);

Storage

- Dedicated areas, including fridges and freezers, with appropriate security and temperature monitoring provisions will be made available for bio specimen storage;
- Under no circumstances will bio specimens be stored in locations used for the storage of food and beverages and/or pharmaceuticals;

- Space for the storage of bio specimens for clinical research in the Clinical Research Centre will be allocated at the project assessment stage via the SCHN CRC Operations Committee;
- Space for the storage of bio specimens outside of the Clinical Research Centre or in addition to previously allocated space(s), must be sought via the responsible Head of Department or Delegate prior to any placement of the item(s);
- The details of the bio specimen(s), as well as their approved, specific storage location must be recorded in accordance with the protocol-specific instructions of the Sponsor or Delegate or equivalent;
- The prompt dispatch of bio specimens from storage is recommended, with reference to the maximum allowable storage time in the protocol or equivalent, to ensure the equitable use of shared equipment for clinical research purposes;

Shipping

- In the context of this procedure, shipping is defined as the temporary or permanent transfer or transport of bio specimens (individually or in batches) for clinical research purposes to the laboratory where the bio specimens are to be stored and/or analysis performed;
- Where bio specimens are sent to an external organisation for storage or analysis(ses) the RGO is consulted for advice with regards to the nature of any Agreement(s) required;
- The transport of Bio specimens to or from NATA-accredited pathology laboratories must comply with the requirements of the NSW Health PD2018_020 - Transport of Pathology Specimens to Laboratories, in addition to the requirements of this procedure;
- The Investigator or Delegate retains responsibility for ensuring that bio specimens for clinical research are packaged and shipped in accordance with all applicable NSW Health, SCHN, regulatory and protocol (or equivalent) requirements including IATA DGRs (if applicable);
- Clinical research personnel involved in the shipping of bio specimens may be required to hold current certification demonstration completion of an IATA approved, CASA certified Dangerous Goods Packaging course for Group F Employees [CASR Part 92.135-1);
- Any certifications must be maintained and filed in accordance with the SCHN Procedure - Clinical Research - Personnel Qualifications and Training Records [DRAFT];
- Consideration should be given to the optimal storage conditions for the bio specimens, the transfer destination, any service disruptions (e.g. couriers, laboratories), as well as any additional safety requirements related to the presence of other hazards (e.g. chemicals, dry ice) through reference to the applicable SDS;
- A laboratory requisition(s) or equivalent documentation, with details corresponding to the labels applied to the bio specimens, must be included with each shipment;

- Any documentation, warnings or labels required should be visible and/or accessible without the transporter or operator needing to open the package;
- Packages being sent to or from overseas may require additional documentation relating to customers and/or quarantine to be included as per the current guidance of the Australian Government Department of Agriculture and Water Resources;
- It is recommended that the Investigator or Delegate requests an acknowledgement of receipt or equivalent to ensure that the shipment is delivered to its destination.

Appendices

Bio Specimen Log

Abbreviations and Definitions

Bio Specimen	Specimens that are collected directly from humans (including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts) that are transported for purposes such as research, diagnosis, investigations, disease treatment and prevention.
CAA	Civil Aviation Act
CASA	Civil Aviation Safety Authority (Australia)
CASR	Civil Aviation Safety Regulations
Category A	An infectious substance which in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals (UN 2814 Infectious substance affecting humans).
Category B	An infectious substance which does not meet the criteria for inclusion in Category A. Most human or animal material ('participant bio specimens') including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts, being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention (UN 3373 Biological Substance, Category B).
Chain of Custody	A series of procedures to account for the integrity of each bio specimen by tracking its processing and storage from point of collection to final disposal.
Dangerous Goods	Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the IATA DGRs or which are classified according to the IATA DGRs.

DGRs	Dangerous Goods Regulations
GMO	Genetically Modified Organism
IATA	International Air Transport Association
ICAO	International Civil Aviation Organisation
ISF	Investigator Site File
MRN	Medical Record Number
NATA	National Association of Testing Authorities
NSW	New South Wales
NUM	Nurse Unit Manager
Outer Packaging	The outer protection of a combination packaging together with absorbent materials, cushioning and any other components necessary to contain and protect the primary receptacle and secondary packaging and make it capable of withstanding the rigours of transport.
PD	Policy Directive
Primary Receptacle	A receptacle in contact with the material (bio specimen) to be transported.
RGO	Research Governance Office
SCHN	Sydney Children's Hospitals Network
SDS	Safety Data Sheet
Secondary Packaging	Leak-proof packaging that provides additional protection for the primary receptacle(s); it may include absorbent material.
TGA	Therapeutic Goods Administration

Related Documents

1. Australian Government Department of Agriculture and Water Resources;- http://www.agriculture.gov.au/biosecurity
2. Civil Aviation Act 1988 - https://www.legislation.gov.au/Details/C2016C01097
3. Civil Aviation Safety Regulations 1998 - https://www.casa.gov.au/rules-and-regulations/standard-page/casr-regulatory-structure
4. International Air Transport Association - Dangerous Goods Regulations - https://www.iata.org/publications/dgr/Pages/index.aspx
5. International Civil Aviation Organisation - Technical Instructions for the Safe Transport of Dangerous Goods by Air - https://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.aspx
6. Human Tissue Act 1983 - http://www8.austlii.edu.au/cgi-bin/viewdb/au/legis/nsw/consol_act/hta1983160/
7. NSW Health PD2017_032 – Clinical Procedure Safety - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_032.pdf
8. NSW Health PD2017_013 - Infection Prevention and Control Policy - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_013.pdf
9. NSW Health PD2018_020 - Transport of Pathology Specimens to Laboratories - https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2018_020.pdf

10. SCHN Policy 2016-9052 - Clinical Procedure Safety - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3791
11. SCHN Policy – Clinical Research [DRAFT]
12. SCHN Policy – Clinical Research – Use of Laboratory Facilities [DRAFT]
13. SCHN Practice Guideline 2016-9029 - Personal Protective Equipment for Infection Control - http://webapps.schn.health.nsw.gov.au/epolicy/policy/2609
14. SCHN Procedure - Clinical Research - Equipment and/or Supplies – Maintenance and Calibration [DRAFT]
15. SCHN Procedure - Clinical Research - Equipment and/or Supplies - Receipt and Storage [DRAFT]
16. SCHN Procedure – Clinical Research - Personnel Qualifications and Training Records – [DRAFT]
17. SCHN Procedure - Clinical Research – Personnel Roles and Responsibilities [DRAFT]
18. SCHN Procedure – Clinical Research - Storage of Chemicals
19. SCHN Procedure – Clinical Research - Use of Biological Safety Cabinet [DRAFT]
20. SCHN Procedure – Clinical Research – Use of Centrifuge [DRAFT]
21. SCHN Procedure – Clinical Research - Use of Dry Ice [DRAFT]
22. SCHN Procedure – Clinical Research – Use of Fridges and Freezer
23. SCHN Procedure – Clinical Research - Use of Fume Hood [DRAFT]
24. SCHN Procedure – Clinical Research - Use of Liquid Nitrogen [DRAFT]
25. SCHN Procedure 2016-9002 - Consent to Participate in Human Research – Participant Information and Consent - http://webapps.schn.health.nsw.gov.au/epolicy/policy/3666
26. SCHN Procedure 2013-9077 - Intravenous Cannulation and Venepuncture - http://webapps.schn.health.nsw.gov.au/epolicy/policy/2993