Transfer of Biospecimens and Trial-related Laboratory Materials between Primary and Satellite Site(s) Guideline

Purpose

This guideline provides direction on the transfer of biospecimens and associated trial-related laboratory materials between a Primary site and one or more Satellite Sites participating in a Teletrial Cluster in line with an approved Supervision Plan. It applies only to transfer processes and does not cover the collection or processing of samples.

Materials covered include diagnostic kits, processed and unprocessed specimens, pathology sub-samples, temperature-sensitive media, and other laboratory items used in clinical trials.

This purpose is to ensure appropriate procedures for ordering, receiving, storing, and issuing and tracking kits, as well as monitoring expiry dates and ensuring correct handling across all jurisdictions nationally.

These measures minimise the risk of invalid samples, ensure staff safety, and maintain the integrity of study data.

All specimen handling must comply with:

- Jurisdictional legislative Standard Operating Procedures (SOPs)
- International Council on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines
- Good Laboratory Practice (GLP)
- Therapeutic Goods Administration (TGA) requirements
- Relevant research governance frameworks
- International Air Transport Association (IATA) requirements, with jurisdictionally approved IATA training for relevant personnel
- Good Manufacturing Practice (GMP), where applicable
- Protocol requirements and laboratory manuals.

Scope and Limitations

This guideline **does not apply to**:

- Biospecimen transfers arranged directly by the sponsor to a laboratory site.
- Materials managed through a third-party vendor external to pathology services.
- Activities requiring relabelling under GMP or TGA manufacturing standards.

Roles and Responsibilities

Wherever possible, guidance can be given by Regional Clinical Coordinating Centre (RCCC) or equivalent staff in the respective jurisdictional regions.

Primary Site – Pathology Services

- Lead development of the supervision plan in relation to transfer of samples and materials which may include approved quotations, laboratory declaration and SOPs with stakeholders.
- Maintain accountability logs and documentation (e.g. tracking, temperature logs)
- Coordinate dispatch, packaging, and courier handover for all trial-related materials.
- Provide protocol-specific training and oversight to satellite site staff (e.g. sample processing).
- Ensure compliance with storage and handling protocols, including cold chain management.
- Maintain appropriate records and chain of custody documentation.

Satellite Site – Pathology Services

- Participate in development and endorsement of the supervision plan
- Receive, log, and store biospecimens and materials in validated storage environments.
- Return unused or processed specimens according to protocol.
- Assist with collection kit setup, data entry, or document control, if required (subject to approval and additional costs).
- Maintain local records and temperature monitoring logs.

Clinical Trial Coordinator / Principal Investigator (or delegated staff)

- Notify both sites of pending shipments and collection requirements.
- Ensure all movement of materials is reflected in ethics/governance and SOPs.
- Maintain oversight and accountability, with responsibilities able to be delegated to appropriately trained staff.
- Ensure delegated staff have relevant qualifications and training.

Sponsor

- Provide trial-specific materials (e.g. kits, documentation)
- Support development of the Teletrial process across participating Pathology Services
- Approve any destruction of unused materials, if required.

Packaging and Handling

All samples and materials must be packaged and handled as follows:

- IATA trained staff follow proper handling procedures to prevent damage or contamination.
- Maintain appropriate humidity levels to prevent degradation of samples.
- Ensure that containers are properly sealed and labelled to prevent contamination and loss.
- Regularly inspect kits for signs of damage or degradation.
- Implement quality control procedures to verify the integrity of kits and samples whilst in storage.
- Ensure staff safety procedures are followed during all handling activities.

Logistics and Accountability

All transfers must be:

- Documented through a Laboratory Information System (LIS) sample tracking.
- Shipped using validated packaging, when applicable (e.g. cold chain, where applicable).
- Escalated immediately if there is evidence of damage, delay, or non-conformance.

The approved laboratory processes should include:

- Booking responsibilities (e.g. which site contacts courier).
- Responsibilities for storage, use, and return.
- Issue management processes.
- Oversight and audit procedures.

Returns and Disposal

Returned materials (e.g. unused kits, remaining biospecimens) must:

- Be checked for condition and completeness.
- Be documented using standard pathology service processes.
- Only be destroyed with written sponsor approval.

All destruction must comply with:

- Pathology services Waste Disposal Guidelines.
- Ethical and research governance frameworks.
- TGA requirements (if applicable).

Operational Workflow

1. Notification

The Clinical Research Coordinator (CRC) or site coordinator notifies the Primary and Satellite Sites about any upcoming transfer of biospecimens and samples with a clear realistic window of timing. E.g. notify the day before/at least 3 hours before shipment etc.

2. Courier selection

Check courier capabilities. E.g. dry ice controlled ambient collections etc. and make a booking.

3. Preparation

The Primary or Satellite Site prepares the biospecimens and samples and /or necessary materials, logs all items, verifies their condition and entered LIS.

4. Sample collection

Where applicable, samples and or biospecimens from participants are collected and stored following the relevant clinical trial procedures.

5. Packaging

The Primary Site or Satellite site packages the necessary materials as per required processes.

6. Dispatch

Materials and /or samples are collected by the courier, tracking and temperature monitoring is initiated, relevant contacts are then notified.

7. Receipt

The Primary or Satellite Site receives the courier delivery, checks the contents and temperature, and completes the necessary documentation or updates in LIS or equivalent.

8. Use and Monitoring

The samples and materials are handled according to protocol. Storage logs and usage documentation are maintained throughout the process.

9. Return or Disposal

Unused items are either returned to the Primary Site or retained and disposed of according to the sponsor's instructions.

10. Documentation

Both sites are required to complete documentation related to the dispatch and handling of samples and materials. The original documents are held at the Satellite Site, with copies provided to the Primary Site or distributed according to an approved plan.

Appendix 1. Booking Request Form

Account no:

Trial / Protocol Name:

Complete the form below, then forward by email to the relevant supplier by email.

<table>
<tr><th colspan="3">Pickup Address</th><th colspan="3">Delivery Address</th></tr>
<tr><td colspan="3">Company name</td><td colspan="3">Company name</td></tr>
<tr><td colspan="3">Street address</td><td colspan="3">Street address</td></tr>
<tr><td>City</td><td>State</td><td>Post Code</td><td>City</td><td>State</td><td>Post Code</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Contact person</td><td colspan="2">Phone number</td><td>Contact person</td><td colspan="2">Phone number</td></tr>
<tr><td></td><td colspan="2"></td><td></td><td colspan="2"></td></tr>
<tr><td colspan="3">Email Address</td><td colspan="3">Email Address</td></tr>
<tr><td colspan="3">Ready Time and Date</td><td colspan="3">Delivery Deadline (time and date)</td></tr>
<tr><th colspan="3">Shipment Details</th><th colspan="3">Special Requirements</th></tr>
<tr><td colspan="3">Description of contents</td><td colspan="3">To be supplied by courier at time of collection:
☐ Thermal Packaging ☐ Temperature Monitor</td></tr>
<tr><td colspan="3">Shipping temperature:
☐ Frozen -80°C ☐ Refrigerated +2°C to +8°C ☐ Ambient</td><td colspan="3">☐ Dry Ice ☐ Gel packs ☐ Other:
Special instructions for this shipment:</td></tr>
<tr><td colspan="3">Number of pieces:
Total Weight:</td><td colspan="3" rowspan="3"></td></tr>
<tr><td colspan="3">Shipment Value</td></tr>
<tr><td colspan="3">Dimensions of package/s (in centimeters (length, width, height))</td></tr>
</table>

Appendix 2. Checklist

Category	Information Required	Checked	
Trial Identification	Full Trial / Protocol Title	☐	☐ NA
	Protocol Version and Date	☐	☐ NA
	Trial Sponsor Name and Contact Details	☐	☐ NA
	Principal Investigator(s) at Primary and Satellite Sites	☐	☐ NA
Site Details	Primary Site Address and Contact Person	☐	☐ NA
	Satellite Site Address and Contact Person	☐	☐ NA
	Approved Supervision Plan (including sample responsibilities and training)	☐	☐ NA
Ethics & Governance	HREC Approval Letter and Site Authorisation Letters (Primary and Satellite)	☐	☐ NA
	Inclusion of transfer procedures in site-specific SOPs	☐	☐ NA
Specimen Details	List of specimen types to be transferred (e.g. blood, tissue, slides)	☐	☐ NA
	Processing and handling requirements (e.g. timeframes, centrifugation)	☐	☐ NA
	Required storage conditions (e.g. -80°C, 2-8°C, ambient)	☐	☐ NA
	Details of any temperature monitoring/logging requirements	☐	☐ NA
Kit Information	Kit type(s) required and quantities	☐	☐ NA
	Kit expiry dates and version control (where applicable)	☐	☐ NA
	Shipping materials needed (e.g. dry ice, validated packaging)	☐	☐ NA
Courier & Logistics	Courier providers contact details and capabilities (e.g. frozen transport)	☐	☐ NA
	Estimated shipment schedule or required pickup windows	☐	☐ NA
	Tracking number and confirmation of handover	☐	☐ NA
Training & Competency	IATA Certification status of shipping personnel	☐	☐ NA
	Record of sample-handling or trial-specific training for all relevant staff	☐	☐ NA
Documentation	Material Transfer Log or Packing List	☐	☐ NA
	Sample tracking records updated in Laboratory Information System (LIS) or other system	☐	☐ NA

	Sponsor approval documentation (e.g. for returns or destruction)	☐	☐ NA
Disposal (if applicable)	Waste Disposal Guidelines (local and sponsor-specific)	☐	☐ NA
	Approval and documentation for destruction of unused/expired materials	☐	☐ NA