# Transfer of Investigational Medicinal Product (IMP) Guideline

## Between Primary Site and Satellite Site(s).

## Purpose

To support the transport of Investigational Medicinal Product (IMP) that is transferred between a Primary Site and Dispensing or Non-dispensing Satellite Site(s) working together as a Teletrial Cluster to deliver a clinical trial using Teletrial methodology under an endorsed Teletrial Supervision Plan.

The term Dispensing in this document refers to "The review of a prescription, and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine including counselling to a patient, their agent or another person who is responsible for the administration of the medicine to that patient." Guidelines for dispensing of medicines, Pharmacy Board of Australia, 2023.

All IMP handling must be undertaken by appropriately qualified staff in accordance with legislation and medication handling policies. This guideline outlines national considerations. Please consult the relevant state or territory Regional Clinical Trial Coordinating Centre (RCCC) for any jurisdictional specific requirements.

The Good Clinical Practice (GCP) – Abbreviated GCP Training for a Teletrial Cluster Guideline (currently being piloted) should be followed to determine the level of abbreviated GCP training that is proportionate to the Non-dispensing Pharmacist/health practitioners' level of trial activity. The Primary Site Pharmacist dispensing the IMP must be GCP trained and delegated to undertake the relevant IMP related activities for the trial. These responsibilities will be clearly outlined in the Teletrial Supervision Plan. In all instances standard practices for the handling of medications are to be followed.

## Limitations

This Guideline does not apply to IMP shipped directly to the Satellite Site by the Sponsor where standard Clinical Trial Pharmacy procedures are to be followed or when the IMP is shipped directly to a third-party compounder who distributes IMP directly to Primary and/or Satellite Sites.

This Guideline does not cover the re-labelling of IMP – if this is required then GMP requirements for medicinal products: PIC/S Guide to GMP PE009-16 clinical trial labelling requirements must be met along with approval from Sponsor.

## Responsibility

### Primary Site Clinical Trials Pharmacy

The Primary Site Clinical Trials Pharmacy must be involved in the development of the Teletrial Supervision Plan. The Primary Site Clinical Trials Pharmacy maintains the accountability logs (including IWRS), and oversees the management of IMP storage, compounding, shipping, dispensing, returns and destruction across the Teletrial Cluster. Any delegation of responsibilities to the Satellite Site(s) must be documented in the Teletrial Supervision Plan and supported by the sponsor. The designated team identified in the Teletrial Supervision Plan at the Primary Site

Clinical Trials Pharmacy must provide the Satellite Site with documentation that includes an overview of the study protocol, IMP handling (e.g. temperature storage, light sensitivity, cytotoxic, hazardous, monoclonal antibody, scheduling, or importation licence), and the cluster Clinical Trial Notification.

### Dispensing Satellite Site Pharmacy

The Dispensing Satellite Site Clinical Trial Pharmacy must be involved in the development of the Teletrial Supervision Plan and may be required to provide a letter of support to the Principal Investigator to confirm their capacity for undertaking clinical trial related activities. The Dispensing Satellite Site Pharmacist is responsible for completing chain of custody documentation, dispensing of IMP, ensuring appropriate temperature-controlled storage for the duration that the IMP is in their carriage and provision of the IMP to the patient or health professional.

The Dispensing Satellite Site Pharmacist must have been appropriately trained and delegated to undertake the required activities, have completed their GCP and dispense the medication following standard practices. These responsibilities will be clearly outlined in the Teletrial Supervision Plan.

### Non-dispensing Satellite Site Pharmacy/Healthcare professional

The Non-dispensing Satellite Site Director of Pharmacy (or equivalent) must be involved in the development of the Teletrial Supervision Plan and may be required to provide a letter of support to the Principal Investigator to confirm their capacity to receive and store IMP. The Non-dispensing Satellite Site Pharmacist or other healthcare professional (who is authorised to handle medications within their scope of practice) is responsible for completing chain of custody documentation, ensuring appropriate temperature-controlled storage for the duration that the IMP is in their carriage and provision of the IMP to the patient or health professional.

### Sponsor

Support Satellite Sites to be established under the Australian Teletrial Program, to enable access to Clinical Trials in regional, rural, and remote locations.

### Logistics Accountability

All transportation and storage of IMP must adhere to sponsor, protocol, pharmacy manual, legislative and medication handling requirements, which may include transportation via validated temperature-controlled shippers and specialty couriers. It will be clearly outlined in the Teletrial Supervision Plan who is responsible for the arrangement of validated temperature-controlled shipping logistics between the Primary Site and the Satellite Site, including who is the account holder and who is responsible for booking the shipments. The Teletrial Supervision Plan should also specify any escalation procedures (i.e. for accountability discrepancies) and if periodic audits are required for Satellite Sites.

### Returns of IMP

Returns of IMP are to be managed as per the protocol/pharmacy manual and the Teletrial Supervision Plan, which may include options for return to Satellite Site or Primary Site and/or require transportation to Primary Site if received at the Satellite Site. Documentation of returns, accountability logs and IWRS are to be completed as outlined in the Teletrial Supervision Plan. Communication between Primary and Satellite Sites regarding returns will occur as per the protocol/pharmacy manual and Teletrial Supervision Plan. If returns are being sent from the Satellite Site to the Primary Site temperature-controlled logistics may not be required but accountability and Chain of Custody is still required (see Appendix 2 – Chain of Custody Form: Returns).

### Destruction

IMP must not be destroyed (whether occurring at the Primary Site or Satellite Site) without prior written authorisation by the Sponsor and must follow the protocol/pharmacy manual, sponsor requirements, Teletrial Supervision Plan, legislation, medication management policies and documented procedures for Waste Management. Accountability and IWRS will be completed as outlined in the Teletrial Supervision Plan. Communication between Primary and Satellite Sites regarding authorisation of destruction and completion of documentation will occur as per the protocol/pharmacy manual and Teletrial Supervision Plan and may include the provision of certificates of destruction.

## Process - Transfer of IMP to Dispensing Satellite Site

1. **Notification to Primary Site and Satellite Site:** The Clinical Research Coordinator (CRC) notifies both the Primary Site and the Dispensing Satellite Site regarding the IMP transfer as soon as practicable, ideally 7 days in advance.
2. **Collection from Primary Site Arrangement:** Collection from the Primary Site is arranged in accordance with the Teletrial Supervision Plan.
3. **IMP Preparation at Primary Site:** The Primary Site selects the IMP stock, completes accountability logs, and updates the IWRS as outlined in the Teletrial Supervision Plan.
4. **Chain of Custody:** The Primary Site completes a Chain of Custody: Supply Form and retains a copy on-site.
5. **Packing and Documentation:** The IMP is packed according to standard procedures, into the required shipper as outlined in the Teletrial Supervision Plan, with required documentation including the Chain of Custody: Supply Form, study overview, CTN (if needed), and any other required documents (e.g., import notice).
6. **Receipt at Satellite Site:** The Dispensing Satellite Site receives the IMP, following standard procedures, placing IMP into the required storage conditions. The temperature data is downloaded, if there has been a temperature excursion, the IMP is quarantined, and the Primary Site is contacted immediately. The Chain of Custody: Supply Form is completed and returned to the Primary Site, along with the temperature records.
7. **Follow-up (if receipt notification not received):** If the Chain of Custody Form and temperature confirmation aren't received by the Primary Site within 48 hours of dispatch, the Primary Site follows up with the Satellite Site and if it has not been received escalates with the courier.
8. **Issue Resolution (if delays, damage or temperature excursions occur during transport):** If there are delays, damage, or temperature excursions during transit, the Primary Site is responsible for completing all necessary documentation and follow-up activities (including Sponsor liaison, arranging for additional IMP shipment, wasting in the IWRS and completing accountability logs).
9. **Temperature Monitoring during storage at the Satellite Site:** Temperature monitoring will be undertaken for the duration of IMP storage at the Satellite Site in accordance with standard procedures and Sponsor requirements. Temperature records must be provided to the Primary Site or Sponsor as required. Where 24/7 recorded temperature monitoring is not in place and is required, an alternate process such as a downloadable temperature logger must be in place.
10. **IMP Dispensing:** The Dispensing Satellite Site follows standard procedures for the dispensing of IMP (including clinical/protocol checks). Activities such as accountability logs and IWRS are completed as outlined in the Teletrial Supervision Plan.
11. **IMP Collection:** Patients, family, or study staff collect the IMP, following standard procedures for the collection of medication.
12. **Final Documentation:** The Chain of Custody: Supply Form is completed and returned to the Primary Site, who will complete any required actions (i.e. accountability logs, IWRS) and retain the copy following study documentation procedures. The original Chain of Custody Form will be retained at the Satellite Site, along with any temperature monitoring data following delivery receipt standard procedures and in the Satellite Site File.

## Process - Transfer of IMP to Non-dispensing Satellite Site

1. **Notification to Primary Site and Satellite Site**: The Clinical Research Coordinator (CRC) notifies both the Primary Site and the Non-Dispensing Satellite Site regarding the IMP transfer as soon as practicable, ideally 7 days in advance.
2. **Collection from Primary Site Arrangement:** Collection from the Primary Site is arranged in accordance with the Teletrial Supervision Plan.
3. **IMP Dispensing at Primary Site:** Primary Site Pharmacy follows standard procedures for the dispensing of IMP (including clinical/protocol checks, dispensing, allocation, IWRS, delegation logs).
4. **Chain of Custody:** The Primary Site completes a Chain of Custody: Supply Form and retains a copy on-site.
5. **Packing and Documentation:** The IMP is packed according to standard procedures, into the required shipper as outlined in the Teletrial Supervision Plan, with required documentation including the Chain of Custody: Supply Form, study overview, CTN (if needed), and any other required documents (e.g., import notice).
6. **Receipt at Satellite Site:** The Non-Dispensing Satellite Site receives the IMP, following standard procedures, placing IMP into the required storage conditions. The temperature data is downloaded, if there has been a temperature excursion, the IMP is quarantined, and the Primary Site is contacted immediately. The Chain of Custody: Supply Form is completed and returned to the Primary Site, along with the temperature records.
7. **Follow-up (if receipt notification not received):** If the Chain of Custody Form and temperature confirmation aren't received by the Primary Site within 48 hours of dispatch, the Primary Site follows up with the Satellite Site and if it has not been received escalates with the courier.
8. **Issue Resolution (if delays, damage or temperature excursions occur during transport):** If there are delays, damage, or temperature excursions during transit, the Primary Site is responsible for completing all necessary documentation and follow-up activities (including Sponsor liaison, arranging for additional IMP shipment, wasting in the IWRS and completing accountability logs).
9. **Temperature Monitoring during storage at the Satellite Site:** Temperature monitoring will be undertaken for the duration of IMP storage at the Satellite Site in accordance with standard procedures and Sponsor requirements. Temperature records must be provided to the Primary Site or Sponsor as required. Where 24/7 recorded temperature monitoring is not in place and is required, an alternate process such as a downloadable temperature logger must be in place.
10. **IMP Collection:** Patients, family or study staff collect the IMP, following standard procedures for the collection of medication.
11. **Final Documentation:** The Chain of Custody: Supply Form is completed and returned to the Primary Site, who will complete any required actions (i.e. accountability logs, IWRS) and retain the copy following study documentation procedures. The original Chain of Custody Form will be retained at the Satellite Site, along with any temperature monitoring data following delivery receipt standard procedures and in the Satellite Site File

## Appendix 1 – Chain of Custody: Supply

| | | | | | |
|---|---|---|---|---|---|
| **Study Title (Protocol)** | | | | | |
| **Sponsor** | | | | | |
| **Primary Site** | | | **Satellite Site** | | |
| Dispensed IMP details | | | | | |
| Name/Subject No | | | IMP/Medication | | |
| Batch and expiry | | | Kit No (if applicable) | | |
| **This product is only to be used according to the Sponsor's guidelines** | | | | | |
| Storage conditions for IMP (tick all that apply) | | | | | |
| ☐ -70°C | ☐ -20°C | ☐ 2°C to 8°C | ☐ 15°C to 25°C | ☐ Protect from light | |
| ☐ Schedule 8 | ☐ Cytotoxic | ☐ Monoclonal Antibody | ☐ Hazardous | ☐ Do not shake | |
| Prepared for transportation | | | | | |
| Date | | | Time | | |
| Name | | | Signature | | |
| Collected by Courier | | | | | |
| Date | | | Time | | |
| Name | | | Signature | | |
| Received at Satellite Site | | | | | |
| ☐ Product unpacked from shipping container and stored in required temperature environment | | ☐ Temperature logger downloaded. | ☐ Temperature verified as in range. If temperature out of range→ quarantine the product and contact Primary Site Pharmacist [Phone number] | ☐ Temperature data sent to [Primary site email address] | |
| Date | | | Time | | |
| Name | | | Signature | | |
| Release from Satellite Site (to be completed by non-dispensing satellite sites only) | | | | | |
| I certify that the storage conditions were met for the duration of the storage at the Satellite Site | | | | | |
| Date | | | Time | | |
| Name | | | Signature | | |
| Collection from Satellite Site (patient, study nurse) (to be completed by non-dispensing satellite sites only) | | | | | |
| Date | | | Time | | |
| Name | | | Signature | | |

*This form must be emailed to the Primary Site Pharmacist [email address] at each step and stored with the site documents/investigator file as per the protocol. The original must be stored at the Satellite Site following delivery receipt standard procedures and in the Satellite Site file.*

## Appendix 2 – Chain of Custody: Returns

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| **Study Title (Protocol)** | | | | |
| **Sponsor** | | | | |
| **Satellite Site** | | **Primary Site** | | |
| Returned IMP details | | | | |
| Name/Subject No | | IMP/Medication | | |
| Batch and expiry | | Kit No (if applicable) | | |
| Storage conditions for IMP (tick all that apply – or leave blank if none apply) | | | | |
| ☐ -70°C | ☐ -20°C | ☐ 2°C to 8°C | ☐ 15°C to 25°C | ☐ Protect from light |
| ☐ Schedule 8 | ☐ Cytotoxic | ☐ Monoclonal Antibody | ☐ Hazardous | ☐ Do not shake |
| Prepared for transportation | | | | |
| Date | | Time | | |
| Name | | Signature | | |
| Collected by Courier/Posted | | | | |
| Date | | Time | | |
| Name | | Signature | | |
| Tracking No (if relevant) | | | | |
| Received at Primary Site | | | | |
| ☐ Product unpacked from shipping container and stored in required temperature environment | | ☐ Temperature logger downloaded (if required) | ☐ Temperature verified as in range. If temperature out of range→ follow standard procedures | |
| Date | | Time | | |
| Name | | Signature | | |

*This form must be emailed to the Satellite Site Pharmacist [email address] as confirmation of receipt and stored in the Satellite Site File. The original must be stored at the Primary Site in the Primary Site File.*