

<p style="text-align: center;">UC San Diego</p> <p style="text-align: center;">Altman Clinical and Translational Research Institute</p> <p style="text-align: center;">Center for Clinical Research</p>	SOP Number	CCR-018
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Transport of Investigational Product		

1 PURPOSE

- 1.1 This SOP defines the process for the secure, compliant, and documented transfer of Investigational Product (IP) from the Investigational Drug Service (IDS) at ACTRI in La Jolla to approved University of California San Diego (UCSD) satellite research sites participating in a clinical trial. The goal is to ensure IP integrity, accountability, and regulatory compliance throughout the transfer process.
 Note: The only approved UCSD satellite research site for this SOP is the ACTRI @ Linda Vista Center for Clinical Research.
- 1.2 This SOP applies to all clinical trials conducted at UCSD satellite research sites where the IP is stored, dispensed, or managed by the ACTRI IDS but requires transfer to the satellite research sites for administration or storage. The study team is responsible for obtaining sponsor approval for IP transport prior to initiating the study protocol. This includes:
 - 1.2.1 Transport of IP between ACTRI IDS and satellite sites
 - 1.2.2 Documentation, chain of custody, and accountability procedures
 - 1.2.3 Roles and responsibilities of personnel involved
- 1.3 This SOP applies to all clinical trials managed by ACTRI IDS that require transfer of IP to approved satellite research sites for research activities involving the following routes of administration:
 - 1.3.1 Enteral routes: oral (PO), sublingual (SL), buccal, rectal (PR), nasogastric (NG) tube or a percutaneous endoscopic gastrostomy (PEG) tube
 - 1.3.2 Parenteral routes: intramuscular (IM), subcutaneous (SC/SQ), intradermal (ID), intrathecal, intraosseous, if dosage form is in prefilled syringes only
 - 1.3.3 Topical, if ACTRI IDS is not required to manipulate/compound final dosage form
 - 1.3.4 Inhalation, if ACTRI IDS is not required to manipulate/compound final dosage form
- 1.4 This SOP does not apply to:
 - 1.4.1 Intravenous administration (IV) studies
 - 1.4.2 IP that requires manipulation or compounding
 - 1.4.3 Studies in which IP is dispensed directly to research participant by the pharmacy without transfer
 - 1.4.4 Transfer to non-approved UCSD satellite research site (sites other than ACTRI at Linda Vista Center for Clinical Research).

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 N/A

3 REQUIREMENTS

- 3.1 The Clinical Research Coordinator (CRC) or designee transporting the IP should be familiar with the following:
 - 3.1.1 Good Clinical Practice (GCP)
 - 3.1.2 Study protocol
 - 3.1.3 Pharmacy manual (reference section on handling of IP)
 - 3.1.4 Use of temperature monitoring device

- 3.2 The CRC or designee transporting the IP should have completed the following:
 - 3.2.1 UC IATA (International Air Transport Association) training
 - 3.2.2 UC Annual Laboratory Hazards training
 - 3.2.3 UC Regulated Waste Disposal
 - 3.2.4 UC Blood Borne Pathogens

4 RESPONSIBILITIES

- 4.1 The Principal Investigator (PI) ensures all transfers are approved per protocol, IRB, and sponsor requirements. The PI retains ultimate responsibility and accountability for all aspects of the study.
- 4.2 The Clinical Research Coordinator (CRC) or designee coordinates logistics, communicates transfer details between sites, receives IP, verifies quantity and condition, ensures secure, temperature-controlled transport, signs Investigational Product Transport and Chain of Custody Form, maintains local accountability logs and ensures documentation is filed in the participant binder (as listed in section 5.4.3).
- 4.3 The Regulatory Coordinator (RC) ensures documentation is filed in the regulatory binder (as listed in section 5.4.2).
- 4.4 ACTRI IDS provides the finished and labeled IP to the CRC or designee for transport.

5 PROCEDURE

- 5.1 Authorization for Transfer
 - 5.1.1 The PI will obtain sponsor and IRB approval for use of ACTRI IDS and IP transfer.
 - 5.1.2 The CRC will send Interactive Response Technology (IRT) information and study specific OPRX to the ACTRI IDS via email to CTRI-IDSpharm@ucsd.edu at least 48 hours prior to IP transport. The OPRX should have been reviewed and approved by both the ACTRI IDS prior to dispensation and transportation of IP. The study specific OPRX should include the following:
 - 5.1.2.1 IRB number and study title
 - 5.1.2.2 Research participant number and ID number
 - 5.1.2.3 IP name
 - 5.1.2.4 Dosage and mode of administration of IP
 - 5.1.2.5 Date and time of research participant visit.
 - 5.1.2.6 Name, signature, date and physician ID approving the OPRX prescription
 - 5.1.3 The CRC will also enter required information into IRT, if required by the sponsor.
- 5.2 Preparation of IP:
 - 5.2.1 Only oral and prefilled syringes (as described in section 1.3) will be transported from the ACTRI IDS to satellite research sites.
 - 5.2.2 For PI-initiated studies, ACTRI IDS will verify expiry date and lot numbers and required quantity for transfer, proper labeling with protocol number, storage conditions, and “Caution: New Drug—Limited by Federal (or United States) law to investigational use” statement. For other studies, the CRC will provide ACTRI IDS the OPRX and IRT assignment of the kits needed that comes directly from the sponsor. ACTRI IDS will double check to make sure the kits are in date and proper lot numbers and kits are dispensed.
 - 5.2.3 The ACTRI IDS will dispense the IP to the CRC or designee. The CRC or designee will then prepare the IP for transport. It is the responsibility of the study team to provide an appropriate transport container with temperature monitoring device.
 - 5.2.4 Sponsor provided instructions for IP transport temperature monitoring should be followed, if available. If sponsor does not provide instructions:
 - 5.2.4.1 Ambient temperature drug: place at least one room temperature gel pack in the bottom of the case. After IP and data logger has been added to the transport case, place one or more room temperature gel packs on top of the IP packed in the case.
 - 5.2.4.2 Refrigerated temperature drug: place at least one frozen gel pack in the bottom of the case, followed by one or more refrigerated gel packs to cover the entire bottom of the case. This should be done approximately 5 minutes prior to adding the IP. After the IP has been added to the case, add more refrigerated gel packs before closing the case.
 - 5.2.5 Investigational product must be packaged and labeled separately for each participant. However, IP for several participants may be packaged together in order to facilitate

efficient delivery and best use of resources, if permitted by sponsor.

- 5.3 Transport of IP:
 - 5.3.1 It is the responsibility of the CRC or designee to pick-up IP and ensure the IP is appropriately packed (as described in 5.2) prior to transport to the satellite clinic. Alternately, the study team may arrange for a courier to pick-up IP and transport to the satellite clinic.
 - 5.3.2 It is the responsibility of the CRC or designee to:
 - 5.3.2.1 Identify when IP will need to be dispensed to a research participant and complete all documentation as described in 5.1.
 - 5.3.2.2 Ensure the person transporting the IP has met requirements described in section 3. If a courier service is used, it is the responsibility of the CRC to ensure the courier company is set up and IP is packaged as described in 5.2.3 and 5.2.4.
 - 5.3.2.3 Pick up IP for transport to the satellite research site (or arrange for the courier service) within 15 minutes of preparation of IP.
 - 5.3.2.4 Complete the Investigational Product Transport and Chain of Custody Form (Appendix B) prior to leaving the ACTRI IDS.
 - 5.3.2.5 Ensure that IP is never left unattended at any point during transportation.
 - 5.3.3 Upon transport and receipt of IP at satellite research site by the CRC or courier service, it is the responsibility of the CRC or designee to:
 - 5.3.3.1 Verify integrity of packaging and labeling.
 - 5.3.3.2 Reconcile quantity and lot number against the Investigational Product Transport and Chain of Custody Form.
 - 5.3.3.3 Complete the satellite section of the Investigational Product Transport and Chain of Custody Form.
 - 5.3.3.4 Record any discrepancies, damage, or temperature excursions and communicate with sponsor to confirm if IP is compromised.
 - 5.3.3.5 Store IP under conditions specified in the protocol and document storage location.
 - 5.3.3.6 Update IP dispensation in the research participant chart.
 - 5.3.3.7 Dispense IP to research participant as indicated in protocol.
- 5.4 Documentation and Recordkeeping
 - 5.4.1 ACTRI IDS will maintain the following records:
 - 5.4.1.1 Shipping receipts/packing list from the initial IP shipment from the sponsor
 - 5.4.1.2 Master IP logs inventory log using the sponsor provided, patient specific participant number
 - 5.4.2 The RC will maintain the following records in site regulatory binder:
 - 5.4.2.1 IP transfer SOP
 - 5.4.3 The CRC or designee will maintain the following records in site participant binder:
 - 5.4.3.1 Temperature Logs
 - 5.4.3.2 Communication (emails, memos)
 - 5.4.3.3 Deviation related reports and correspondences
- 5.5 Return or Disposal:
 - 5.5.1 For capsules or tablets: Any unused IP at the satellite site (returned by the participant to the study team) must be returned to ACTRI IDS for accountability and disposal the same day. For times where dispensing occurs after hours, returning the IP the next business day would be acceptable. The returned IP must be physically returned to the ACTRI IDS. ACTRI IDS will not accept large quantities of IP returns at time of study closure. Upon receipt of returned drug, ACTRI IDS will update the study protocol accountability logs and will dispose of the drug according to ACTRI IDS SOPs. It is the responsibility of the study team to update IRT systems as needed.
 - 5.5.2 For all other forms of IP: ACTRI IDS will not be able to accept returned or unused IP. Please follow sponsor's instructions for return or disposal.
- 5.6 Deviations:
 - 5.6.1 Any deviation from this SOP must be reported to the sponsor and IRB as required. A copy of the correspondence and deviation reports must be filed in the participant binder.

6 MATERIALS

6.1 N/A

7 REFERENCES

- 7.1 ICH-GCP E6(R2)
- 7.2 21 CFR Part 312 – Investigational New Drug Application
- 7.3 Institutional Policy on Handling of Investigational Drugs
- 7.4 Sponsor Pharmacy Manual
- 7.5 ICF CFR 312 – Investigational New Drugs – Drugs for Human Use
- 7.6 ICF 45 CFR 46 – Protection of Human Subjects
- 7.7 FDA Industry Guidelines and Information Sheets

8 APPENDICES

- 8.1 Appendix A: Definitions
- 8.2 Appendix B: Investigational Product Transport and Chain of Custody Form
- 8.3 Appendix C: Temperature Excursion Log

Appendix A: Definitions

- a. **Ambient temperature gel pack:** A gel-filled pack which has been maintained at room temperature (15°C/59°F to 25°C/77°F).
- b. **Approved satellite research site:** An approved satellite site for a clinical trial is a secondary location, affiliated with the main institution that has formal authorization to carry out clinical trial activities for a specific protocol. If the site is not covered by IDS, additional approval is required.
- c. **Designee of the Clinical Research Coordinator (CRC):** A designee is someone given the authority to carry out duties of the Clinical Research Coordinator (CRC) by the Principal Investigator (PI) of the study.
- d. **Drug Accountability:** Drug storage, handling, dispensing, and documentation of administration, return and/or destruction of the drug.
- e. **Frozen gel pack:** A gel-filled pack which has been maintained in a freezer (-25°C to -10°C).
- f. **Investigational Product:** A new drug or biological drug that is used in a clinical investigation. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous for purposes of this part. Any drug which has not received FDA approval for use in humans. Also refers to any drug, which is FDA approved and is being used under protocol for human research, possibly outside of FDA approved labeling.
- g. **Investigational Product Transport and Chain of Custody Form:** The chain of custody form for transporting investigational products to an off-site clinic delineates responsibilities at each stage, from dispensing pharmacy to transport and delivery of Investigational Product (IP) to study participant, outlining who is accountable for each task. This form facilitates clear communication and accountability among personnel involved in the transportation process, ensuring adherence to regulatory requirements and study protocols.
- h. **Investigational Drug Service (IDS):** A function of the Investigational Drug Services (IDS) that provides support to ensure the safety and efficiency of trials at the University of California San Diego (UCSD) that use investigational product(s)/investigational drug(s).
- i. **Interactive Response Technology (IRT):** Interactive Response Technology (IRT) is an umbrella term that refers to both Interactive Voice Response Systems (IVRS) and Interactive Web Response Systems (IWRS). These systems are used to manage patient enrollment, randomization, drug supply, reporting, and more during clinical trials.
- j. **OPRX:** (Outpatient Prescription) refers to a prescription for Investigational Product (IP), designed specifically for participants enrolled in a clinical trial.
- k. **Refrigerated gel pack:** a gel-filled pack which has been maintained in a refrigerator (2°C to 8°C). A refrigerated gel pack will be flexible if the gel inside is not frozen.
- l. **Sponsor:** An individual, company, institution, or organization that takes responsibility of the initiation, management, and/or financing of a clinical trial.
- m. **Transport:** the physical moving of investigational product (IP) dispensed by ACTRI IDS to another site for administration to a research participant.

Appendix B: Investigational Product Transport and Chain of Custody Form

Protocol: _____ PI: _____ IRB#: _____

Participant ID Number: _____ Participant Initials: _____

Visit: _____ Date of visit: _____

Investigational Product (IP) being transported:

Name	Amount	Lot #	Kit #	Exp. Date

Transportation Details

Date of Transport: _____

Packaged by: _____
Print Name of Study Team Member

Transported by: _____
Print Name of Study Team Member OR Courier Service Name and Company

Study Drug placed into secure, temperature monitored container

Transported from:

Location name: _____

Address: _____

Time left dispensing site: _____ Temp inside container: _____ F/C

Transported to:

Location name: _____

Address: _____

Signature of person packaging IP: _____ Date: _____

Signature of person transporting IP: _____ Date: _____

Satellite section (to be completed by study team member receiving IP at the satellite site)

Time arrived at receiving site: _____ Temp inside container: _____ F/C

Was IP Temperature Maintained per study protocol? _____ YES _____ NO

Signature of person receiving IP: _____ Date: _____

Name of person receiving IP: _____

Appendix C: Temperature Excursion Reporting Form

Protocol: _____ PI: _____ IRB#: _____

Investigational Product (IP) being transported and affected by temperature excursion:

Date of Transport: _____

Time arrived at receiving site: _____

Minimum Temperature: _____

Maximum Temperature: _____

Duration: _____

Reason for Temperature Excursion: _____

Confirm IP impacted by temperature excursion has been segregated and placed in quarantine.

Confirm copy of temperature monitor logs for date(s) of excursion are attached

Signature of person receiving IP: _____ Date: _____

Name of person receiving IP: _____