

## Unit Procedure

### Shipment of Specimens

SOP No./WI No.: CTSI-CRC-PL-159

Department: Processing Laboratory

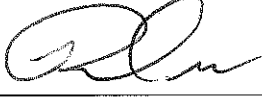
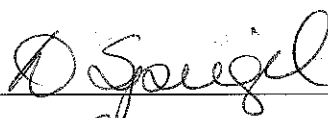
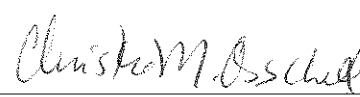
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Review Period: 2 years

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Date	06 JAN 2017	5 Jan 2017	Jan 6, 2017



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**1. OBJECTIVE**

This Standard Operating Procedure (SOP) describes the process for shipment of biological specimens in accordance with university and federal regulations at the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL).

**2. SCOPE**

This SOP is intended for all laboratory staff that have completed and are current with the Environmental Health and Safety's Shipment of Biological Materials training or equivalent International Air Transport Association (IATA)/DOT approved training.

**3. RESPONSIBILITIES**

- 3.1. It is the responsibility of the personnel processing specimens to ensure that requisite study shipment documentation is completed according to receiving lab guidelines.
- 3.2. It is the responsibility of personnel shipping specimens to verify package contents prior to shipping and that shipping is done in accordance with Environmental Health and Safety's (EH&S) Shipment of Biological Materials regulations.
- 3.3. It is the responsibility of CTSL management to ensure that staff EH&S /IATA training remains current.

**4. DEFINITIONS**

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	IATA: International Air Transport Association
EH&S: Environmental Health and Safety	FedEX: Federal Express
PL: Processing Lab	SOP: Standard Operating Procedure
UPS: United Parcel Service	

**5. ASSOCIATED DOCUMENTS**

- 5.1. CTSI-CRC-QA-003 Document Control and Management
- 5.2. CTSI-CRC-CLN-030 Handling of SOP Deviations
- 5.3. CTSI-CRC-PL-121 General Safety
- 5.4. CTSI-CRC-PL-151 Management of Requests for Sample Processing Support

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## 6. PROCEDURE

- 6.1. Shipping of samples will be performed by trained and certified personnel only. Current certification through Environmental Health and Safety's Shipment of Biological Materials course or equivalent IATA training is required.
- 6.2. Procedures for shipping of biological samples shall follow EH&S guidelines.
  - 6.2.1. Refer to EH&S Shipment of Biological Materials training module located at O:\DMCT\CTSIProcessingLabs\CTSL\_Overall\SOPs\Current SOPs\Shipment of Biological Materials
  - 6.2.2. Lab personnel will ship Category B or exempt samples only unless otherwise directed.
    - 6.2.2.1. If notified by study personnel that samples to be shipped may contain Category A infectious diseases, inform management immediately.
    - 6.2.2.2. Mark potential Category A samples with Do Not Ship and place samples in a location separate from other samples.
    - 6.2.2.3. Contact study staff immediately to inform them that other arrangements for shipping the Category A specimens must be made.
- 6.3. Verification of shipment
  - 6.3.1. Processor performs the following:
    - 6.3.1.1. Verify expected blood collection tubes/samples have been collected for the visit at time of processing and note any discrepancies on the protocol specific from CTSI-CRC-PL-FM508 Lab Processing Sheet.
    - 6.3.1.2. If the expected number of aliquots was not collected, indicate actual number of aliquots collected and reason (if applicable) with a footnote on the protocol specific CRC-PL-FM508 Lab Processing Sheet.
    - 6.3.1.3. Complete any required information and document if any samples were not collected on study shipment requisition.
    - 6.3.1.4. Place aliquots, study shipment requisitions and completed protocol specific CRC-PL-FM508 Lab Processing Sheet in the designated Ship holding areas.
    - 6.3.1.5. Enter the following information on the CTSI-CRC-PL-LG618 Specimen Shipment Log.
      - 6.3.1.5.1. Protocol ID (CRC/CTSL protocol number)
      - 6.3.1.5.2. Study subject ID (patient name, MRN, PPI)
      - 6.3.1.5.3. Number of samples of each storage type A=Ambient, R=Refrigerated, F=Frozen.
      - 6.3.1.5.4. Processing technician's initials.
  - 6.3.2. Shipper performs the following:
    - 6.3.2.1. Shipping technician must not be the same as the processing technician unless authorized by management.

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- 6.3.2.1.1. When a technician must ship the samples they processed, all documentation must be reviewed as soon as possible by a second party.
- 6.3.2.1.2. Reviewer will note in the comments section of the appropriate entry line on the CTSI-CRC-PL-LG618 Specimen Shipment Log the time/date of post-shipment review and reviewer's initials.
- 6.3.2.2. Review requisitions for completeness and accuracy.
- 6.3.2.3. Verify that all aliquots processed are present.
  - 6.3.2.3.1. Place a checkmark next to the number of aliquots collected (number in the Actual column) on the CTSI-CRC-PL-FM508 Lab Processing Sheet indicating that the number of aliquots present at shipping is the same as the number of aliquots processed.
  - 6.3.2.3.2. Rectify any discrepancies and update study shipment requisition as required.
  - 6.3.2.3.3. If any specimens that are listed on the study shipment requisition were not collected and/or processed, document that the specimen was not shipped on the study shipment requisition.
  - 6.3.2.3.4. Some protocols require that backup samples be sent separate from primary samples.
    - 6.3.2.3.4.1. Pack verified backup samples in acceptable shipping bags and place back in appropriate storage.
    - 6.3.2.3.4.2. Keep a copy of the requisition (top page at minimum) with the samples.
    - 6.3.2.3.4.3. Log backup samples on designated backup sample copy of CTSI-CRC-PL-LG618 Specimen Shipment Log.
    - 6.3.2.3.4.4. Ship backup samples at least one day after primary samples have shipped.
    - 6.3.2.3.4.5. Pack backups in boxes with other samples going to same central lab if possible.
    - 6.3.2.3.4.6. Document shipment of backup samples on the specified entry line on the designated backup sample CTSI-CRC-PL-LG618 Specimen Shipment Log.
- 6.3.2.4. Document shipper's signature, date of shipment and number of samples shipped on the associated CTSI-CRC-PL-FM508 Lab Processing Sheet.



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6.4. Packing and Shipping

- 6.4.1. Examine packing supplies for compliance to EH&S shipping guidelines regarding shipping container integrity, labeling and construction.
- 6.4.2. Complete packaging of samples per EH&S shipping standards and as described in the receiving lab's specific instructions (when available). Include the original copy of the study shipment requisition.
  - 6.4.2.1. Surround frozen specimens with dry ice on all four sides by placing a layer of dry ice at the bottom, place the specimens in the center of the box and then fill the remaining space with dry ice.
  - 6.4.2.2. Place the original study shipment requisition in the box either just under the top flaps or per receiving lab's specific instructions.
  - 6.4.2.3. Seal boxes that contain dry ice with a minimum of 2 pieces of packing tape lengthwise across the center of each end. To allow for venting of gas, do not seal along the edges of the box.
- 6.4.3. Retain a copy of the requisition and airbill/tracking number and attach to the applicable CTSI-CRC-PL-LG618 Specimen Shipment Log.
  - 6.4.3.1. If labels with the package tracking number are available, attach a label to the copy of the study shipment requisition.
  - 6.4.3.2. If not labels are available, make a copy of the shipping label and retain with the copy of the study shipment requisition.
- 6.4.4. Complete the entry on the CTSI-CRC-PL-LG618 Specimen Shipment Log by documenting the shipper's initials and date/time samples were packed.
- 6.4.5. Contact the appropriate shipping carrier to schedule a pickup.
- 6.4.6. Shipping Schedule
  - 6.4.6.1. Shipping of frozen samples will be performed on Monday through Thursday only unless authorized by study personnel and/or receiving lab. Record the name of the authorizing personnel on the appropriate line of the CTSI-CRC-PL-LG618 Specimen Shipment Log.
  - 6.4.6.2. Ambient samples should be shipped the day of processing. If shipment is delayed, samples must be shipped the following workday. Store ambient samples according to receiving lab instructions if shipping is delayed.
  - 6.4.6.3. If frozen samples are shipped on Friday, verify that Saturday Delivery is indicated on the shipping airbill (UPS labels have 1+S printed on the label) or place a label on the package indicating Saturday delivery is requested (FedEx yellow label with the letters SDR).

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## 7.0 REFERENCES

- 71. Environmental Health and Safety's Shipment of Biological Materials Training
- 7.2. Presentation O:\DMCT\CTSIProcessingLabs\CTSL\_Overall\SOPs\Current
- 7.3. SOPs\Shipment of Biological Materials

## 8.0 APPENDICES

None

## 9.0 AMENDMENT HISTORY

Date of Amendment: 05 Jan 2017

Amendment Request by: Robert Orr

Change Control No, if applicable: CTSI-CRC-PL-DC-2016-030

Details of Amendment: Updated to footer file location; Corrected SOP noted in 5.2; added to the definition list of acronyms; added section 6.3.2.3.4 for backup sample process; updated for clarity.