	<b>SOP: Specimens Shipment (Biological and Non-biological)</b>				
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## 1. PURPOSE

The purpose of this SOP is to describe the procedures related to packing and shipping biological exempt human specimens and non-biological specimens.

## 2. REVISIONS FROM PREVIOUS VERSION

2.1 Version 4.0, 01/Mar/2021, updated the date and version number

## 3. POLICY

Potentially hazardous materials must be packaged to withstand leakage of contents, shocks, temperature and pressure changes and other conditions that may occur during transportation procedures. Biological materials must be packed with the triple packaging principle to include primary receptacle, leak proof secondary container with absorbent material and durable outer container. The packages must comply with the package instructions from IATA such as PI 602 for infectious substances. Buying certified packages from suppliers that are specific to the materials you want to ship will ensure compliance with the packing requirements. The proper shipping name, labels and UN markings must also be on the package before sending out for shipment. If using dry ice or liquid nitrogen with your shipment, these materials must be declared, and packages properly labeled. Dry ice should never be placed in a sealed container, or the package may be at risk of exploding.

All study staff shipping specimens must complete Shipping Hazardous Materials training prior to first shipment.

Handling of all samples must adhere to the OSHA Bloodborne Pathogen Standard using Universal precautions (i.e. PPE).

Frozen specimens must be transported in insulated containers surrounded by an ample amount of dry ice to keep the specimen frozen until it reaches the laboratory.

## 4. RESPONSIBILITIES

### 4.1 Principal Investigator (PI)

4.1.1 Ensure all study team members who will pack, and ship specimens complete the required FAU EHS trainings (prior to first shipment) as per the FAU EHS policy and procedures (i.e. Bloodborne pathogens, Shipping Hazardous Materials, etc.).


4.1.2 Ensure all study team members have access to required shipping supplies.

4.1.3 Ensure all biological specimen shipments comply with IATA Dangerous Goods Regulations and/or 49 CFR 100-185.

4.1.4 Provide specific instructions if packing or shipment differs from this SOP.

### 4.2 Clinical Research Professional (CRP)

4.3.1 Confirm all study team members who will pack, and ship specimens

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have completed initial Shipping Hazardous Materials training (prior to first shipment) and annual renewal conducted by FAU EHS, Florida DOH or CITI (renewals).

- 4.3.2 Confirm all study team members have access to required packing and shipping supplies.
- 4.3.3 Confirm shipping carrier arrangements (i.e. account number, shipping forms).
- 4.3.4 Confirm documentation of all specimen shipment(s).

## 5. PROCEDURE

- 5.1 Review and confirm the sample packaging requirements and transportation instructions as indicated in the protocol or this SOP.
- 5.2 Determine if the samples being shipped are Biological or non-Biological (i.e. pathology slides). Non-Biological samples do not require special shipping precautions.
- 5.3 Determine if any special form, permits, or custom processes are required for shipment of biological specimens and complete as required.
- 5.4 Determine the proper timing for shipments and the anticipated turnaround time for results if applicable.
- 5.5 Ensure the receiving lab/facility will be open to receive the shipment on the anticipated delivery date/time.
- 5.6 Order or obtain appropriate amount of dry ice, if applicable and as determined by protocol.
- 5.7 Complete all required shipping documentation.
- 5.8 Confirm all specimens are labeled with identifiable bar code or study information (i.e. PI name, IRB #, participant ID, sample #, visit #, sample type, collection date/time).
- 5.9 Package the samples as indicated in the protocol if the instructions are different from the instructions provided in this SOP. If different, verify they are compliant with FAU, Federal and IATA regulations.
- 5.10 For liquid specimens (i.e: blood, urine) use watertight containers with a positive closure such as a screw-on, snap-on or push-on lid, taped for an additional seal. When packing fragile primary receptacles in a single secondary receptacle, they must be individually wrapped or separated to prevent contact between them. Ensure that all specimen container caps and lids are **properly tightened** to prevent leakage.
- 5.11 For multiple tubes/specimens, use a tube rack to hold the samples.
- 5.12 Make sure all fields on the study information form are filled out, folded with information showing and place inside the front pocket of the specimen bag.
- 5.13 Place absorbent material between the primary and secondary receptacles, using enough material to absorb the entire contents of all primary receptacles. Acceptable absorbent materials include cellulose wadding, cotton balls, super-absorbent packets, and paper towels.
- 5.14 Place specimen (s) in biohazard bag and seal the bag.

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- 5.15 Place the specimen upright in the Styrofoam container.
- 5.16 Place 2 freezer ice packs on the outside of each of the refrigerated ice packs. (Note: freezer ice packs should not contact the specimen)
- 5.17 Stuff the remaining spaces with paper and close the lid. Add scotch tape if needed.
- 5.18 Add a biohazard sticker on the top of the Styrofoam box.
- 5.19 Place the Styrofoam container inside the shipping box and tape the box.
- 5.20 Place 3 biohazard stickers on the shipping box. (One on the top and one on each side)
- 5.21 Weigh the container and write it on the given space on the shipping label. Place prefilled shipping label inside protective sleeve and stick it on the box. (Be sure to keep the senders copy for our records)
- 5.22 If dry ice is needed, use the proper dry ice handling technique.
- 5.23 Record the specimens included in shipment.
- 5.24 Close and tape the container. If dry ice is used, make sure not to seal all box edges to allow CO2 released from the dry ice to escape.
- 5.25 Confirm all required labels are affixed to shipping container (i.e. Shipping label, Biological Specimens Category B label, Dry Ice label, etc.)
- 5.26 Contact pre-arranged carrier (i.e. UPS, FedEx) to schedule pick-up and record confirmation number.
- 5.27 Document the shipment using lab requisition form or the CRU Specimen Shipping log. When courier comes to pick up the package, be sure to get representative name, confirmation number and the time it was picked up.
- 5.28 Retain a copy of the shipping receipt (or courier waybill) and/or commercial invoice.
- 5.29 Send an e-mail to the recipient to inform the package was mailed and to confirm once they have received it.
- 5.30 Documentation
  - 5.30.1 Shipping Hazardous Materials training certificate(s).
  - 5.30.2 Lab requisition or specimen shipping log.
  - 5.30.3 Copy of shipping receipt (or courier waybill) and/or commercial invoice.
  - 5.30.4 E-mail to inform shipment.

**6. MATERIALS**

- 6.1
  - CRU Specimen Shipping Log
  - Styrofoam secondary container
  - 4G type fiberboard outer box minimum dimensions of at least 4" x 4
  - Human Exempt Specimen label
  - Frozen Gel Packs (Frozen at -20°C)
  - Leak-proof primary – NUNC vials, Sarstedt Tubes, etc.
  - Leak-proof secondary (not subject to pressure test) – Ziploc Bags
  - Absorbent material to contain all liquid in package
  - Biohazard Labels



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- If applicable Dry Ice labels (Dangerous Goods, Category 9, UN1845, White with Black)

**7. REFERENCES**

- 7.1 FAU Environmental Health & Safety policies and procedures
- 7.2 The OSHA Lab Standard (29 CFR§1910.1450)
- 7.3 IATA Dangerous Goods Regulations
- 7.4 49 CFR 100-185

**8. SIGNATURES**

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Date: 20 July 2023

Approved by: Peter J. Holland  
Peter J. Holland, MD  
CRU Medical Director

Date: 26 July 2023