

Blood Collection and Shipping for Germline DNA Sequencing		
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## 1.0 PURPOSE/SCOPE

This Standing Operating Procedure (SOP) describes the procedures for collecting, preparing, and shipping human blood specimens from Clinical Centers for germline DNA whole exome sequencing to use with patient-derived models generated from the same patient's tumor material. This SOP was developed by NCI-F/FNLCR in collaboration with the Developmental Therapeutics Clinic, National Cancer Institute and NCI-designated Cancer Centers participating on an NCI multicenter Tissue Procurement Protocol. This SOP is used/performed by the Clinical Centers collected patient blood samples and the Biological Testing Branch (BTB) at NCI-Frederick, Frederick National Laboratory for Cancer Research.

## 2.0 SAFETY

All fresh human tissue, including whole blood and its purified components, are handled under Biosafety Level 2 (BSL2) conditions. All work is conducted in a biological safety cabinet (BSC) using personal protective equipment and avoiding the use of sharps where possible. All materials potentially exposed to the human material is treated with a 10% bleach solution for a minimum of 10 minutes, double bagging for autoclaving or incineration. Consult with your facility safety professionals regarding the safe handling of BSL2 studies.

## 3.0 MATERIALS & EQUIPMENT

### 3.1 Blood Collection

- 3.1.1 Cell-Free DNA BCT<sup>®</sup> (Streck) glass blood tube, 10-mL draw capacity, (Streck, Inc., Cat#: 218962)

### 3.2 Overnight Shipping

- 3.2.1 Falcon conicals with absorbent material enclosed
- 3.2.2 Specimen tube label
- 3.2.3 ZipLock bag - to protect Shipping Manifest upon return
- 3.2.4 Two (2) Controlled room temperature (CRT) gel packs
- 3.2.5 Styrofoam box
- 3.2.6 Shipping cardboard box

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## 4.0 OPERATING PROCEDURES

### Important:

- Processing limitations:
  - A minimum volume of 4-5-mL blood draw per Streck blood is needed for processing.
- Blood specimens **MUST** be prepared and shipped at 22°C ± 3°C (RT).
- All samples should be shipped on day of collection and received within 24-h of collection at the processing laboratory for DNA extraction.
- Tumor and blood specimens are shipped in **SEPARATE** containers under **DIFFERENT** shipping conditions.

### 4.1 Day of Blood Collection, Just Prior to Specimen Receipt

- 4.1.1 Prepare specimen tube labels with specimen ID.
- 4.1.2 Remove the Streck Cell-Free DNA BCT® tube from the Shipping Kit and apply the label. If the tubes are kept in the patient suite, bring the labels to the suite so they can be applied to the tubes immediately following blood collection.
- 4.1.3 If shipping material to an external site, ensure that overnight shipping has been arranged.

### 4.2 Whole Blood Collection into Streck Cell-Free DNA BCT® tube

- 4.2.1 Clinical Specimen Support Lab Personnel should arrive at the collection site early enough to allow sufficient time to set up supplies, collect relevant clinical information, and ensure rapid transport of specimens to the laboratory for preparation for shipping.
- 4.2.2 Collect whole blood aseptically by venipuncture or from a venous port into one 10-mL Streck tube. Due to the potential for unanticipated technical variables, blood should not be obtained from an arterial source.
- 4.2.3 Fill each tube with a **minimum of 4-5-mL volume** until the blood flow stops to ensure the correct ratio of sample to anticoagulant. If <4-5 mL of blood is collected, the analysis results may be significantly compromised due to an incorrect ratio of additive-to-blood.
- 4.2.4 **Gently invert** the tube 8-10 times to mix; tube inversion prevents clotting. **Do not shake** the tube; vigorous mixing can cause hemolysis.
- 4.2.5 **Do not** refrigerate or freeze specimen; keep tubes at room temperature.

**Important:** Do not place tube on ice. If the clinical staff placed the tube on ice, make a notation on the Specimen Log ([Appendix 1](#)) and place the tube at room temperature before proceeding.

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## 5.0 PACKAGING OF BLOOD SPECIMENS FOR OVERNIGHT SHIPMENT

### Important:

- For overnight shipping: All whole blood tubes MUST be shipped on the day of collection and received within 24-h of collection at the processing laboratory for isolation of germline DNA.
- Germline DNA should be extracted no longer than 48-72 hours after blood draw.

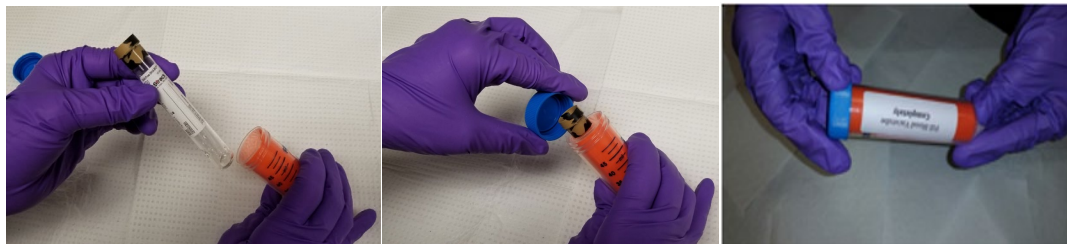
**5.1 Complete a Shipping Manifest ([Appendix 1](#))** for each specimen collected on the day of shipment.

### 5.2 Packaging Instructions

- 5.2.1** Open the Blood Shipping kit which has been stored at room temperature and remove all contents.
- 5.2.2** Place a room temperature gel pack in the bottom of a Styrofoam shipping container.



- 5.2.3** Place the specimen filled Streck tube labeled with the Protocol ID into the provided 50-mL Falcon centrifuge conical. Ensure that the absorbent material remains in the conical and lines the interior surface.



- 5.2.4** Place the 50-mL Falcon centrifuge conical into the Styrofoam box on top of the first gel pack, and then put a second room temperature gel pack on top of the conical.



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- 5.2.5 Place the completed Shipping Manifest** with the Chain of Custody section signed on line #1 ([Appendix 1](#)) **in a sealed zip lock bag** and then place on top of the gel pack. Close the Styrofoam box and then seal the cardboard shipping box.



### 5.3 Shipping Instructions

- 5.3.1** Once the cardboard box is sealed, attach a return shipping label to the outside of the box **and a UN3373 label.**
- 5.3.2 Important:** Patient samples that are being shipped are “live” specimens. Do not leave specimen boxes on shipping docks for prolonged lengths of time as a severe temperature drop or rise could compromise the viability of the patient specimens.

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## APPENDIX 1: SHIPPING MANIFEST AND CHAIN OF CUSTODY

Specimen ID
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### 1. Shipping Manifest

Include a copy of the manifest and signed, chain of custody section with every patient-derived model collection.

To be completed by the Clinical Center					
Blood Tube Type	Collection Date	Collection Time with time zone	Patient Gender	Diagnosis (e.g., Colon cancer, Breast cancer, SCLC, etc.)	CTEP SDC Code*
<input type="checkbox"/> 1 Cell-Free DNA BCT® (Streck) with a min. of 4-5-mL		<input type="checkbox"/> Eastern <input type="checkbox"/> Central <input type="checkbox"/> Mountain <input type="checkbox"/> Pacific	<input type="checkbox"/> Male <input type="checkbox"/> Female		

\*CTEP SDC Codes: [http://ctep.cancer.gov/protocolDevelopment/docs/SDCv10\\_M10.xls](http://ctep.cancer.gov/protocolDevelopment/docs/SDCv10_M10.xls)

### 2. Chain of Custody Signatures

Prior to shipping the Clinical Center Specimen Handling personnel should verify contents of and sign and date on line 1 below to verify contents of container.

Task	Responsible Party	Signature	Date
1. Shipment of blood tubes (22°C ± 3°C controlled temperature gel packs)	Clinical Center		/ /
2. Receipt of specimen: log receipt, verify specimen(s), and verify shipping conditions. If deidentification is required, remove provided ID label and replace with anonymized research ID.	Research Site: Receiving/ Honest Brokers		/ /
3. Receipt of specimen for research use.	Research Site: Laboratory		/ /

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## APPENDIX 2: OVERNIGHT SHIPPING TEMPERATURE MONITORING

### 1. Example Summer Blood Sample Shipment:

#### A. Target Shipping temperature range for blood sample: 10°C to 28°C

- Shipment with two ambient temperature-controlled gel packs.
- Blood Shipping Kit temperatures have been stable in our hands in various seasons. Interior box temperature fluctuates no more than 4°C (n = 47).

- California to Maryland; June 17-18, 2014
  - 6/17/2014 CA regional temp max, 29°C
  - 6/18/2014 MD regional temperature max, 33°C
- 21 h 5 m monitoring period, 253 data points
- Min: +20.6°C
- Max +22.8°C

