1.0 PURPOSE

This work instruction provides the specific steps necessary to pack and ship the PAXgene bloods in the Comprehensive Biospecimen Resource (CBR) issued BBRB/BPV Dry Ice Kit (The White Kit).

The procedure section is divided into four subsections: the kit receipt at the biospecimen source site (BSS), packing instructions, shipping instructions, and alert of shipment.

2.0 ENVIRONMENTAL HEALTH & SAFETY

2.1. Persons packaging and/or signing transport documents must be trained and/or certified to ship the appropriate hazard class according to International Air Transport Association/ International Civil Aviation Organization regulations.

2.2. Persons packaging the shipment must be trained in the use, handling, and shipping of dry ice (UN1845).

3.0 PROCEDURE

Kit Receipt at the BSS

3.1. Contents correspond to supplies shown in Figure 1.

3.1.1. Contents include:

- Styrofoam™ insulation box and lid
- Reusable secondary pressure vessel (plastic jar) with lid and o-ring containing:
  - Foam insert
  - Absorbent pad
- Fiberboard inner box containing fiberboard coil
- **BPV Discrepancy Checklist for White Kit (OP-0014-W3-F1)** with bag for paperwork (not shown in Figure 1)
- Pre-printed FedEx return label

3.1.2. Upon receipt and before kit is used, verify the contents. Do NOT use the kit if it is incomplete when verified against the **BPV Discrepancy Checklist for White Kit (OP-0014-W3-F1)**.

3.1.3. If the kit is incomplete or broken:

3.1.3.1. Complete BPV Discrepancy Checklist for White Kit (OP-0014-W3-F1).

3.1.3.2. Convert to PDF and email to the appropriate email address or call the provided phone number.

3.1.3.3. CBR will follow up with an action for resolution.

Figure 1: White Kit (Dry Ice)

Packing Instructions

3.2. On the day the kit is to be shipped, complete the following steps:

NOTE: The BSSs will be directed by the BSS technical project manager (TPM) or CBR TPM to ship 8 cases (2 tubes/case) at a time to reduce shipping costs. PAXgene blood will be held at a temperature of 75°C ± 5°C until eight cases are ready to ship. BSSs may also be directed to ship earlier with fewer cases under direction of the TPM. The White Kit will hold 16 frozen PAXgene vials (2 vials/case). There will be 3 empty spots.

3.2.1. Remove an insulated White Kit from the storage area.

3.2.2. Locate dry ice and have available to fill the kit.

3.2.3. Remove 8 cases (16 tubes total) of PAXgene tubes from –75°C ± 5°C storage. Keep on dry ice until ready to pack.

3.2.4. Place the tubes upright in the foam insert in the inner plastic jar of the White Kit. Once loaded in the plastic jar, close the lid and place the plastic jar into the inner fiberboard box.

3.2.5. Close the inner fiberboard box (do not tape/seal) and ensure the inner box is placed in the center of the White Kit such that the box sits in the groove.

3.2.6. Fill the White Kit with dry ice. Ensure dry ice fills the kit surrounding the inner box on all sides. Dry ice should be filled up to the edges of the white Styrofoam. Do not place dry ice on top of the inner fiberboard box; otherwise, closing will be difficult.

3.2.7. Activate the dry ice data logger according to the **Dry Ice Data Logger Usage (PBS-01.092)**.

3.2.8. Place the activated logger into the inner fiberboard box and on top of the lid of the plastic jar (see Figure 2). Re-close the inner fiberboard box (no need to seal this inner box. The Styrofoam lid will ensure it stays closed).

Figure 2: White (Dry Ice) Data logger placement

3.2.9. Place the Styrofoam™ lid on the insulated shipper.

3.2.10. Place a manifest and the **Chain of Custody Form (OP-0011-F1)** on top of the Styrofoam™ lid. (Note: Ensure you keep a copy of each of these forms for your records.)

3.2.11. Fold the plastic bag over the lid, close the outer shipping box, and tape it closed.

3.2.12. Apply the provided pre-printed FedEx label to the top of the box.

3.2.13. Remove the yellow colored "PEEL OFF LABEL BEFORE SAMPLES ARE SHIPPED" label on the outside of the shipping package so that the UN3373 labeling underneath is visible.

3.2.14. Remove the yellow colored "PEEL OFF LABEL BEFORE SAMPLES ARE SHIPPED" labels on the outside of the shipping package so that the CLASS 9 MISCELLANEOUS SHIPPING LABEL (dry ice label) is visible. This label must be **totally** uncovered; otherwise, FedEx may refuse the package.

NOTE: The uncovered label should already have the amount of dry ice (6 kg) written on the exposed label. Be sure to verify this has been written on the dry ice label. COURIER (FedEx) WILL REFUSE SHIPMENT IF THE DRY ICE WEIGHT IS NOT LISTED!

Shipping Instructions

3.3. Contact the CBR to coordinate a shipment prior to sending the White Kit.

3.4. Verify all steps are complete and ship to the CBR via FedEx overnight to the appropriate address (using the included pre-printed FedEx return label). Deliver or call FedEx for shipment of the White Kit.

Alert of Shipment

3.5. Timeline of alert to CBR

3.5.1. Upon shipment of specimens. Be sure this has been coordinated with the BSS TPM and CBR TPM.

3.6. Method of alert to CBR: **EMAIL**

3.6.1. Please include ALL BPV Case IDs (x8) in the subject line of all emails.

3.6.2. Indicate notice of pending shipment.

3.6.3. Indicate date of anticipated shipment.

3.6.4. Indicate date of anticipated arrival at the CBR.

3.6.5. Indicate tracking number/company used to ship.

3.7. Use the following instructions for the email template for correspondence to the CBR:

3.7.1. Subject line: Name of BSS, ALL BPV Case IDs (x8), White Kit

3.7.2. Body of email:

"*Hello CBR,*
Please consider this email notification that a Dry Ice shipment containing (how many) BPV cases is being packed and is being shipped.

- *The FedEx shipment will be shipped to you on <INSERT DATE> and is expected to arrive by <INSERT DATE>. The tracking number of the shipment to the CBR is <INSERT TRACKING NUMBER>.*

Thank You,
<Insert Site Name>

3.8. Email a copy of the **Chain of Custody Form (OP-0011-F1)** to the appropriate authority. Please fill out all pertinent sections for the BSS.

4.0 ACRONYMS

BPV Biospecimen Pre-Analytical Variables

BSS Biospecimen Source Site

CBR Comprehensive Biospecimen Resource

TPM Technical Project Manager

5.0 REFERENCES

- Biospecimen Pre-Analytical Variables (BPV) Program Surgical Tissue Collection and Fixation, PR-0006
- Biospecimen Pre-Analytical Variables (BPV) Program Blood Sample Collection and Processing, PR-0005
- Dry Ice Data Logger Usage, PBS-01.092
- Chain of Custody Procedure, OP-0011

6.0 ATTACHMENTS

- BPV Discrepancy Checklist for White Kit, OP-0014-W3-F1
- Chain of Custody Form, OP-0011-F1