

# Biospecimen Pre-Analytical Variables (BPV) Kit Receipt, Supplies, and Shipping Procedure

OP-0014

VER. 03.00

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Page 1 of 4

## 1.0 PURPOSE

This procedure describes the process that biospecimen source sites (BSSs) follows to receive collection kits from the Comprehensive Biospecimen Resource (CBR) and the process that the BSSs use to package biospecimens and ship them to the CBR.

## 2.0 SCOPE

This procedure applies to all of the organizations involved in the migration of biospecimens, specifically the CBR and the BSSs.

## 3.0 RESPONSIBILITY

- 3.1 **BSS:** will collect and ship biospecimens to the appropriate processing/analysis facility.
- 3.2 **CBR:** will manage the preparation and distribution of the shipping kits and receipt of the Red Kit, White Kit, and Blue Kit specimen collections.
- 3.3 **Study Management Group:** will train the BSSs on the type of biospecimens to be collected and their transportation requirements (e.g., shipping temperature, International Air and Transportation Association [IATA] regulation).

## 4.0 ACRONYMS AND DEFINITIONS

<b>BPV</b>	Biospecimen Pre-Analytical Variables
<b>BSS</b>	Biospecimen Source Site, an institution contracted to perform tissue and data procurement.
<b>CBR</b>	Comprehensive Biospecimen Resource
<b>CDR</b>	Comprehensive Data Resource
<b>FFPE</b>	Formalin-Fixed, Paraffin-Embedded
<b>IATA</b>	International Air Transport Association, the oversight authority for the airline industry
<b>TPM</b>	Technical Project Manager

## 5.0 ENVIRONMENTAL HEALTH AND SAFETY

- 5.1 Persons packaging and/or signing transport documents must be trained and/or certified to ship the appropriate hazard class according to IATA/International Civil Aviation Organization regulations.
  - 5.1.1 Training may be conducted through the BSS or offered through LBRI.

- 5.1.2 Verification of training materials, testing, and certification must be provided to the LBRI team to certify all staff involved with shipping procedures.
- 5.2 Persons handling liquid nitrogen and dry ice should be aware of the hazards associated with packing these shipments. Dry ice must be identified under UN1845.
- 5.3 Appropriate personal protective equipment should be worn at all times, including but not limited to the following:
- Gown or lab coat
  - Hair bonnet, mask, and shoe covers; per institutional requirements
  - Latex or nitrile rubber gloves
  - Freezer or LN<sub>2</sub> gloves

## 6.0 MATERIALS AND EQUIPMENT

- 6.1 BBRB/BPV Dry Ice PAXgene Blood Specimen Collection (the White Kit)
- 6.2 BBRB/BPV LN<sub>2</sub> Vapor Phase Blood Derivatives and Tissue Collection (the Red Kit)
- 6.3 BBRB/BPV FFPE and Slide Collection (the Blue Kit)

## 7.0 PROCEDURE

### Kit Supplies to the BSSs

- 7.1 The CBR will provide the following kits to each BSS: the White Kit, the Red Kit, and the Blue Kit. Follow the appropriate work instructions when receiving each kit (**OP-0014-W1, OP-0014-W2, OP-0014-W3**).
- 7.2 The BSS verifies the contents of routine kit shipments against the appropriate discrepancy checklists **OP-0014-W1-F1, OP-0014-W2-F1, OP-0014-W3-F1, and OP-0014-F1**.

### Collection Event and Packing

- 7.3 Once a donor has been identified, retrieve a Blue Kit and BPV Overpack from the kit storage location. **NOTE: The BPV Red Kit and White Kit are used only for shipping samples back to the CBR after eight donors have been collected and are ready to be shipped or as directed by BSS technical project manager (TPM) in conjunction with the CBR TPM.**
- 7.4 Collect the specimen(s) by using **BPV Program Blood Sample Collection and Processing (PR-0005)** and **BPV Program Surgical Tissue Collection and Fixation (PR-0006)**.

## Biospecimen Pre-Analytical Variables (BPV) Kit Receipt, Supplies, and Shipping Procedure

OP-0014

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Effective Date: TBD

Page 3 of 4

- 7.5 Upon collection of dry ice samples (White Kit), immediately store specimens at -18°C to -22°C for 24 hours and then place in a -70°C to -80°C freezer until at least eight cases are ready to be shipped to the CBR.
- 7.6 Upon collection of liquid nitrogen vapor phase samples (Red Kit), immediately store specimens in a liquid nitrogen vapor phase storage unit at -135°C to -196°C until at least eight cases are ready to be shipped to the CBR or as directed by the BSS TPM.
- 7.7 Prepare the collected specimen(s) for shipment by using the appropriate color-coded work instruction: use the **BPV Work Instruction for FFPE Blue Kit Receipt and Shipping (OP-0014-W1)**, the **BPV Work Instruction for the (LN2) Red Kit Receipt and Shipping (OP-0014-W2)**, or the **BPV Work Instruction for White Kit Receipt and Shipping (OP-0014-W3)**.
- 7.8 All cases will be shipped regardless of whether they are complete. Incomplete cases are considered in the total number that a BSS has been requested to collect.

### Alerts and Kit Shipping

- 7.9 Manually alert the CBR of the collection shipment by using the appropriate color-coded work instruction: for the Blue Kit, use the Alert of Pending Collection subsection in the **BPV Work Instruction for FFPE Blue Kit Receipt and Shipping (OP-0014-W1)**; for the Red Kit, use the Alert of Shipment subsection in the **BPV Work Instruction for Red (LN2) Kit Receipt and Shipping (OP-0014-W2)**; and for the White Kit, use the Alert of Shipment subsection in the **BPV Work Instruction for White Kit Receipt and Shipping (OP-0014-W3)**.
- 7.10 Ship each kit according to the appropriate color-coded work instructions: For the Blue Kit, use the Shipping Instructions subsection in the **BPV Work Instruction for FFPE Blue Kit Receipt and Shipping (OP-0014-W1)**; for the Red Kit, use the Shipping Instructions subsection in the **BPV Work Instruction for the Red (LN2) Kit Receipt and Shipping (OP-0014-W2)**; and for the White Kit, use the Shipping Instructions subsection in the **BPV Work Instruction for White Kit Receipt and Shipping (OP-0014-W3)**.

## 8.0 REFERENCES

- 8.1 Biospecimen Pre-Analytical Variables (BPV) Program Blood Sample Collection and Processing, PR-0005
- 8.2 Biospecimen Pre-Analytical Variables (BPV) Program Surgical Tissue Collection and Fixation, PR-0006
- 8.3 Biospecimen Pre-Analytical Variables (BPV) Program FFPE Tissue Processing, OP-0003

## Biospecimen Pre-Analytical Variables (BPV) Kit Receipt, Supplies, and Shipping Procedure

OP-0014

VER. 03.00

Effective Date: TBD

Page 4 of 4

### 9.0 ATTACHMENTS

- 9.1 BPV Discrepancy Checklist for Overpack Kit, OP-0014-F1
- 9.2 BPV Work Instruction for FFPE Blue Kit Receipt and Shipping, OP-0014-W1
- 9.3 BPV Discrepancy Checklist for Blue Kit, OP-0014-W1-F1
- 9.4 BPV Blue Kit Manifest, OP-0014-W1-F2
- 9.5 BPV Work Instruction for the Red (LN2) Kit Receipt and Shipping, OP-0014-W2
- 9.6 BPV Discrepancy Checklist for Red Kit, OP-0014-W2-F1
- 9.7 BPV Work Instruction for White Kit Receipt and Shipping, OP-0014-W3
- 9.8 BPV Discrepancy Checklist for White Kit, OP-0014-W3-F1