

Biospecimen Pre-Analytical Variables (BPV) Blood Collection and Processing Form

PR-0005-F1

VER. 03.06

Effective Date: 1/12/2015

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BPV Case ID _____

Affix BPV Case ID Barcode Label

Form Completed By: _____

Date Form Was Completed: ____/____/____

(MM/DD/YYYY)

Tissue Bank ID: _____

Blood Collection Instructions

1. **Blood Collection and Processing Standard Operating Procedure (SOP): PR-0005 BPV Blood Collection and Processing**

PLEASE NOTE: Collection of blood in the plasma ethylenediamine tetraacetic acid (EDTA) tube is mandatory. The volume of blood to be collected in the EDTA tube is 10.0 mL such that at least 12 plasma aliquots (0.25 mL plasma per aliquot) and three whole cell pellet aliquots (1.0 mL whole cell pellet per aliquot) are collected. Collection of blood in the DNA PAXgene/RNA PAXgene tubes is optional. If blood is collected in the optional tubes, the minimum requirement is as follows: (1) DNA PAXgene blood tube with 4.0 mL blood and (1) RNA PAXgene blood tube with 1.0 mL blood. If the minimum requirement for pre-operative blood collection as specified in the SOP is not met, this participant is NOT ELIGIBLE to continue in the study. Do not collect tissue from this participant.

2. **a. The Minimum Requirement Was Met for Pre-Operative Blood Collection as per the SOP (EDTA Tube): Select one:**

☐ Yes

☐ No *If No, answer question 2b.*

2. **b. Was approval received from Leidos Biomedical Research, Inc., to proceed with collection? Select one:**

☐ Yes *If Yes, upload the approval to Case Detail Page to proceed.*
☐ No *If No, the questions below are not applicable. Do not continue.*

3. **Blood Draw Type. Select one:**

☐ Pre-Operative (Pre-Anesthesia)

☐ Other, Specify

Specify Other Blood Draw Type:

4. **Date and Time Blood Was Drawn:**

 ____/____/____
 (MM/DD/YYYY)

 ____:____
 (HH:MM)

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5. **Blood Draw Was Performed By:** *Select one:*

- ☐ Anesthesiologist
- ☐ Consent or Research Analyst/Coordinator
- ☐ Nurse
- ☐ Nurse Anesthetist
- ☐ O.R. Technician
- ☐ Phlebotomist
- ☐ Unknown
- ☐ Other, Specify

Specify Role of Other Blood Drawer: _____

Name of Person Who Performed Blood Draw: _____

Plasma Randomization Key ID: _____

Blood Collection Tube Details: Enter Information for Each Tube Collected

- ☐ **Specimen Tube Type:** EDTA Tube (Mandatory)
Collection Tube Specimen Barcode ID: _____
Processed for: Blood, Plasma
Volume Collected: _____ mL
- ☐ **Specimen Tube Type:** DNA PAXgene Tube (Optional)
Collection Tube Specimen Barcode ID: _____
Processed for: Blood, DNA
Volume Collected: _____ mL
- ☐ **Specimen Tube Type:** RNA PAXgene Tube (Optional)
Collection Tube Specimen Barcode ID: _____
Processed for: Blood, RNA
Volume Collected: _____ mL

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6. Blood Source: *Select one:*
☐ Fresh Venous Needle Stick

☐ Other, Specify:

Specify Other Blood Source: _____

7. Blood Collection Comments:
Blood Processing Overview
8. Date and Time Blood Received in the Lab:

 ____/____/_____
 (MM/DD/YYYY)

 ____:____
 (HH:MM)

9. Blood Tube(s) Received in Lab By: _____

10. Temperature in Lab When Blood Was Received: _____ °C

11. Humidity in Lab When Tube(s) Were Received: _____ %

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Optional: (1) DNA PAXgene Tube (Minimum of 4.0 mL of Blood Required)

12. DNA PAXgene Tube Specimen Barcode ID: _____

 13. Time DNA PAXgene Tube Was Frozen at $-20^{\circ}\text{C} \pm 2^{\circ}\text{C}$: ____:____
 (HH:MM)

 14. Time DNA PAXgene Tube Was Transferred to Storage at $-75^{\circ}\text{C} \pm 5^{\circ}\text{C}$: ____:____
 (HH:MM)

15. DNA PAXgene Tube Was Stored By: _____

Note Deviations From SOP, Processing or Storage Issues

 16. DNA PAXgene Tube Was Collected and Stored in Accordance With the Specified SOP. *Select one*
☐ Yes
☐ No

17. DNA PAXgene Tube Collection Comments:

18. DNA PAXgene Tube Storage Comments:

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 (MM/DD/YYYY)

Optional (1) RNA PAXgene Tube (Minimum of 1.0 mL of Blood Required)

19. RNA PAXgene Tube Specimen Barcode ID: _____

 20. Time RNA PAXgene Tube Was Frozen at $-20^{\circ}\text{C} \pm 2^{\circ}\text{C}$: ____:____
 (HH:MM)

 21. Time RNA PAXgene Tube Was Transferred to Storage at $-75^{\circ}\text{C} \pm 5^{\circ}\text{C}$: ____:____
 (HH:MM)

22. RNA PAXgene Tube Was Stored By: _____

Note Deviations From SOP, Processing or Storage Issues

 23. RNA PAXgene Tube Was Collected and Stored in Accordance With the Specified SOP. *Select one:*
☐ Yes

☐ No

24. RNA PAXgene Tube Collection Comments:

25. RNA PAXgene Tube Storage Comments:

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 (MM/DD/YYYY)

Mandatory: Plasma Aliquots — 12 (0.25 mL) Plasma Aliquots
EDTA Tube Centrifugation

26. EDTA Collection Tube Specimen Barcode ID: _____

 27. Time Plasma Processing Began: ____:____
 (HH:MM)

28. Conical Centrifuge Tube Code: _____

29. a. Conical Tube Volume: _____ mL

**b. Aliquot Details: Enter Information for Each Aliquot Derived from Conical Centrifuge Tube
 (Minimum of 12 Aliquots Containing 0.25 mL of Plasma, 1.2 mL Cryovials)**

	Plasma Aliquot Specimen Barcode ID:	Plasma Aliquot Volume (mL):	Time Placed on Dry Ice: (HH:MM)	Scanned ID of Cryovial When Transferred:	Time Transferred to Freezer: (HH:MM)	Freezer Type Transferred to:
Aliquot 1						
Aliquot 2						
Aliquot 3						
Aliquot 4						
Aliquot 5						
Aliquot 6						
Aliquot 7						
Aliquot 8						
Aliquot 9						
Aliquot 10						
Aliquot 11						
Aliquot 12						
Aliquot 13						
Aliquot 14						
Aliquot 15						
Aliquot 16						

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30. Plasma Aliquots Were Processed By: _____

31. Frozen Plasma Transfer Completed By: _____

Note Deviations from SOP, Processing or Storage Issues

32. Plasma Processing Was Performed in Accordance With Specified SOP. *Select one:*

☐ Yes

☐ No

33. Plasma Processing Comments:

34. Was Presence of Gross Hemolysis of Plasma Observed? *Select one:*

☐ Yes

☐ No

35. Plasma Storage Issues:

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Mandatory: Whole Cell Pellet – (3) 1.0 mL aliquots

Whole Cell Pellet Information

36. a. Volume of Whole Cell Pellet: _____ mL

This is the volume remaining after the plasma has been removed

b. Aliquot Details: Enter information for Each Aliquot Derived From Collection Tube

	Whole Cell Pellet Aliquot Specimen Barcode ID:	Whole Cell Pellet Aliquot Volume (mL):
Aliquot 1		
Aliquot 2		
Aliquot 3		
Aliquot 4		
Aliquot 5		

 37. Time Whole Cell Pellet Aliquots Processing Was Completed: ____:____
 (HH:MM)

 38. Time Whole Cell Pellet Aliquots Were Frozen (-80 °C): ____:____
 (HH:MM)

 39. Time Whole Cell Pellet Aliquots Were Transferred to Storage: ____:____
 (HH:MM)

40. Whole Cell Pellet Aliquots Were Processed By: _____

Note Deviations from SOP, Processing or Storage Issues

 41. Whole Cell Pellet Processing Was Performed in Accordance With the Specified SOP. *Select one:*
☐ Yes

☐ No

42. Whole Cell Pellet Processing Comments:

43. Whole Cell Pellet Storage Issues: