

Lab Processing Chart
P1107

Observational Study of Cord Blood Transplantation Using CCR5Δ32 Donor Cells
For the Treatment Underlying Disease in HIV Infected Patients and its Effect on HIV-1 Eradication

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Section 1: Schedule of Laboratory Evaluations (Copied from Protocol Document v.1.0, Appendix IA Pre-transplant Cohort – Participants ≥ 50kg)

APPENDIX I-A
SCHEDULE OF EVALUATIONS - Participants ≥ 50kg
Pre-transplant Cohort

	Entry ¹	Pre-conditioning	Day 0 ⁶ HSCT	Monthly	Day 100	Week 26	Week 52	Week 78	Week 104	Week 130	Week 156	Week 182	Week 208	Week 234	Week 260	PRN as done for standard of care	Early D/C	Death
Visit Windows					±2wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk			
Laboratory Evaluations																		
Resting CD4+T cell latent reservoir		50mL						50 mL		50 mL		50 mL		50mL			50mL	
Chimerism - CCR5Δ32 ²	3.5mL				3.5 mL		3.5 mL ⁷										3.5mL	
HIV-1 tropism		6mL							6mL		6mL	6mL						
Immunology assays ³	30mL				40 mL	20mL ⁸	30 mL		30 mL		30 mL		30 mL		30mL			
Virology assays ⁴																		
Biopsy specimens ⁵																X		
Autopsy																		X
TOTAL BLOOD VOLUMES (mL)	33.5 mL	56mL	0mL		43.5 mL	20mL	33.5 mL	50 mL	36 mL	50 mL	36 mL	56 mL	30 mL	50mL	30mL	0mL	53.5 mL	0mL

If a subject on Appendix I-A stops taking ARVs post Day 100 for longer than 14 consecutive days, they should switch to Appendix I-C since they will have more frequent blood draws for a short time. If they subsequently then re-start ARVs, they should complete the 'Back on ART' visit in Appendix I-C and then switch back to their original SOE at their current post-transplant time point (Appendix I-A).

Footnotes

1. Entry visit should include documentation of HIV-1 infection, HIV-1 diagnosis.
2. All chimerism assays except for CCR5Δ32 will be done as part of standard of care by the bone marrow team as part of the transplant.
3. Special immunology tests include the following: Immune activation markers, HIV-1 specific cytokine response by flow, IV specific cytokine responses by Elispot, T cell maturation subsets, B cell maturation subsets.
4. Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot, in vitro susceptibility testing of donor cells to HIV-1 infection (day 100 and week 52 only).
5. Gut biopsies will only be performed as part of standard of care. If the subject provides consent, a specimen should be collected for research purposes. Gut pathology: HIV-1 RNA/DNA isolation and quantitation and CCR5 expression by PCR. Please contact the team for further guidance.
6. Day 0 (HSCT) is the day of transplant. There is no participant study visit on this date.
7. The chimerism assay should only be repeated if the Day 100 chimerism was <95%.
8. Special immunology/virology tests to be performed at this time point include the following: Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot and immune activation markers

For insufficient blood draws, priorities are as follows: Standard of care tests, EDTA tubes (P1107 study bloods).

At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available i.e., <50mL) should be shipped to Lab 428 for the resting CD4+ T cell assay.

Section 2: Safety/Clinical Laboratory Evaluations

Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.

Evaluation	Tube Type	Tests	CRF # DMC Test Code
<p>Biopsy specimens If participants undergo biopsy for standard of care clinical indications, residual tissue will be requested for study purposes</p>	<p>EDTA for Bone Marrow</p>	<p>Residual sections of biopsies-formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment. to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Gut Biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Mon-Wed. Bone marrow specimens- are to be processed according to instructions in Section 7. Cryopreserved cells are to be shipped to Dr. Persaud's Lab 428 Mon-Wed. Other biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed.</p>	<p>BXW1 F3008 STORMIX</p>
<p>Autopsy If autopsy is performed, residual tissue will be requested for study purposes</p>	<p>N/A</p>	<p>Residual sections of formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Specimens are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed. At a minimum these specimens are requested: thymus, lymph nodes, spleen and tonsil specimens.</p>	<p>BXW1 F3008 STORMIX</p>

Priority of specimen collection: All blood samples are collected in EDTA tubes. At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available) should be shipped to Lab 428 for the resting CD4+ T cell assay.

Section 3: Specimen Processing – Refer to Section 4 for collection volumes for these assays at each visit

Evaluation	Tube Type	Special Collection Notes	CRF # DMC Test Code	Processing	Shipping
Resting CD4+T cell latent reservoir	EDTA	N/A	F3008 CXHIVUS	N/A	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Dr. Deborah Persaud’s Lab (LDMS Lab 428). Notify lab the week before of upcoming visits. Notify lab by fax/ phone the day the sample is being shipped.
Chimerism -CCR5Δ32	EDTA	N/A	F3008 GENOHUM	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (6 X 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship 1 x 2.5@10⁶ PBMC in dry nitrogen shipper to Stemcyte TBD lab upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
HIV-1 tropism	EDTA	N/A	F3008 CTHIVPHN	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (10 x 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC on dry ice to Monogram upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
Immunology / Virology assays	EDTA	N/A	F3008 STORMIX	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25-0.5mL aliquots. If specimen collected is QNS, aliquot plasma 0.25mL/vial to achieve desired number of aliquots. Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC in dry nitrogen shipper to Dr. Pahwa/Dr. Bryson/Dr. Persaud or alternate lab upon team request. Plasma to be shipped on dry ice.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.

Section 4: Evaluations by Visit

Appendix I-A Entry (LDMS Vst/Vst unit = 0/ENT)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism -CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Pre-conditioning: ± 3 days (LDMS Vst/Vst unit= 0/EDV)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Day 100: ± 2 weeks (LDMS Vst/Vst unit= 15/WK) Same Wk as on CRF

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism –CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	40mL EDTA	F3008	Processing Lab: 38 x 0.5mL BLD/EDT/PL2 16 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Week 26: ± 8 weeks (LDMS Vst/Vst unit= 26/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	20mL EDTA	F3008	Processing Lab: 18 x 0.5mL BLD/EDT/PL2 8 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Week 52: ± 8 weeks (LDMS Vst/Vst unit= 52/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism - CCR5Δ32 only required at this visit if the Day 100 chimerism was <95%.	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Should only be repeated if the Day 100 chimerism was <95%. Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Week 78: ± 8 weeks (LDMS Vst/Vst unit= 78/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix I-A Week 104: ± 8 weeks (LDMS Vst/Vst unit= 104/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Week 130: ± 8 weeks (LDMS Vst/Vst unit= 130/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix I-A Week 182: ± 8 weeks (LDMS Vst/Vst unit= 182/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Week 208: ± 8 weeks (LDMS Vst/Vst unit= 208/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Week 234: ± 8 weeks (LDMS Vst/Vst unit= 234/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix I-A Week 260: ± 8 weeks (LDMS Vst/Vst unit= 260/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A PRN as done for SOC (LDMS Vst/Vst unit= X/EDV)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Biopsy Specimens	Refer to Section 2 and 7.	BXW1 F3008	To be determined by Primary Specimen and processing.	Refer to LDMS User Manual Appendix A: LDMS codes. Bone marrow=BMA/EDT/CLN/DMS	To be performed as SOC with extra specimens to be collected and shipped to Lab 528 or Lab 428 or Lab 130 determined by specimen type.

Appendix I-A Early D/C (LDMS Vst/Vst unit= X/EXT)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-A Death (LDMS Vst/Vst unit = X/AUT)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Autopsy	Refer to Section 2.	BXW1 F3008	N/A	Refer to LDMS User Manual Appendix A: LDMS codes.	To be performed as SOC with extra specimens to be collected and shipped to Dr. Peter Anton's lab (LDMS Lab 528). Dr. Grace Aldrovandi's lab (LDMS Lab 130).

APPENDIX I-B
SCHEDULE OF EVALUATIONS - Participants ≥ 50kg
Post-transplant Cohort

	Entry into study ¹	Monthly	Day 100	Week 26	Week 52	Week 78	Week 104	Week 130	Week 156	Week 182	Week 208	Week 234	Week 260	PRN as done for standard of care	Early D/C	Death
Visit Windows	-	-	±2wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	-	-	-
Laboratory Evaluations																
Resting CD4+T cell latent reservoir	50mL					50mL		50mL		50mL		50mL			50mL	
Chimerism CCR5Δ32 ²	3.5mL		3.5mL		3.5mL ⁶										3.5mL	
HIV-1 tropism							6mL		6mL	6mL						
Special Immunology ³	30mL		40mL	20mL ⁷	30mL		30mL		30mL		30mL		30mL			
Special virology ⁴																
Biopsy specimens														X		
Autopsy																X
TOTAL BLOOD VOLUMES (mL)	83.5mL		43.5 mL	20mL	33.5 mL	50mL	36mL	50mL	36mL	56mL	30mL	50mL	30mL	0mL	53.5mL	0mL

NOTE: If a subject on Appendix I-B stops taking ARVs post Day 100 for longer than 14 consecutive days, they should switch to Appendix I-C since they will have more frequent blood draws for a short time. If they subsequently then re-start ARVs, they should complete the 'Back on ARV' visit in Appendix I-C and then switch back to their original SOE (Appendix I-B).

Footnotes

1. Entry visit should include documentation of HIV-1 infection, HIV-1 diagnosis.
2. All chimerism assays except for CCR5 Δ 32 will be done as standard of care by the bone marrow team as part of the transplant. The chimerism assay should only be repeated if the Day 100 chimerism was <95%.
3. Special immunology tests include the following: Immune activation markers, HIV-1 specific cytokine response by flow, HIV specific cytokine responses by Elispot, T cell maturation subsets, B cell maturation subsets.
4. Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot, in vitro susceptibility testing of donor cells to HIV-1 infection (day 100 and week 52 only).
5. Gut biopsies will only be performed as part of standard of care. If the subject provides consent, a specimen should be collected for research purposes. Gut pathology: HIV-1 RNA/DNA isolation and quantitation and CCR5 expression by PCR. Please contact the team for further guidance.
6. The chimerism assay should only be repeated if the Day 100 chimerism was <95%.
7. Special immunology/virology tests to be performed at this time point include the following: Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot and immune activation markers.

For insufficient blood draws, priorities are as follows: Standard of care tests, EDTA tubes (P1107 study bloods)

At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available) should be shipped to Lab 428 for the resting CD4+ T cell assay.

Section 2: Safety/Clinical Laboratory Evaluations

Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.

Evaluation	Tube Type	Tests	CRF # DMC Test Code
<p>Biopsy specimens If participants undergo biopsy for standard of care clinical indications, residual tissue will be requested for study purposes</p>	<p>EDTA for Bone Marrow</p>	<p>Residual sections of biopsies-formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment. to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Gut Biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Mon-Wed. Bone marrow specimens- are to be processed according to instructions in Section 7. Cyropreserved cells are to be shipped to Dr. Persaud's Lab 428 Mon-Wed. Other biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed.</p>	<p>BXW1 F3008 STORMIX</p>
<p>Autopsy If autopsy is performed, residual tissue will be requested for study purposes</p>	<p>N/A</p>	<p>Residual sections of formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Specimens are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed. At a minimum these specimens are requested: thymus, lymph nodes, spleen and tonsil specimens.</p>	<p>BXW1 F3008 STORMIX</p>

Section 3: Specimen Processing – Refer to Section 4 for collection volumes for these assays at each visit					
Evaluation	Tube Type	Special Collection Notes	CRF # DMC Test Code	Processing	Shipping
Resting CD4+T cell latent reservoir	EDTA	N/A	F3008 CXHIVUS	N/A	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428). Notify lab the week before of upcoming visits. Notify lab by fax/ phone the day the sample is being shipped.
Chimerism - CCR5Δ32	EDTA	N/A	F3008 GENOHUM	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (6 X 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship 1 x 2.5@10⁶ PBMC in dry nitrogen shipper to Stemocyte TBD lab upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi's LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
HIV-1 tropism	EDTA	N/A	F3008 CTHIVPHN	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (10 x 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC on dry ice to Monogram upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi's LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
Immunology / Virology assays	EDTA	N/A	F3008 STORMIX	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25-0.5mL aliquots. If specimen collected is QNS, aliquot plasma 0.25mL/vial to achieve desired number of aliquots. Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC in dry nitrogen shipper to Dr. Pahwa/Dr. Bryson/Dr. Persaud or alternate lab upon team request. Plasma to be shipped on dry ice.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi's LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.

Section 4: Evaluations by Visit

Appendix I-B Entry (LDMS Vst/Vst unit = 0/ENT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Day 100: ± 2 weeks (LDMS Vst/Vst unit= 15/WK) Same Wk as on CRF					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism – CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	40mL EDTA	F3008	Processing Lab: 38 x 0.5mL BLD/EDT/PL2 16 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Week 26: ± 8 weeks (LDMS Vst/Vst unit= 26/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	20mL EDTA	F3008	Processing Lab: 18 x 0.5mL BLD/EDT/PL2 8 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Week 52: ± 8 weeks (LDMS Vst/Vst unit= 52/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Week 78: ± 8 weeks (LDMS Vst/Vst unit= 78/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix I-B Week 104: ± 8 weeks (LDMS Vst/Vst unit= 104/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.25mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Week 130: ± 8 weeks (LDMS Vst/Vst unit= 130/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix I-B Week 156: ± 8 weeks (LDMS Vst/Vst unit= 156/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Week 182: ± 8 weeks (LDMS Vst/Vst unit= 182/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Week 208: ± 8 weeks (LDMS Vst/Vst unit= 208/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Week 234: ± 8 weeks (LDMS Vst/Vst unit= 234/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix I-B Week 260: ± 8 weeks (LDMS Vst/Vst unit= 260/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B PRN as done for SOC (LDMS Vst/Vst unit= X/EDV)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Biopsy Specimens	Refer to Section 2 and 7.	BXW1 F3008	To be determined by Primary Specimen and processing.	Refer to LDMS User Manual Appendix A: LDMS codes. Bone marrow=BMA/EDT/CLN/DMS	To be performed as SOC with extra specimens to be collected and shipped to Lab 528 or Lab 428 or Lab 130 determined by specimen type.

Appendix I-B Early D/C (LDMS Vst/Vst unit= X/EXT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-B Death (LDMS Vst/Vst unit = X/AUT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Autopsy	Refer to Section 2.	BXW1 F3008	N/A	Refer to LDMS User Manual Appendix A: LDMS codes.	To be performed as SOC with extra specimens to be collected and shipped to Dr. Peter Anton's lab (LDMS Lab 528). Dr. Grace Aldrovandi's lab (LDMS Lab 130).

APPENDIX I-C
SCHEDULE OF EVALUATIONS - Participants ≥ 50kg
Participants who stop antiretrovirals after Day 100

	Week 0 post-ART	Monthly	Week 4 post-ART	Week 12 post-ART	Week 26 post-ART	Every 26 weeks	Every 52 weeks	PRN as done for standard of care	Back on ART visit ¹	Early D/C	Death
Visit Windows	-	-	±4wk	±4wk	±8wk	±8wk	±8wk	-	-	-	-
Laboratory Evaluations											
Resting CD4+T cell latent reservoir	50 mL				50 mL		50mL		50 mL	50 mL	
Chimerism - CCR5Δ32									3.5mL	3.5mL	
HIV-1 tropism	6 mL				6 mL	6mL	6mL		6 mL	6 mL	
Immunology assays	30 mL		30mL	30mL	30mL	30mL	30mL				
Virology assays											
Biopsy specimens								X			
Autopsy											X
TOTAL BLOOD VOLUMES (mL)	86 mL		30 mL	30 mL	86 mL	36mL	86mL	0mL	59.5 mL	59.5 mL	0mL

NOTE: A participant is considered off ART if they have discontinued ART for longer than 14 consecutive days post Day 100. A participant may stop and then re-start ART more than once during the post-transplant period; each stop event post Day 100 requires re-starting the Appendix I-C SOE at Week 0.

Footnotes

1. If the participant or physicians choose to re-start ART, a 'Back on ART' visit is necessary. Once this visit has been completed, the subject should follow the original SOE (Appendix I-A or Appendix I-B) until the end of the study, starting where they left off.

For insufficient blood draws, priorities are as follows: Standard of care tests, EDTA tubes (P1107 study bloods) At 26 weeks visit if insufficient blood is obtained priority is blood to send to Miami for special virology and then the resting cell assay.

At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available) should be shipped to Lab 428 for the resting CD4+ T cell assay.

Section 2: Safety/Clinical Laboratory Evaluations			
<i>Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.</i>			
Evaluation	Tube Type	Tests	CRF # DMC Test Code
<p>Biopsy specimens</p> <p>If participants undergo biopsy for standard of care clinical indications, residual tissue will be requested for study purposes</p>	<p>EDTA for Bone Marrow</p>	<p>Residual sections of biopsies-formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment. to Dr. Peter Anton's lab.</p> <p>Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice.</p> <p>Gut Biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Mon-Wed.</p> <p>Bone marrow specimens- are to be processed according to instructions in Section 7. Cryopreserved cells are to be shipped to Dr. Persaud's Lab 428 Mon-Wed.</p> <p>Other biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed.</p>	<p>BXW1 F3008 STORMIX</p>
<p>Autopsy</p> <p>If autopsy is performed, residual tissue will be requested for study purposes</p>	<p>N/A</p>	<p>Residual sections of formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment to Dr. Peter Anton's lab.</p> <p>Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Specimens are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed. At a minimum these specimens are requested: thymus, lymph nodes, spleen and tonsil specimens.</p>	<p>BXW1 F3008 STORMIX</p>

Section 3: Specimen Processing – Refer to Section 4 for collection volumes for these assays at each visit					
Evaluation	Tube Type	Special Collection Notes	CRF # DMC Test Code	Processing	Shipping
Resting CD4+T cell latent reservoir	EDTA	N/A	F3008 CXHIVUS	N/A	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Dr. Deborah Persaud’s Lab (LDMS Lab 428). Notify lab the week before of upcoming visits. Notify lab by fax/ phone the day the sample is being shipped.
Chimerism - CCR5Δ32	EDTA	N/A	F3008 GENOHUM	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (6 X 0.2mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10 ⁶ . Processing lab to ship 1 x 2.5@10 ⁶ PBMC in dry nitrogen shipper to Stemcyte TBD lab upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
HIV-1 tropism	EDTA	N/A	F3008 CTHIVPHN	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (10 x 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10 ⁶ . Processing lab to ship PBMC on dry ice to Monogram upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
Immunology / Virology assays	EDTA	N/A	F3008 STORMIX	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25-0.5mL aliquots. If specimen collected is QNS, aliquot plasma 0.25mL/vial to achieve desired number of aliquots. Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10 ⁶ . Processing lab to ship PBMC in dry nitrogen shipper to Dr. Pahwa/Dr. Bryson/Dr. Persaud or alternate lab upon team request. Plasma to be shipped on dry ice.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.

Section 4: Evaluations by Visit

Appendix I-C Week 0 Post-ART: ± 8 weeks (LDMS Vst/Vst unit= 0/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C Week 4 Post-ART: ± 4 weeks (LDMS Vst/Vst unit= 4/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C Week 12 Post-ART : ± 4 weeks (LDMS Vst/Vst unit= 12/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C Week 26 Post-ART: ± 8 weeks (LDMS Vst/Vst unit= 26/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C Every 26 Weeks Post-ART: ± 8 weeks (LDMS Vst/Vst unit= X/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C Every 52 Weeks Post-ART ± 8 weeks (LDMS Vst/Vst unit= X/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C PRN done as Standard of Care (LDMS Vst/Vst unit= X/EDV)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Biopsy Specimens	Refer to Section 2 and 7.	BXW1 F3008	To be determined by Primary Specimen and processing.	Refer to LDMS User Manual Appendix A: LDMS codes. Bone marrow=BMA/EDT/CLN/DMS	To be performed as SOC with extra specimens to be collected and shipped to Lab 528 or Lab 428 or Lab 130 determined by specimen type.

Appendix I-C Back on ART visit (LDMS Vst/Vst unit= X/EDV)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C Early D/C visit (LDMS Vst/Vst unit= X/EXT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	50mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix I-C Death (LDMS Vst/Vst unit = X/AUT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Autopsy	Refer to Section 2.	BXW1 F3008	N/A	Refer to LDMS User Manual Appendix A: LDMS codes.	To be performed as SOC with extra specimens to be collected and shipped to Dr. Peter Anton's lab (LDMS Lab 528). Dr. Grace Aldrovandi's lab (LDMS Lab 130).

**APPENDIX II-A
SCHEDULE OF EVALUATIONS - Participants < 50kg
Pre-transplant Cohort**

	Entry ¹	Pre-conditioning	Day 0 ⁶ HSCT	Monthly	Day 100	Week 26	Week 52	Week 78	Week 104	Week 130	Week 156	Week 182	Week 208	Week 234	Week 260	PRN as done for standard of care	Early D/C	Death
Visit Windows	-				±2wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk			
Laboratory Evaluations																		
Resting CD4+T cell latent reservoir		40mL						40 mL		40 mL		40 mL		40mL			40mL	
Chimerism - CCR5Δ32 ²	3.5mL				3.5 mL		3.5 mL ⁷										3.5mL	
HIV-1 tropism		6mL							6mL		6mL	6mL						
Immunology assays ³	25mL				30 mL	20mL ⁸	25 mL		25 mL		25 mL		25 mL		25mL			
Virology assays ⁴																		
Biopsy specimens ⁵																X		
Autopsy																		X
TOTAL BLOOD VOLUMES (mL)	28.5 mL	46mL	0mL		33.5 mL	20mL	28.5 mL	40 mL	31 mL	40 mL	31 mL	46 mL	25 mL	40mL	25mL	0mL	43.5 mL	0mL

- If a subject on Appendix II-A stops taking ARVs post Day 100 for longer than 14 consecutive days, they should switch to Appendix IIC since they will have more frequent blood draws for a short time. If they subsequently then re-start ARVs, they should complete the 'Back on ART' visit in Appendix I-C and then switch back to their original SOE at their current post-transplant time point (Appendix I-A).

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Footnotes

1. Entry visit should include documentation of HIV-1 infection, HIV-1 diagnosis.
2. All chimerism assays except for CCR5Δ32 will be done as part of standard of care by the bone marrow team as part of the transplant.
3. Special immunology tests include the following: Immune activation markers, HIV-1 specific cytokine response by flow, IV specific cytokine responses by Elispot, T cell maturation subsets, B cell maturation subsets.
4. Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot, in vitro susceptibility testing of donor cells to HIV-1 infection (day 100 and week 52 only).
5. Gut biopsies will only be performed as part of standard of care. If the subject provides consent, a specimen should be collected for research purposes. Gut pathology: HIV-1 RNA/DNA isolation and quantitation and CCR5 expression by PCR. Please contact the team for further guidance.
6. Day 0 (HSCT) is the day of transplant. There is no participant study visit on this date.
7. The chimerism assay should only be repeated if the Day 100 chimerism was <95%.
8. Special immunology/virology tests to be performed at this time point include the following: Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot and immune activation markers

For insufficient blood draws, priorities are as follows: Standard of care tests, EDTA tubes (P1107 study bloods)

At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available) should be shipped to Lab 428 for the resting CD4+ T cell assay.

Section 2: Safety/Clinical Laboratory Evaluations

Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.

Evaluation	Tube Type	Tests	CRF # DMC Test Code
<p>Biopsy specimens If participants undergo biopsy for standard of care clinical indications, residual tissue will be requested for study purposes</p>	<p>EDTA for Bone Marrow</p>	<p>Residual sections of biopsies-formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment. to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Gut Biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Mon-Wed. Bone marrow specimens- are to be processed according to instructions in Section 7. Cyropreserved cells are to be shipped to Dr. Persaud's Lab 428 Mon-Wed. Other biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed.</p>	<p>BXW1 F3008 STORMIX</p>
<p>Autopsy If autopsy is performed, residual tissue will be requested for study purposes</p>	<p>N/A</p>	<p>Residual sections of formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Specimens are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed. At a minimum these specimens are requested: thymus, lymph nodes, spleen and tonsil specimens.</p>	<p>BXW1 F3008 STORMIX</p>

Section 3: Specimen Processing – Refer to Section 4 for collection volumes

Evaluation	Tube Type	Special Collection Notes	CRF # DMC Test Code	Processing	Shipping
Resting CD4+T cell latent reservoir	EDTA	N/A	F3008 CXHIVUS	N/A	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428). Notify lab the week before of upcoming visits. Notify lab by fax/ phone the day the sample is being shipped.
Chimerism -CCR5Δ32	EDTA	N/A	F3008 GENOHUM	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (6 X 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship 1 x 2.5@10⁶ PBMC in dry nitrogen shipper to Stemcyte TBD lab upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi's LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
HIV-1 tropism	EDTA	N/A	F3008 CTHIVPHN	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (10 x 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC on dry ice to Monogram upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi's LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
Immunology / Virology assays	EDTA	N/A	F3008 STORMIX	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25-0.5mL aliquots. If specimen collected is QNS, aliquot plasma 0.25mL/vial to achieve desired number of aliquots. Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC in dry nitrogen shipper to Dr. Pahwa/Dr. Bryson/Dr. Persaud or alternate lab upon team request. Plasma to be shipped on dry ice.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi's LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.

Section 4: Evaluations by Visit

Appendix II-A Entry (LDMS Vst/Vst unit = 0/ENT)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism -CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Pre-conditioning: ± 3 days (LDMS Vst/Vst unit= 0/EDV)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Day 100: ± 2 weeks (LDMS Vst/Vst unit= 15/WK) Same Wk as on CRF

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism –CCR5Δ32	3.5mL	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Week 26: ± 8 weeks (LDMS Vst/Vst unit= 26/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	20mL EDTA	F3008	Processing Lab: 18x 0.5mL BLD/EDT/PL2 8 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Week 52: ± 8 weeks (LDMS Vst/Vst unit= 52/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism -CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Week 78: ± 8 weeks (LDMS Vst/Vst unit= 78/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix II-A Week 104: ± 8 weeks (LDMS Vst/Vst unit= 104/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Week 130: ± 8 weeks (LDMS Vst/Vst unit= 130/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix II-A Week 156: ± 8 weeks (LDMS Vst/Vst unit= 156/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Week 182: ± 8 weeks (LDMS Vst/Vst unit= 182/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Week 208: ± 8 weeks (LDMS Vst/Vst unit= 208/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10 ⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Week 234: \pm 8 weeks (LDMS Vst/Vst unit= 234/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix II-A Week 260: \pm 8 weeks (LDMS Vst/Vst unit= 260/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A PRN as done for SOC (LDMS Vst/Vst unit= X/EDV)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Biopsy Specimens	Refer to Section 2 and 7.	BXW1 F3008	To be determined by Primary Specimen and processing.	Refer to LDMS User Manual Appendix A: LDMS codes. Bone marrow=BMA/EDT/CLN/DMS	To be performed as SOC with extra specimens to be collected and shipped to Lab 528 or Lab 428 or Lab 130 determined by specimen type.

Appendix II-A Early D/C (LDMS Vst/Vst unit= X/EXT)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-A Death (LDMS Vst/Vst unit = X/AUT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Autopsy	Refer to Section 2.	BXW1 F3008	N/A	Refer to LDMS User Manual Appendix A: LDMS codes.	To be performed as SOC with extra specimens to be collected and shipped to Dr. Peter Anton's lab (LDMS Lab 528). Dr. Grace Aldrovandi's lab (LDMS Lab 130).

APPENDIX II-B
 SCHEDULE OF EVALUATIONS - Participants < 50kg
 Post-transplant Cohort

	Entry into study ¹	Monthly	Day 100	Week 26	Week 52	Week 78	Week 104	Week 130	Week 156	Week 182	Week 208	Week 234	Week 260	PRN as done for standard of care	Early D/C	Death
Visit Windows	-	-	±2wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	±8wk	-	-	-
Laboratory Evaluations																
Resting CD4+T cell latent reservoir	40mL					40mL		40mL		40mL		40mL			40mL	
Chimerism CCR5Δ32 ²	3.5mL		3.5mL		3.5mL ⁶										3.5mL	
HIV-1 tropism							6mL		6mL	6mL						
Special Immunology ³	25mL		30mL	20mL ⁷	25mL		25mL		25mL		25mL		25mL			
Special virology ⁴																
Biopsy specimens ⁵														X		
Autopsy																X
TOTAL BLOOD VOLUMES (mL)	68.5mL		33.5 mL	20mL	28.5 mL	40mL	31mL	40mL	31mL	46mL	25mL	40mL	25mL	0mL	43.5mL	0mL

NOTE: If a subject on Appendix II-B stops taking ARVs post Day 100 for longer than 14 consecutive days, they should switch to Appendix II-C since they will have more frequent blood draws for a short time. If they subsequently then re-start ARVs, they should complete the 'Back on ARV' visit in Appendix I-C and then switch back to their original SOE (Appendix I-B).

Footnotes

1. Entry visit should include documentation of HIV-1 infection, HIV-1 diagnosis.
2. All chimerism assays except for CCR5Δ32 will be done as standard of care by the bone marrow team as part of the transplant. The chimerism assay should only be repeated if the Day 100 chimerism was <95%.
3. Special immunology tests include the following: Immune activation markers, HIV-1 specific cytokine response by flow, HIV specific cytokine responses by Elispot, T cell maturation subsets, B cell maturation subsets.
4. Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot, in vitro susceptibility testing of donor cells to HIV-1 infection (day 100 and week 52 only).
5. Gut biopsies will only be performed as part of standard of care. If the subject provides consent, a specimen should be collected for research purposes. Gut pathology: HIV-1 RNA/DNA isolation and quantitation and CCR5 expression by PCR. Please contact the team for further guidance.
6. The chimerism assay should only be repeated if the Day 100 chimerism was <95%.
7. Special immunology/virology tests to be performed at this time point include the following: Special virology tests include: HIV-1 DNA quantification, un-integrated DNA detection, plasma viral load (single copy assay), HIV-1 sequencing (Deep sequencing: envelope tropism), Western blot and immune activation markers.

For insufficient blood draws, priorities are as follows: Standard of care tests, EDTA tubes (P1107 study bloods)

At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available) should be shipped to Lab 428 for the resting CD4+ T cell assay.

Section 2: Safety/Clinical Laboratory Evaluations <i>Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.</i>			
Evaluation	Tube Type	Tests	CRF # DMC Test Code
<p style="text-align: center;">Biopsy specimens</p> <p>If participants undergo biopsy for standard of care clinical indications, residual tissue will be requested for study purposes</p>	<p>EDTA for Bone Marrow</p>	<p>Residual sections of biopsies-formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment. to Dr. Peter Anton's lab.</p> <p>Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice.</p> <p>Gut Biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Mon-Wed.</p> <p>Bone marrow specimens- are to be processed according to instructions in Section 7. Cryopreserved cells are to be shipped to Dr. Persaud's Lab 428 Mon-Wed.</p> <p>Other biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed.</p>	<p>BXW1 F3008 STORMIX</p>
<p style="text-align: center;">Autopsy</p> <p>If autopsy is performed, residual tissue will be requested for study purposes</p>	<p>N/A</p>	<p>Residual sections of formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment to Dr. Peter Anton's lab.</p> <p>Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Specimens are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed. At a minimum these specimens are requested: thymus, lymph nodes, spleen and tonsil specimens.</p>	<p>BXW1 F3008 STORMIX</p>

Section 3: Specimen Processing – Refer to Section 4 for collection volumes					
Evaluation	Tube Type	Special Collection Notes	CRF # DMC Test Code	Processing	Shipping
Resting CD4+T cell latent reservoir	EDTA	N/A	F3008 CXHIVUS	N/A	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Dr. Deborah Persaud’s Lab (LDMS Lab 428). Notify lab the week before of upcoming visits. Notify lab by fax/ phone the day the sample is being shipped.
Chimerism - CCR5Δ32	EDTA	N/A	F3008 GENOHUM	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (6 X 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship 1 x 2.5@10⁶ PBMC in dry nitrogen shipper to StemCyte TBD lab upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
HIV-1 tropism	EDTA	N/A	F3008 CTHIVPHN	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (10 x 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC on dry ice to Monogram upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
Immunology / Virology assays	EDTA	N/A	F3008 STORMIX	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25-0.5mL aliquots. If specimen collected is QNS, aliquot plasma 0.25mL/vial to achieve desired number of aliquots. Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC in dry nitrogen shipper to Dr. Pahwa/Dr. Bryson/Dr. Persaud or alternate lab upon team request. Plasma to be shipped on dry ice.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.

Section 4: Evaluations by Visit

Appendix II-B Entry (LDMS Vst/Vst unit = 0/ENT)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Day 100: ± 2 weeks (LDMS Vst/Vst unit= 15/WK) Same Wk as on CRF

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism – CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	30mL EDTA	F3008	Processing Lab: 28 x 0.5mL BLD/EDT/PL2 12 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Week 26: ± 8 weeks (LDMS Vst/Vst unit= 26/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	20mL EDTA	F3008	Processing Lab: 18 x 0.5mL BLD/EDT/PL2 8 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Week 52: ± 8 weeks (LDMS Vst/Vst unit= 52/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Chimerism -CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Week 78: ± 8 weeks (LDMS Vst/Vst unit= 78/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix II-B Week 104: ± 8 weeks (LDMS Vst/Vst unit= 104/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Week 130: ± 8 weeks (LDMS Vst/Vst unit= 130/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix II-B Week 156: ± 8 weeks (LDMS Vst/Vst unit= 156/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Week 182: ± 8 weeks (LDMS Vst/Vst unit= 182/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Week 208: ± 8 weeks (LDMS Vst/Vst unit= 208/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Week 234: ± 8 weeks (LDMS Vst/Vst unit= 234/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).

Appendix II-B Week 260: ± 8 weeks (LDMS Vst/Vst unit= 260/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B PRN as done for SOC (LDMS Vst/Vst unit= X/EDV)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Biopsy Specimens	Refer to Section 2 and 7.	BXW1 F3008	To be determined by Primary Specimen and processing.	Refer to LDMS User Manual Appendix A: LDMS codes. Bone marrow=BMA/EDT/CLN/DMS	To be performed as SOC with extra specimens to be collected and shipped to Lab 528 or Lab 428 or Lab 130 determined by specimen type.

Appendix II-B Early D/C (LDMS Vst/Vst unit= X/EXT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-B Death (LDMS Vst/Vst unit = X/AUT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Autopsy	Refer to Section 2.	BXW1 F3008	N/A	Refer to LDMS User Manual Appendix A: LDMS codes.	To be performed as SOC with extra specimens to be collected and shipped to Dr. Peter Anton's lab (LDMS Lab 528) Dr. Grace Aldrovandi's lab (LDMS Lab 130) .

APPENDIX II-C
SCHEDULE OF EVALUATIONS - Participants < 50kg
Participants who stop antiretrovirals after Day 100

	Week 0 post-ART	Monthly	Week 4 post-ART	Week 12 post-ART	Week 26 post-ART	Every 26 weeks	Every 52 weeks	PRN as done for standard of care	Back on ART visit ¹	Early D/C	Death
Visit Windows	-	-	±4wk	±4wk	±8wk	±8wk	±8wk	-	-	-	-
Laboratory Evaluations											
Resting CD4+T cell latent reservoir	40 mL				40 mL		40mL		40 mL	40 mL	
Chimerism - CCR5Δ32									3.5mL	3.5mL	
HIV-1 tropism	6 mL				6 mL	6mL	6mL		6 mL	6 mL	
Immunology assays	25 mL		25mL	25mL	25mL	25mL	25mL				
Virology assays											
Biopsy specimens								X			
Autopsy											X
TOTAL BLOOD VOLUMES (mL)	71 mL		25 mL	25 mL	71 mL	31mL	71mL	0mL	49.5 mL	49.5 mL	0mL

NOTE: A participant is considered off ART if they have discontinued ART for longer than 14 consecutive days post Day 100. A participant may stop and then re-start ART more than once during the post-transplant period; each stop event post Day 100 requires re-starting the Appendix I-C SOE at Week 0.

Footnotes

1. If the participant or physicians choose to re-start ART, a 'Back on ART' visit is necessary. Once this visit has been completed, the subject should follow the original SOE (Appendix I-A or Appendix I-B) until the end of the study, starting where they left off.

For insufficient blood draws, priorities are as follows: Standard of care tests, EDTA tubes (P1107 study bloods) At 26 weeks visit if insufficient blood is obtained priority is blood to send to Miami for special virology and then the resting cell assay.

At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available) should be shipped to Lab 428 for the resting CD4+ T cell assay.

Section 2: Safety/Clinical Laboratory Evaluations

Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.

Evaluation	Tube Type	Tests	CRF # DMC Test Code
<p>Biopsy specimens If participants undergo biopsy for standard of care clinical indications, residual tissue will be requested for study purposes</p>	<p>EDTA for Bone Marrow</p>	<p>Residual sections of biopsies-formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment. to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Gut Biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Mon-Wed. Bone marrow specimens- are to be processed according to instructions in Section 7. Cyropreserved cells are to be shipped to Dr. Persaud's Lab 428 Mon-Wed. Other biopsies are to be stored locally at -70°C until shipped on dry ice to Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed.</p>	<p>BXW1 F3008 STORMIX</p>
<p>Autopsy If autopsy is performed, residual tissue will be requested for study purposes</p>	<p>N/A</p>	<p>Residual sections of formalin-fixed, paraffin-embedded tissue samples require no additional preparation prior to shipment to Dr. Peter Anton's lab. Residual tissue samples that have not been fixed are transferred individually from the biopsy forceps using a histological pick or blunt needle and transferred into a empty, pre-labeled 1.8mL cryovial containing 1mL RPMI or PBS, one tissue sample per vial. Specimens are immediately flash frozen in liquid nitrogen or placed on dry-ice. Specimens are to be stored locally at -70°C until shipped on dry ice to Dr. Peter Anton's lab (LDMS Lab 528) Dr. Grace Aldrovandi's lab (LDMS Lab 130) Mon-Wed. At a minimum these specimens are requested: thymus, lymph nodes, spleen and tonsil specimens.</p>	<p>BXW1 F3008 STORMIX</p>

Section 3: Specimen Processing – Refer to Section 4 for collection volumes					
Evaluation	Tube Type	Special Collection Notes	CRF # DMC Test Code	Processing	Shipping
Resting CD4+T cell latent reservoir	EDTA	N/A	F3008 CXHIVUS	N/A	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Dr. Deborah Persaud’s Lab (LDMS Lab 428). Notify lab the week before of upcoming visits. Notify lab by fax/ phone the day the sample is being shipped.
Chimerism - CCR5Δ32	EDTA	N/A	F3008 GENOHUM	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (6 X 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship 1 x 2.5@10⁶ PBMC in dry nitrogen shipper to Stemcyte TBD lab upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
HIV-1 tropism	EDTA	N/A	F3008 CTHIVPHN	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25mL aliquots (10 x 0.25mL). Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC on dry ice to Monogram upon team request.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.
Immunology / Virology assays	EDTA	N/A	F3008 STORMIX	After receipt at processing lab: Centrifuge specimen 10min at 400xg. Remove plasma and respin at 800xg for 10 min. Freeze all plasma in 0.25-0.5mL aliquots. If specimen collected is QNS, aliquot plasma 0.25mL/vial to achieve desired number of aliquots. Cryopreserve PBMCs according to Cross Network Method and aliquot 2.5x10⁶. Processing lab to ship PBMC in dry nitrogen shipper to Dr. Pahwa/Dr. Bryson/Dr. Persaud or alternate lab upon team request. Plasma to be shipped on dry ice.	Ship ambient same day (preferably Mon-Wed, Thursday possible) as collected to Quest Diagnostics LDMS Lab 33 or Dr. Grace Aldrovandi’s LDMS Lab 130. Determine lab by discussion with team and locale. Notify lab prior to shipment.

Section 4: Evaluations by Visit

Appendix II-C Week 0 Post-ART: ± 8 weeks (LDMS Vst/Vst unit= 0/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C Week 4 Post-ART: ± 4 weeks (LDMS Vst/Vst unit= 4/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C Week 12 Post-ART : ± 4 weeks (LDMS Vst/Vst unit= 12/WK)

Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C Week 26 Post-ART: ± 8 weeks (LDMS Vst/Vst unit= 26/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C Every 26 Weeks Post-ART: ± 8 weeks (LDMS Vst/Vst unit= X/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
HIV-1 tropism	6mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C Every 52 Weeks Post-ART (LDMS Vst/Vst unit= X/WK)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
Immunology / Virology assays	25mL EDTA	F3008	Processing Lab: 22 x 0.5mL BLD/EDT/PL2 10 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C PRN done as Standard of Care (LDMS Vst/Vst unit= X/EDV)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Biopsy Specimens	Refer to Section 2 and 7.	BXW1 F3008	To be determined by Primary Specimen and processing.	Refer to LDMS User Manual Appendix A: LDMS codes. Bone marrow=BMA/EDT/CLN/DMS	To be performed as SOC with extra specimens to be collected and shipped to Lab 528 or Lab 428 or Lab 130 determined by specimen type.

Appendix II-C Back on ART visit (LDMS Vst/Vst unit= X/EDV)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5 mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C Early D/C visit (LDMS Vst/Vst unit= X/EXT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Resting CD4+T cell latent reservoir	40mL EDTA	F3008	N/A	BLD/EDT/BLD	Ship ambient same day as collected to Dr. Deborah Persaud's Lab (LDMS Lab 428).
Chimerism - CCR5Δ32	3.5 mL EDTA	F3008	Processing Lab: 6 x 0.25mL BLD/EDT/PL2 2 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.
HIV-1 tropism	6 mL EDTA	F3008	Processing Lab: 10 x 0.25mL BLD/EDT/PL2 2-3 @ 2.5x10⁶ BLD/EDT/CEL/DMS	BLD/EDT/BLD	Ship ambient same day as collected to Quest Diagnostics LDMS Lab 33 or Lab 130.

Appendix II-C Death (LDMS Vst/Vst unit = X/AUT)					
Evaluation	Specimen	CRF	Aliquots	LDMS Code	Special Notes
Autopsy	Refer to Section 2.	BXW1 F3008	N/A	Refer to LDMS User Manual Appendix A: LDMS codes.	To be performed as SOC with extra specimens to be collected and shipped to Dr. Peter Anton's lab (LDMS Lab 528). Dr. Grace Aldrovandi's lab (LDMS Lab 130).

Section 5: Helpful Links and Shipping Addresses

Prepare and ship specimens in accordance with IATA regulations and ACTN Guidelines for Category B substances.

ACTG/IMPAACT Laboratory Manual, Shipping Information and other useful information: <http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx>

*****IMPORTANT NOTE***: Site and Laboratory are to determine in advance where ambient specimens will be processed of the two processing labs listed here.**

Immunology / Virology assays / Chimerism-CCR5Δ32/HIV-1 Tropism

Ship overnight Monday through Wednesday preferred, Thursday possible.

INCLUDE Quest IMPAACT P1107 Test Requisition (found on PSWP) in shipment.

Email electronic LDMS manifest to denise.L.bopst@questdiagnostics.com and BALResearch@questdiagnostics.com

Quest Diagnostics Incorporated
Attn: Special Studies - Denise Bopst
1901 Sulphur Spring Rd.
Baltimore, MD 21227

Phone: 410-536-1713
FAX: 410-536-1474

Contacts: Denise Bopst and Kimberly Adams
Denise.L.bopst@questdiagnostics.com
Kimberly.a.adams@questdiagnostics.com
BALResearch@questdiagnostics.com

LDMS Lab code: 33

Immunology / Virology assays / Chimerism-CCR5Δ32/HIV-1 Tropism

Ship overnight Monday through Wednesday preferred, Thursday possible.

Email electronic LDMS manifest to: mesaavedra@mednet.ucla.edu and szabih@mednet.ucla.edu

UCLA Macdonald Research Laboratory
675 Charles E. Young Drive South, Room 4629
Los Angeles, CA 90095

Phone: 310 825 7708
FAX: 310 206 1303

Contacts: Monica Saavedra and Sara Zabih
mesaavedra@mednet.ucla.edu
szabih@mednet.ucla.edu
grace@mac.com

LDMS Lab code: 130

<p>Resting CD4+T cell latent reservoir and Bone Marrow Cryopreserved cells Dr. Deborah Persaud JHU Pediatric Infectious Diseases 720 Rutland Avenue Ross Building Room 1170 Baltimore, MD 21205</p> <p>Phone: 443-287-3733 Fax: 410-614-1315 Email: dpers@jhmi.edu</p> <p>LDMS Lab code: 428</p>	<p>Gut Biopsy and Autopsy Specimens Dr. Peter Anton Julie Elliott Karen Tanner UCLA CPR 675 Charles Young Drive South, 1529 MRL Los Angeles, CA 90095</p> <p>Phone: 310-794-7195 Fax: 310-267-0289</p> <p>Email: jelliott@mednet.ucla.edu and ktanner@mednet.ucla.edu and panton@mednet.ucla.edu</p> <p>LDMS Lab code: 528</p>
<p>Bone Marrow Specimens Dr. Deborah Persaud JHU Pediatric Infectious Diseases 720 Rutland Avenue Ross Building Room 1170 Baltimore, MD 21205</p> <p>Phone: 443-287-3733 Fax: 410-614-1315 Email: dpers@jhmi.edu</p> <p>LDMS Lab code: 428</p>	<p>Biopsy Specimens with the exception of Gut and Bone Marrow Specimens UCLA Macdonald Research Laboratory 675 Charles E. Young Drive South, Room 4629 Los Angeles, CA 90095</p> <p>Phone: 310 825 7708 FAX: 310 206 1303</p> <p>Contacts: Monica Saavedra and Sara Zabih mesaavedra@mednet.ucla.edu szabih@mednet.ucla.edu grace@mac.com</p> <p>Email electronic LDMS manifest to: mesaavedra@mednet.ucla.edu and szabih@mednet.ucla.edu</p> <p>LDMS Lab code: 130</p>

Section 6: Revision History	
Version & Date	Comments
1.0, CM1 28FEB2014	Edited shipping of Immunology / Virology assays / Chimerism-CCR5Δ32/HIV-1 Tropism to Dr. Grace Aldrovandi's Laboratory, LDMS Lab 130.
1.0, CM1 28FEB2014	Edited storage temperature from -80°C to -70°C for frozen biopsy and autopsy specimens prior to shipment.
1.0, CM1, CM2 11AUG2017	Edited shipping information to Quest Diagnostics for Immunology / Virology assays / Chimerism-CCR5Δ32/HIV-1 Tropism specimens.
1.0, CM1, CM2 08DEC2017	Included processing lab instructions throughout document.
1.0, CM1, CM2 08DEC2017	Added Bone Marrow instructions in Section 7
1.0, CM1, CM2 08DEC2017	Added Dr. Grace Aldrovandi's Lab 130 throughout as an alternative processing lab.
1.0, CM1, CM2 26FEB2018	Edited autopsy specimens to be shipped to Dr. Grace Aldrovandi's lab (Lab 130) throughout LPC.
1.0, CM1, CM2 26FEB2018	Edited shipping addresses to include, bone marrow specimens to be shipped to Dr. Persuad's lab and biopsy specimens (with the exception of gut and bone marrow) to be shipped to Dr. Aldrovandi's lab.
1.0, CM1, CM2 26FEB2018	Added priority statement after footnotes for each SOE: "At visits when samples are to be collected for the resting CD4+ T cell assay and other assays, samples should be prioritized for the other assays first, and all remaining blood (regardless of volume available, i.e. <50mL) should be shipped to Lab 428 for the resting CD4+ T cell assay."

Section 7: Appendix**Bone Marrow Instructions****Bone Marrow Collection**

1. Place 2-3mL bone marrow aspirate into appropriate size sterile EDTA tube. Provide as many tubes as possible. Mix well by inversion to avoid specimen clotting. Alternate tube size and volume are acceptable as long as tubes are not overfilled.
2. Maintain samples at room temperature and deliver to processing lab within 2 hours.

Bone Marrow Processing

1. Initiate processing for cell separation immediately upon receipt.
2. Mononuclear Cell Separation – all reagents and procedures should be performed at room temperature.
3. Dilute sample 1:2 with sterile bone marrow wash buffer (PBS/10% FBS/2mM EDTA) or alternatively use sterile (PBS/10%FBS). Use Ca⁺⁺/Mg⁺⁺ free PBS.
4. Strain through 100µm cell strainer pre-moistened with sterile PBS. (Alternatively a 70µl filter may be used.)
5. Gently overlay up to 30mL diluted bone marrow onto 15mL Ficoll-Hypaque (or alternative sterile lymphocyte separation media) in a 50mL conical tube.
6. Centrifuge at 400xg for 30 minutes with brake OFF at room temperature.
7. Continue processing the Bone Marrow Specimen following the Cross-Network PBMC Processing SOP at https://www.hanc.info/labs/Documents/HANC-LAB-P0001_v5.2_2014-09-22_PBMC_SOP.pdf.
8. Carefully remove mononuclear cells from the interphase to a new (50mL) sterile conical centrifuge tube wash twice with PBS as described in 9-20, below.

Wash One

9. Transfer the collected cells from one conical centrifuge tube to a single corresponding, pre-labeled, sterile 50mL conical centrifuge tube containing 25mL PBS.
10. QS the PBMC fraction to approximately 45mL for 50mL conical centrifuge tubes by adding PBS. Mix gently.
11. Centrifuge diluted cells at 400 x g for 10 minutes at 15 to 30°C (brake optional).
12. Remove the tubes from the centrifuge and check for the cell pellet.
13. Remove and discard the supernatant without disturbing the cell pellet.
14. Re-suspend each pellet in a small volume of PBS mixing, gently but thoroughly into a homogenous cell suspension.
15. Combine the pellet suspensions from the same PTID/anticoagulant.
16. Use a small volume of PBS to rinse the tubes from which the pellets were transferred. Collect the PBS rinse in the harvested cell tube.

Wash Two

17. QS to 45mL the PBMC fraction by adding PBS and mix gently.
18. Re-cap the tubes and place the tubes in the centrifuge.
19. Centrifuge diluted cells at 400 x g for 10 minutes at 15 to 30°C (brake optional).
20. Aspirate and discard supernatant and re-suspend cell pellet(s) in RPMI.

Cell Counting

21. Complete the cell count using the SOP for the cell counting method approved at the laboratory. For an example manual cell counting SOP, refer to <http://www.hanc.info/labs/labresources/procedures/Pages/pbmcSop.aspx>.
22. Cryopreserve cells in 2.5 x 10⁶ per vial.
23. LDMS code (BMA/EDT/CLN/DMS)