



## IMPAACT 2016 Laboratory Processing Chart

### Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence Among Youth Living with HIV in Low Resource Settings

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Protocol-Required Non-Standard Reagents and Supplies		
Evaluation	Reagent or supply	Order information
Hair Collection and Storage	Aluminium Foil	<b>Quill Diagnostics, product name Handy Foil or Standard Aluminium Foil</b> , catalogue number 035-11205: 12 inches x 100 feet. Alternatively, the foil can be purchased locally, if sites can find a better price.
	Desiccant Packs	<b>Order from U-Line.</b> Phone: 1-800-295-5510; fax: 1-800-295-5571. The product is called <b>1/2 g Silica Gel Desiccants</b> , catalogue number S-8032: 1 pail (6000bags/container), \$133.00 or purchase similar product locally.
	Scissors/Razors/Hair Clips	Purchased locally.
	Zipper Bags	Should be small and can be purchased locally.
	Alcohol swabs/pads	Can be purchased locally.

Section 1A: Appendix 1-A: Schedules of Evaluations for Youth – Pilot Test

Section 1A: Appendix 1-A: Schedules of Evaluations for Youth – Pilot Test								
Study Visit/Session	Screen	Pre-Entry <sup>1</sup>	Entry/ Session 1 <sup>3</sup>	Session 2	Session 3	Session 4	Session 5	Session 6/ Exit Visit
<b>Clinical Evaluations</b>								
Informed Consent/Assent	X							
Review medical records (eligibility)/collect screen data	X							
Medical/medications history		X						
Youth decision on caregiver participation	X							
Mock hair sample (ART concentration)		X <sup>2</sup>						
<b>Laboratory Evaluations</b>								
HIV-1 test (confirmatory tests as needed)	5 mL							
Mock HIV-1 RNA (Viral Load) – no blood collected		X <sup>2</sup>						
Mock plasma for inflammatory biomarkers – no blood collected		X <sup>2</sup>						
Total Maximum blood volume	5 mL							

1. Pre-Entry Visit procedures should be conducted on the same day or up to 14 days prior to enrollment.

2. Mock blood and hair collection: no specimens are collected. Please refer to protocol Section 3.1.2.

3. Entry (enrollment) must occur within 60 days of screening and will be on the same day of Group Session 1. The day of Group Session 1 is considered Day 0 for youth.

**Section 2A: Safety/Clinical Laboratory Evaluations for Youth - Pilot Test**

Section 2A: Safety/Clinical Laboratory Evaluations for Youth - Pilot Test			
Defer to local clinical specimen collection guidelines for tube types and collection volumes as needed.			
Evaluation	Tube Type	Tests	eCRF #
HIV-1 Test (Confirmatory tests as needed)	SST or NON or EDTA	<i>Note: If sufficient documentation of HIV status as specified in Inclusion Criterion 4.1.3 is not available, HIV diagnostic testing is to be done according to the specified algorithm.</i>	LBW10008: Qualitative HIV-1 Results, LBW10052: HIV-1 Plasma Viral Load

**Section 3A: Specimen Processing and Shipping Instructions for Youth - Pilot Test**

Section 3A: Specimen Processing and Shipping Instructions for Youth – Pilot Test					
Evaluation	Tube Type	Special Collection Notes	eCRF #	Processing	Shipping
Mock HIV-1 RNA (viral load) – no blood collected <sup>1</sup>	N/A	N/A	N/A	N/A	N/A
Mock plasma for inflammatory biomarkers – no blood collected <sup>1</sup>	N/A	N/A	N/A	N/A	N/A
Mock hair sample (ART Concentration) <sup>1</sup>	N/A	N/A	N/A	N/A	N/A

1. Mock blood and hair collection: no specimens are collected. Please refer to protocol Section 3.1.2.

Section 4A: Evaluations by Visit for Youth - Pilot Test

Section 4A: Evaluations by Visit for Youth – Pilot Test					
Screen: Must be completed within 60 days prior to study entry					
Evaluation	Specimen	eCRF	Aliquots	LDMS Code	Special Notes
HIV-1 Test (Confirmatory tests as needed)	5 mL EDTA	LBW10008: Qualitative HIV-1 Results, LBW10052: HIV-1 Plasma Viral Load	Perform collection, testing and/or processing for HIV testing per algorithm noted in Inclusion Criterion 4.1.3	N/A	Collect blood only if needed per inclusion criterion 4.1.3 for: Confirmatory HIV testing

Pre-entry: Should be completed within 14 days prior to study entry					
LDMS Visit Code= N/A					
Evaluation	Specimen	eCRF	Aliquots	LDMS Code	Special Notes
Mock HIV-1 RNA (Viral Load) – no blood collected <sup>1</sup>	N/A	N/A	N/A	N/A	N/A
Mock Plasma for Inflammatory Biomarkers – no blood collected <sup>1</sup>	N/A	N/A	N/A	N/A	N/A
Mock Hair Sample (ART Concentration) <sup>1</sup>	N/A	N/A	N/A	N/A	N/A

1. Mock blood and hair collection: no specimens are collected. Please refer to protocol Section 3.1.2.

Section 1B: Appendix II-A: Schedules of Evaluations for Youth – Randomized Trial of TI-CBT Intervention

Section 1B: Appendix II-A: Schedules of Evaluations for Youth – Randomized Trial of TI-CBT Intervention											
Study Visit/Session	Screen	Pre-Entry <sup>1</sup>	Youth Group Sessions (within 8 weeks of youth’s session 1)						Youth Follow-up <sup>7</sup>		
			Entry/ Session 1 <sup>2</sup>	Session 2	Session 3	Session 4	Session 5	Session 6	IPL <sup>5</sup>	6-mo	12-mo/ Exit
Clinical Evaluations											
Informed Consent/Assent	X										
Review medical records (eligibility)/collect screen data	X										
Medical/medications history		X <sup>3</sup>							X	X	X
Youth decision on caregiver participation	X										
Hair sample (ART concentration)		X <sup>3</sup>							X	X	X
Laboratory Evaluations											
HIV-1 test (confirmatory tests as needed)	5 mL										
HIV-1 RNA (viral load)		10 mL <sup>3</sup>							10 mL	10 mL	10 mL
Plasma for inflammatory biomarkers		5 mL <sup>3</sup>								5 mL	5 mL
Total maximum blood volumes	5 mL	15 mL							10 mL	15 mL	15 mL

1: Pre-Entry Visit procedures should be conducted on the same day or up to 14 days prior to enrollment.

2: Entry (enrollment and randomization) must occur within 60 days of screening and will be on the day of Group Session 1.

3: Baseline measures.

5: Immediately post-last group session (IPL) follow-up evaluations are targeted to be conducted immediately following Group Session 6 on the same day or within 30 days.

7: 6 and 12-month Follow-Up evaluations are targeted to be conducted with associated allowable windows on Day 182 ± 30 days and Day 365 ± 30 days. The day of Group Session 1 is considered Day 0 for youth.

Section 2B: Safety/Clinical Laboratory Evaluations for Youth - Randomized Trial of TI-CBT Intervention

Section 2B: Safety/Clinical Laboratory Evaluations for Youth – Randomized Trial of TI-CBT Intervention			
Evaluation	Tube Type	Tests	eCRF #
HIV-1 Test (Confirmatory tests as needed)	EDTA	<i>Note: If sufficient documentation of HIV status as specified in Inclusion 4.1.3 is not available, HIV diagnostic testing is to be done according to the specified algorithm.</i>	LBW10008: Qualitative HIV-1 Results, LBW10052: HIV-1 Plasma Viral Load



**Section 3B: Specimen Processing and Shipping Instructions for Youth - Randomized Trial of TI-CBT Intervention**

Section 3B: Specimen Processing and Shipping Instructions for Youth – Randomized Trial of TI-CBT Intervention					
Refer to Section 4 for tube types and collection volumes.					
Evaluation	Tube Type	Special Collection Notes	eCRF #	Processing	Shipping
HIV-1 RNA (Viral Load)	K2 or K3 EDTA 10mL	N/A	SPW10000: Specimen Tracking Log, LBW10052: HIV-1 Plasma Viral Load	Spin blood at 800xg for 10 min. Remove plasma; respin plasma at 800 x g for 10 min. Freeze 2 x 1.8mL plasma (-65°C to -95°C)  Note: This test should <u>NOT</u> be performed on diluted plasma  LDMS spec. code: BLD/DPE or EDT/PL2	Send to local DAIDS- VQA-certified laboratory.
Plasma for Inflammatory Biomarkers	EDTA 5mL	N/A	SPW10000: Specimen Tracking Log	Spin blood at 400xg for 10 min. Remove plasma, respin plasma at 800 x g for 10mins. Freeze 2 x 1.0mL plasma and all additional plasma in a 3 <sup>rd</sup> aliquot (-65°C to -95°C) LDMS spec. code: BLD/DPE or EDT/PL2	Store locally until instructed to ship.
Hair sample (ART Concentration)	50-60 strands of hair, with the distal end taped to the foil unless the hair length is 1 cm or less, then folded in foil and stored in zipper bag	See IMPAACT 2016 MOP for detailed collection and labelling instructions.	PKW10063: IMPAACT 2016 Pharmacokinetics Specimen Collection	Store on site at room temperature in a dark place until requested by protocol team for batch testing at the centralized pharmacology laboratory. LDMS spec. code: HAR/NON/HAR	Store locally until instructed to ship to LDMS Lab 607 (Gandhi).

Section 4B: Evaluations by Visit for Youth - Randomized Trial of TI-CBT Intervention

Section 4B: Evaluations by Visit for Youth – Randomized Trial of TI-CBT Intervention					
Screen: Must be completed within 60 days prior to study entry					
Evaluation	Specimen	eCRF	Aliquots	LDMS Code	Special Notes
HIV-1 Test (Confirmatory tests as needed)	5 mL EDTA	LBW10008: Qualitative HIV-1 Results, LBW10052: HIV-1 Plasma Viral Load	Perform collection, testing and/or processing for HIV testing per algorithm noted in Inclusion Criterion 4.1.3	N/A	Collect blood only if needed per inclusion criterion 4.1.3 for: Confirmatory HIV testing

Pre-entry: Should be completed within 14 days prior to study entry					
LDMS Visit Code= 0/PE					
Evaluation	Specimen	eCRF	Aliquots	LDMS Code	Special Notes
HIV-1 RNA (Viral Load)	K2 or K3 EDTA 10mL	SPW10000: Specimen Tracking Log, LBW10052: HIV-1 Plasma Viral Load	Freeze 2 x 1.8mL plasma (-65°C to -95°C)	BLD/DPE or EDT/PL2	Send to local DAIDS-VQA certified laboratory.
Plasma for Inflammatory Biomarkers	K2 or K3 EDTA 5mL	SPW10000: Specimen Tracking Log	Freeze 2 x 1.0 mL plasma and all additional plasma in a 3 <sup>rd</sup> aliquot (-65°C to -95°C)	BLD/DPE or EDT/PL2	Store locally until instructed to ship.
Hair sample (ART Concentration)	50-60 strands of hair, with the distal end taped to the foil unless the hair length is 1 cm or less, then folded in the foil and stored in zipper bag	PKW10063: IMPACT 2016 Pharmacokinetics Specimen Collection	1 EA/stored hair sample	HAR/NON/HAR	Store locally until instructed to ship to LDMS Lab 607 (Gandhi).

IPL: Targeted to be conducted immediately following Group Session 6 on the same day or within 30 days.					
LDMS Visit Code = 1/FUP					
Evaluation	Specimen	eCRF	Aliquots	LDMS Code	Special Notes
HIV-1 RNA (Viral Load)	K2 or K3 EDTA 10mL	SPW10000: Specimen Tracking Log, LBW10052: HIV-1 Plasma Viral Load	Freeze 2 x 1.8mL plasma (-65°C to - 95°C)	BLD/DPE or EDT/PL2	Send to local DAIDS-VQA certified laboratory.
Hair sample (ART Concentration)	50-60 strands of hair, with the distal end taped to the foil unless the hair length is 1 cm or less, then folded in foil and stored in zipper bag	PKW10063: IMPAACT 2016 Pharmacokinetics Specimen Collection	N/A	HAR/NON/HAR	Store locally until instructed to ship to LDMS Lab 607 (Gandhi).

6 Months (Day 182 ± 30 days)					
LDMS Visit Code = 6/Mo					
12 Months (Day 365 ± 30 days)					
LDMS Visit Code = 12/Mo					
Evaluation	Specimen	eCRF	Aliquots	LDMS Code	Special Notes
HIV-1 RNA (Viral Load)	K2 or K3 EDTA 10mL	SPW10000: Specimen Tracking Log, LBW10052: HIV-1 Plasma Viral Load	Freeze 2x 1.8mL plasma (-65°C to - 95°C)	BLD/DPE or EDT/PL2	Send to local DAIDS-VQA certified laboratory.
Plasma for Inflammatory Biomarkers	K2 or K3 EDTA 5mL	SPW10000: Specimen Tracking Log	Freeze 2 x 1.0 mL plasma and all additional plasma in a 3 <sup>rd</sup> aliquot (-65°C to -95°C)	BLD/DPE or EDT/PL2	Store locally until instructed to ship.
Hair sample (ART Concentration)	50-60 strands of hair, with the distal end taped to the foil unless the hair length is 1 cm or less, then folded in foil and stored in zipper bag	PKW10063: IMPAACT 2016 Pharmacokinetics Specimen Collection	1 EA/stored hair sample	HAR/NON/HAR	Store locally until instructed to ship to LDMS Lab 607 (Gandhi).

## Section 5: Helpful Links and Shipping Addresses

### Section 5: Helpful Links and Shipping Addresses

ACTG/IMPACT Laboratory Manual, Shipping Information and other useful information:

<http://www.hanc.info/labs/labresources/Pages/informationActgImpactLabs.aspx>

**NOTE:** Please contact the laboratories prior to shipment to ensure they can receive the samples at the designated time. Do not ship until you receive approval from the receiving lab. Ensure that all import permits are up to date and accurate prior to shipping samples.

- Include an LDMS shipping manifest in EXCEL format.
- Notify lab >48 hours in advance of pending shipment
- Notify the receiving lab of shipment, include excel format of shipping manifest, Courier, and Tracking #
- Ship on Monday or Tuesday ONLY

### PHARMACOLOGY

#### Hair for ARV Drug Levels

Dr. Monica Gandhi

Attention: Dr. Hideaki Okochi

513 Parnassus Ave

Medical Sciences Building, Room S-907

San Francisco, CA 94143

USA

Email: [Hideaki.Okochi@ucsf.edu](mailto:Hideaki.Okochi@ucsf.edu)

Email: [Monica.Gandhi@ucsf.edu](mailto:Monica.Gandhi@ucsf.edu)

Email: [Karen.Kuncze@ucsf.edu](mailto:Karen.Kuncze@ucsf.edu)

Phone: (415) 476-8192

Phone: (415) 476-9960

Fax number: (415) 476-6770

LDMS Lab code: 607

## Section 6: Revision History

Section 6: Revision History		
Protocol Version	LPC Change Date	Description
1.0	27 August 2019	Correct email address for Karen Kuncze at UCSF: <a href="mailto:karen.kuncze@ucsf.edu">karen.kuncze@ucsf.edu</a>
1.0	5 December 2019	Corrected volume of plasma being stored from 5ml EDTA for Inflammatory Markers and reduced the number of aliquots from 4 aliquots to 3 aliquots.
2.0	10 April 2023	Added contact detail and email address for Dr. Hideaki Okochi at UCSF. Updated wording in LPC to reflect current terminology as per the IMPAACT LPC format. Added additional LC representative: Leah Spalding Removed BRI from Helpful Links and Shipping Addresses since BRI cannot be used as pass-through. Plasma samples are going to be stored locally until instructed to ship. Added additional hair processing instructions as indicated by the UCSF Gandhi Lab. Updated eCRF references. Added Pre-entry table to indicate mock testing in Section 4. Aligned wording for lab evaluations with Protocol Version 2.0. Removed SPW10000 from screening visits for Pilot test and RT groups.
2.1	23 May 2023	Revised plasma inflammatory biomarkers to include the following language: "Freeze 2 x 1.0 mL plasma and all additional plasma in a 3 <sup>rd</sup> aliquot".