

# IMPAACT 2016 Laboratory Considerations

Protocol Version 2.0  
29 June 2023

# Presentation Overview

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- Protocol requirements – reagents and supplies
- Appendix 1-A: Pilot Testing
- Appendix 11-A: Randomised Control Trial
- Shipping
- Shipping requirements

# IMPAACT 2016 Laboratory Processing Chart

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Site staff, in addition to the laboratories, are required to read and understand the Laboratory Processing Chart (LPC)

The LPC contains specimen **collection, processing, transport and storage** instructions, as well as **time sensitive processing procedures** that will require special planning and coordination with your local testing laboratory.



# IMPAACT 2016 Laboratory Team

## 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

**Protocol Version:** 2.0

**Protocol Version Date:** 13 January 2023

**LPC Revised/Updated:** 23 May 2023

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# Laboratory Processing Chart

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## 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.<br>Updated wording in LPC to reflect current terminology as per the IMPAACT LPC format.<br>Added additional LC representative: Leah Spalding<br>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.<br>Added additional hair processing instructions as indicated by the UCSF Gandhi Lab.<br>Updated eCRF references.<br>Added Pre-entry table to indicate mock testing in Section 4.<br>Aligned wording for lab evaluations with Protocol Version 2.0.<br>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".   |

# Protocol-Required Non-Standard Reagents and Supplies

| Protocol-Required Non-Standard Reagents and Supplies |                            |   |
|--|----------------------------|---|
| Evaluation   | Reagent or supply          | Order information   |
| Hair Collection and Storage                          | Aluminium Foil             | Quill Diagnostics, product name Handy Foil or Standard Aluminium Foil, 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            | Order from U-Line. Phone: 1-800-295-5510; fax: 1-800-295-5571. The product is called 1/2 g Silica Gel Desiccants, 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.   |

# Protocol Required Non-Standard Supplies

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- Items to be ordered by sites prior to study start
  - blood tubes
  - Hair collection consumables
  - Hair storage supplies

## Protocol Required Non-Standard Supplies

- These can include scissors for hair collection
- Phlebotomy consumables, needles etc.



# 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/<br>Session 1 <sup>3</sup> | Session 2 | Session 3 | Session 4 | Session 5 | Session 6/<br>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

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| 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:<br>Qualitative HIV-1 Results,<br>LBW10052:<br>HIV-1 Plasma<br>Viral Load |

# Section 3A: Specimen Processing and Shipping Instructions for Youth – Pilot Test

## 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

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| 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<br>(Confirmatory tests as needed)                  | 5 mL EDTA | LBW10008:<br>Qualitative HIV-1<br>Results, LBW10052:<br>HIV-1 Plasma Viral<br>Load | Perform collection, testing and/or<br>processing for HIV testing per algorithm<br>noted in Inclusion Criterion 4.1.3 | N/A       | Collect blood only if needed per inclusion<br>criterion 4.1.3 for: Confirmatory HIV testing |

# Section 4A: Evaluations by Visit for Youth – Pilot Test

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| 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<br>(within 8 weeks of youth’s session 1) |           |           |           |           |           | Youth Follow-up <sup>7</sup> |       |                |
|   |        |                        | Entry/<br>Session 1 <sup>2</sup>                              | Session 2 | Session 3 | Session 4 | Session 5 | Session 6 | IPL <sup>5</sup>             | 6-mo  | 12-mo/<br>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

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## 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,<br>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.<br>Freeze 2 x 1.8mL plasma (-65°C to -95°C)<br><br>Note: This test should <u>NOT</u> be performed on diluted plasma<br><br>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.<br>Freeze 2 x 1.0mL plasma and all additional plasma in a 3 <sup>rd</sup> aliquot (-65°C to -95°C)<br>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.<br>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<br>(Confirmatory tests as needed)   | 5 mL EDTA | LBW10008: Qualitative HIV-1 Results,<br>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 |



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

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| 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<br>10mL   | SPW10000:<br>Specimen<br>Tracking Log,<br>LBW10052: HIV-1<br>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<br>5mL  | SPW10000:<br>Specimen<br>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:<br>IMPAACT 2016<br>Pharmacokinetics<br>Specimen<br>Collection        | 1 EA/stored hair sample  | 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

| 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<br>10mL   | SPW10000:<br>Specimen<br>Tracking Log,<br>LBW10052: HIV-1<br>Plasma Viral Load | Freeze 2 x 1.8mL plasma (-65°C to -<br>95°C) | BLD/DPE or EDT/PL2 | Send to local DAIDS-VQA<br>certified laboratory.                       |
| Hair sample (ART<br>Concentration)   | 50-60 strands of hair, with<br>the distal end taped to the<br>foil unless the hair length is 1<br>cm or less, then folded in foil<br>and stored in zipper bag | PKW10063:<br>IMPAACT 2016<br>Pharmacokinetics<br>Specimen<br>Collection        | N/A  | HAR/NON/HAR        | Store locally until<br>instructed to ship to<br>LDMS Lab 607 (Gandhi). |

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

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

# Section 5: Helpful Links and Shipping Addresses

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| Section 5: Helpful Links and Shipping Addresses   |   |
|---|---|
| <p>ACTG/IMPAACT Laboratory Manual, Shipping Information and other useful information:<br/><a href="http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx">http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx</a></p> <p><u>NOTE:</u> 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.</p> | <ul style="list-style-type: none"><li>• Include an LDMS shipping manifest in EXCEL format.</li><li>• Notify lab &gt;48 hours in advance of pending shipment</li><li>• Notify the receiving lab of shipment, include excel format of shipping manifest, Courier, and Tracking #</li><li>• Ship on Monday or Tuesday ONLY</li></ul> |



# IMPAACT 2016 Laboratory Shipping to UCSF Gandhi Laboratory

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- Reminder that hair samples for ARV Drug Levels for IMPAACT 2016 are to be stored locally until instructed to ship to UCSF Gandhi Lab (LDMS 607).

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## **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

# MTA and export permits

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- Establish MTA with Dr Monica Gandhi's Lab
- Apply timeously for the export permit to this laboratory

# Questions

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- Please email any questions to [impaact.team2016@fstrf.org](mailto:impaact.team2016@fstrf.org), and someone from the LC will reply if they are laboratory related.
- Protocol team members can be found in the Protocol. LC staff members can be found on the LPC.

