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

IMPAACT 2016

Activation and Implementation Meeting

Community Stakeholder Engagement and Focus Group Overview

20 February 2019

Protocol Chairs: Geri Donenberg and Dorothy Dow

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International Maternal Pediatric
Adolescent AIDS Clinical Trials Network

Protocol Team

Co-Chairs: **Geri Donenberg** and **Dorothy Dow**
Medical Officers: **Ellen Townley** (NIAID); **Sonia Lee** (NICHD); **Susannah Allison** (NIMH)
Clinical Trials Specialist: **Jennifer Libous, Nicole Montañez, Kathy George**
Statistician: **Meredith Warshaw**
Investigators: **Suad Kapetanovic**
Community Advisory Board: **Emanueli Msuya**
Protocol Data Managers**: Christina "Tia" Reding** and **Lindsey Miller**
Laboratory Data Manager: **Mark Lojacono**
Laboratory Technologist: **Natasha Samsunder** and **Amy James Loftis**
Laboratory Center Representative: **Dale Dayton**

Study location

- Botswana
  - Gaborone Prevention/Treatment Trials CRS 12701
  - Molepolole Prevention/Treatment Trials CRS 12702
- Malawi
  - University of North Carolina Lilongwe CRS 12001
  - College of Medicine JHU Blantyre CRS 30301
- Zimbabwe
  - St. Mary's (Chitungwiza) CRS 30303
  - Seke North (Harare) CRS 30306
  - Harare Family Care CRS 31890
- South Africa
  - Soweto IMPAACT (Johannesburg) CRS 8052

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International Maternal Pediatric Adolescent AIDS Clinical Trials Network

Virtual IMPAACT 2016 Activation and Implementation Meeting

Community Stakeholder Engagement and Focus Group Overview

Wednesday, 20 February 2019
9:00 am EST (4:00 pm SAST) – 11:00 am EST (6:00 pm SAST)

Time	Topic	Lead
9:00	**Introduction** (Slides 1-3)	Geri
9:05	**Agenda Review, and Goals of the Meeting** (Slides 4-5) *Materials:* - Access to training slides via webinar - IMPAACT 2016 Study Activation Checklist Version 1.0 dated 14 January 2019; - Guidance Document: Preparation and Adaptation of Trauma-Informed Cognitive Behavioral Therapy (TI-CBT) Intervention V1.0 dated 19 February 2019; *Expected Outcome:* For sites to understand the activation requirements, timepoints, and overview of the focus group and community engagements.	Jen
9:10	**IMPAACT 2016 Implementation Requirements** (Slides 6-13) *Associated Materials: Activation Checklist* • Review Study Activation and Focus Group Implementation Requirements for all sites to initiate (page 1) • Review Focus Group Implementation Requirements (page 1) • Potential Site Timeline • Ask sites to provide IRB updates; allow Q&A for any issues that may have arrived • Description of Adaptation Guidance Document • Description of TI-CBT Manuals: Caregiver Intervention Manual, Youth Intervention Manual, and TI-CBT Training Manual	Jen
9:30	**Community Stakeholder Engagement** (Slides 14-18) *Associated Materials: Guidance Document: Preparation and Adaptation of Trauma-Informed Cognitive Behavioral Therapy (TI-CBT) Intervention V1.0 dated 19 February 2019* Adaptation of TI-CBT • Community Stakeholder Engagement Preparation • Review ways to conduct Community Stakeholder Engagement ▪ Review Community Engagement Feedback Form	Dorothy
10:00	**Focus Group** (Slides 19-27) *Associated Materials: Guidance Document: Preparation and Adaptation of Trauma-Informed Cognitive Behavioral Therapy (TI-CBT) Intervention V1.0 dated 19 February 2019* • Overview of Focus Groups • Recruitment of youth and caregivers • Focus Groups Preparation • Review Focus Group Adaptation Feedback From and review adaptation process	Geri
10:30	**Recruitment of Indigenous Youth Leaders, Adult Study Staff, and Local Supervisors** (Slides 28-36) • Criteria for selection • Training for Indigenous Youth Leaders and Adult Study Staff (Local Supervisors to attend) • Review Pilot Test Adaptation Conduct, Feedback Form, and review adaptation process	Dorothy
10:45	**IMPAACT 2016 Implementation and Activation Requirements** (Slides 37-44) • Review Study Activation requirements for all sites (page 2-4)	Nicole
11:00	**Adjourn**	

IMPAACT 2016 Site-Specific Study Activation Checklist

CRS XX: Site Name
(City, Country)

Requirements for all sites		
Study Activation and Focus Group Implementation Requirement	**Approval Date**	**Comments**
Preparatory Activities		
Protocol registration approval for protocol Version 1.0		*To be confirmed by IMPAACT Ops*
Confirmation of clinical trials insurance (CTI)		*Site IoR (or designee) to submit copy of CTI certificate (if CTI required) OR documentation of CTI not required to IMPAACT Ops**
Confirmation of on-site review of Guidance Document: TI-CBT Intervention Adaptation		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Requirements for sites hosting Focus Groups**		
Focus Group Implementation Requirement	**Approval Date**	**Comments**
Preparatory Activities		
Confirmation of Focus Group host site		*To be confirmed by IMPAACT Ops*
Completion of study-specific delegation of duties log for Focus Group		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Translation and back-translation of study-specific TI-CBT manuals: • TI-CBT Youth Intervention Manual • TI-CBT Caregiver Intervention Manual		*To be reviewed and approved by the protocol chairs and Site IoR (or designee)**
Submit the Community Stakeholder Engagement Adaptation Feedback Form		*To be reviewed and approved by the protocol chairs**
Confirmation of Focus Group Supplies on site		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Trainings		
Community Stakeholder Engagement and Focus Group Overview		*Site IoR (or designee) to document confirmation of attendance at site*
Focus Group Conduct		
Focus Group-Specific SOPs		
Eligibility determination		*To fulfill these requirements, sites may either prepare study-specific SOPs or add study-specific addenda (as needed) to pre-existing site SOPs.*
Obtaining informed consent (including considerations for minors)		
Approval for Focus Group Implementation		*To be confirmed by IMPAACT Ops*

**For each item confirmed by the site IoR, corresponding documentation must be on file at the site and available for inspection/monitoring at any time.*

***Host site by default is the first site within a country to receive all IRB/EC approvals and protocol registration unless otherwise indicated. If your site is confirmed to be the host site, all requirements in the above table must be completed prior to implementation of the Focus Groups. The remaining study activation requirements do not have to be met prior to implementation of the Focus Group. As a non-host site, your site is encouraged to collaborate with the host site on Focus Group activities such as translations, community stakeholder engagement, and trainings.*

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IMPAACT 2016

Evaluating a Group-Based Intervention to Improve Mental Health and ART Adherence in HIV-Infected Adolescents in Low Resource Settings

Guidance Document: Preparation and Adaptation of Trauma-Informed Cognitive Behavioral Therapy (TI-CBT) Intervention

19 February 2019
Version 1.0

IMPAACT 2016 Site-Specific Study Activation Checklist

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(City, Country)

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IMPAACT 2016 Site-Specific Study Activation Checklist

CRS XX: Site Name
(City, Country)

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Study Activation and Focus Group Implementation Requirement	**Approval Date**	**Comments**
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Focus Group Implementation Requirement	**Approval Date**	**Comments**
Preparatory Activities		
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Approval for Focus Group Implementation		*To be confirmed by IMPAACT Ops*

**For each item confirmed by the site IoR, corresponding documentation must be on file at the site and available for inspection/monitoring at any time.*

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Potential Site Timeline

First Site	Last Site	Milestone
November 2018		Version 1.0 to sites
February - April 2019		Focus Group Preparations: community stakeholder engagement, manual translations, focus group training
April 2019		Open to Accrual
April 2019	July 2019	Site IRB/EC Review and Approval
April 2019	July 2019	Focus Group • 1-day Focus Group • Review and integrate changes into intervention manuals
May-June 2019	Aug 2019	IYL/Adult Study Staff Training by Expert Trainer
May-Aug 2019		Regional Study Training on Pilot Testing and Randomized Trial
July-Oct 2019	Sept-Dec 2019	Pilot Test • Participants enroll on same day (one group per site) • 6-week intervention, no follow-up • Review data and integrate changes into intervention manual

IRB/EC/Local Regulatory Reviews

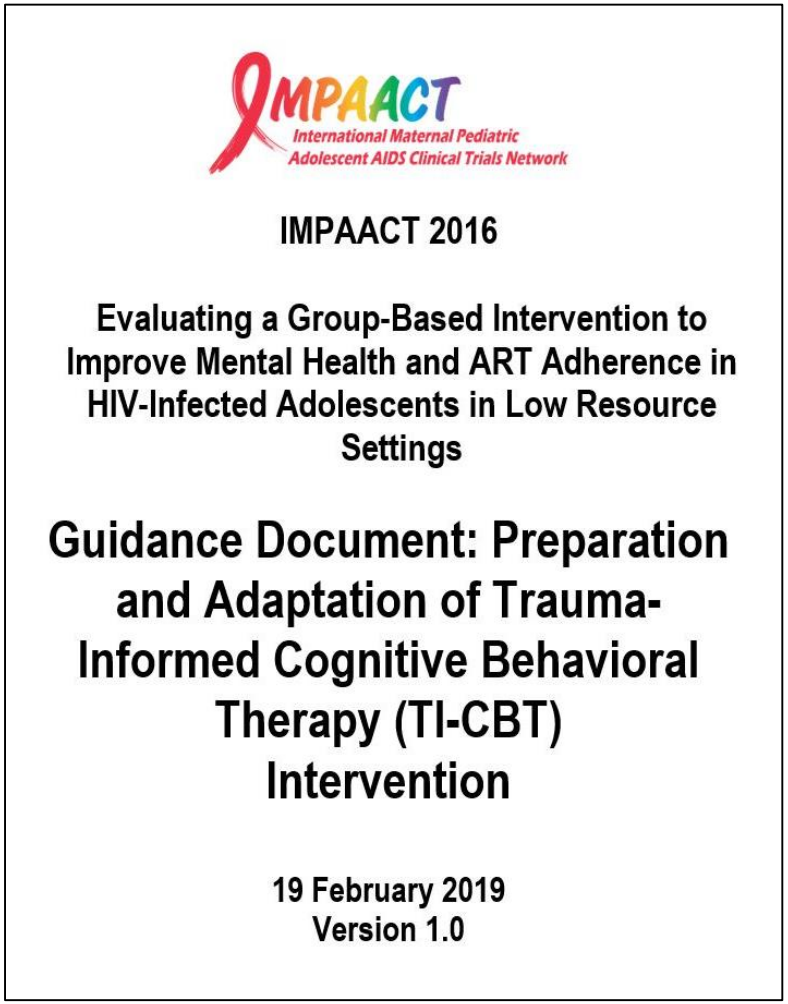
Site updates on review status
Q&A for issues in the review process

Adaptation of TI-CBT to Local Context through Community Stakeholder Engagement and Focus Groups

Adaptation Guidance Document

- **Adaptation Team**: Comprised of the co-chairs, protocol investigator, and clinical trial specialists) who will oversee the adaptation of the intervention along with the local supervisor and site staff at the specific site.

- **TI-CBT Intervention Adaptation questions (e.g. community engagement, focus groups, manual adaptations):** email Adaptation Team alias at impaact.adapt2016@fstrf.org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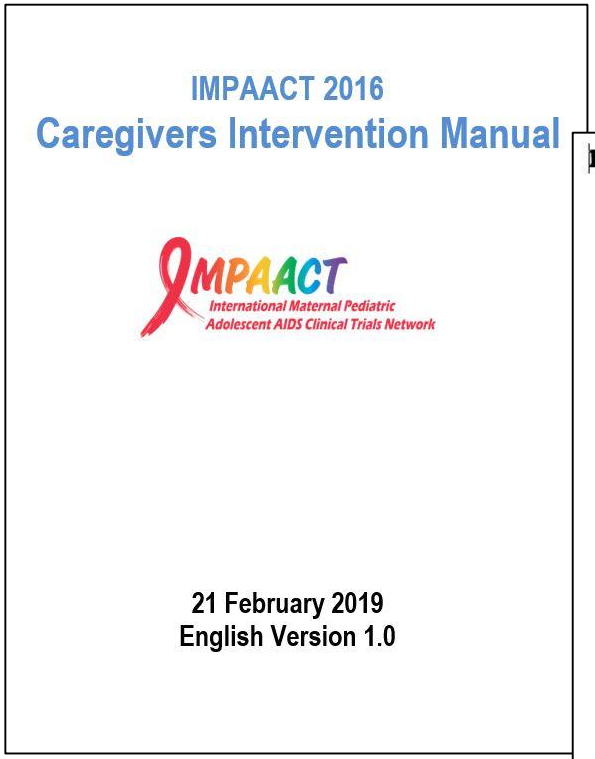
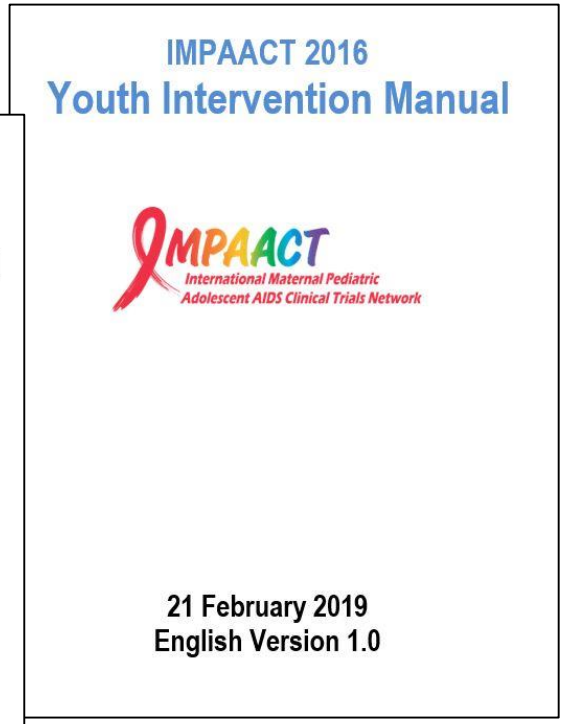
19 February 2019
Version 1.0

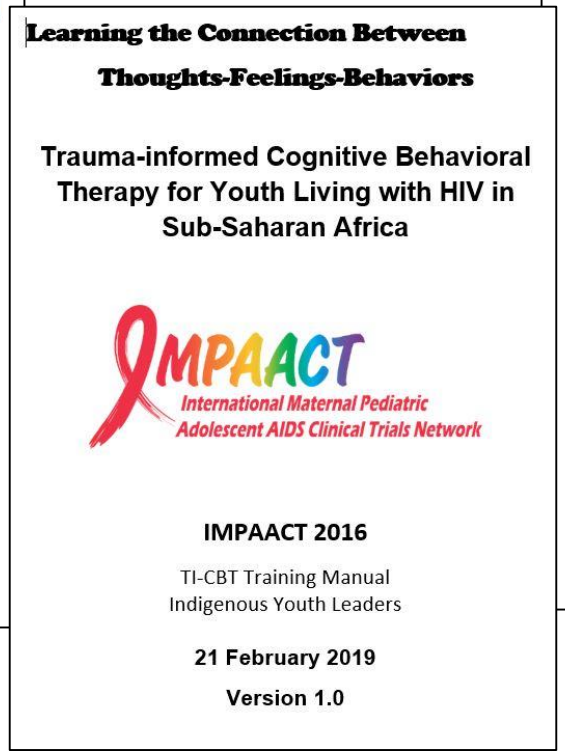
TI-CBT Manuals

Caregiver Intervention Manual



Youth Intervention Manual





TI-CBT Training Manual

Adaptation of TI-CBT: Step 3

Community Stakeholder Engagement

Step	Description
Step 1: Assessment	Steps 1 and 2 have been completed; no action is required by study sites.
Step 2: Decision	
Steps 3-8 will be completed prior to the Randomized Trial.	
Step 3: Administration	• Administration will involve identifying components of the Youth and Caregiver Intervention Manuals that may be adapted to support local context through community stakeholder engagement.
	• Components identified will be delivered in Focus Groups to the target population (youth and caregivers) in each country having participating sites.

Community Stakeholder Engagement Preparation

- An in-person meeting(s) to include but not limited to community and youth advisory boards, site study staff, adult study staff/local supervisors (who will be administering the Focus Group), and other key stakeholders at the discretion of the IoRs (or designee).

- Please be aware that future IYL or study staff to be trained should not be aware of intervention content in order to avoid research "contamination"

- Site study staff will be responsible for identifying and inviting stakeholders as well as scheduling and facilitating the meeting(s).

- **Supplies/Resources required (supplies list in Appendix I)**: Youth Intervention Manual, Caregiver Intervention Manual, Community Stakeholder Engagement Feedback Form (Appendix V in Adaptation Guidance Document), notepad, requirements for translated manuals

Community Stakeholder Engagement Conduct

- **Facilitators:** site staff (ideally the local supervisor or adult study staff) – should not be a IYL. Facilitators will read all sections of the manuals and ask for feedback.

- **Stakeholders:** are asked to provide feedback on strengths and weaknesses of each component. Prompted for feedback around feasibility, acceptability, wording for local context, concepts, and possible barriers to administering each component (*sites to use the Community Stakeholder Engagement Feedback Form for specific questions to ask stakeholders*)

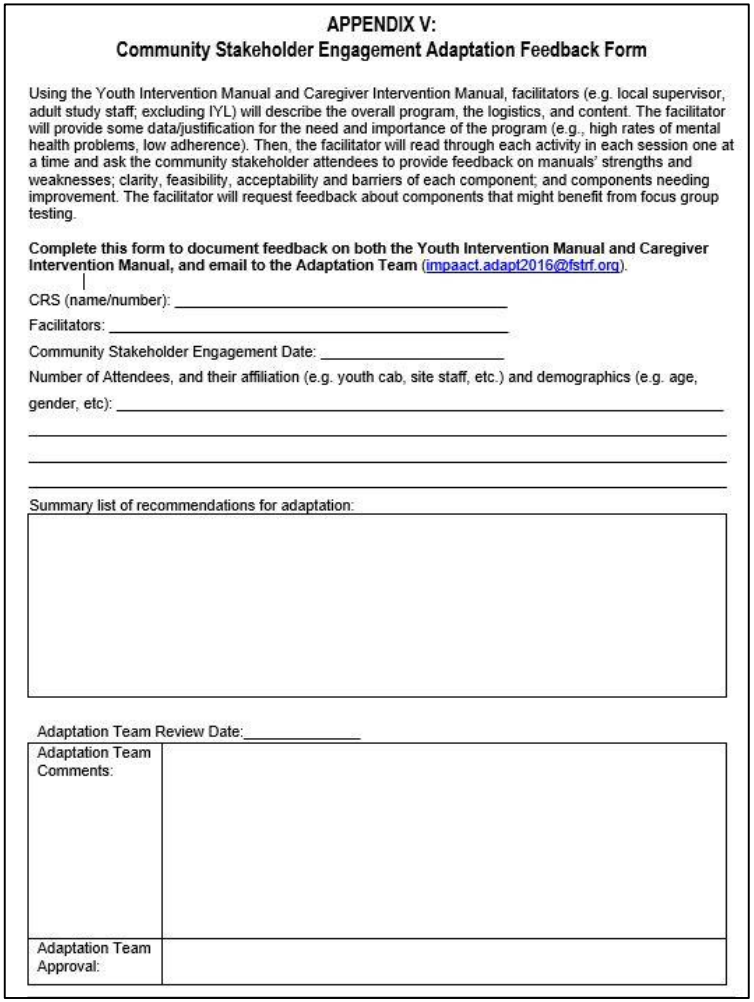
- **Stakeholder Feedback Documentation:** One site study staff will be designated to document the discussion in meeting minutes and complete a Community Stakeholder Engagement Adaptation Feedback Form for each the Youth Intervention Manual and Caregiver Intervention Manual (*document feedback and recommended components for delivery in Focus Group)*

Community Stakeholder Engagement Conclusion (Feedback Form)

- Site staff email completed Community Stakeholder Engagement Adaptation Feedback Forms to the Adaptation Team alias (impaact.adapt2016@fstrf.org)

- The Adaptation Team will review forms and discuss with local supervisor and relevant staff as needed

- Adaptation Team will email site staff and IoRs confirmation to proceed with delivering the recommended components in the Focus Groups



APPENDIX V:
Community Stakeholder Engagement Adaptation Feedback Form

Using the Youth Intervention Manual and Caregiver Intervention Manual, facilitators (e.g. local supervisor, adult study staff; excluding IYL) will describe the overall program, the logistics, and content. The facilitator will provide some data/justification for the need and importance of the program (e.g., high rates of mental health problems, low adherence). Then, the facilitator will read through each activity in each session one at a time and ask the community stakeholder attendees to provide feedback on manuals' strengths and weaknesses; clarity, feasibility, acceptability and barriers of each component; and components needing improvement. The facilitator will request feedback about components that might benefit from focus group testing.

Complete this form to document feedback on both the Youth Intervention Manual and Caregiver Intervention Manual, and email to the Adaptation Team (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Facilitators: _____

Community Stakeholder Engagement Date: _____

Number of Attendees, and their affiliation (e.g. youth cab, site staff, etc.) and demographics (e.g. age, gender, etc): _____

Summary list of recommendations for adaptation:

Adaptation Team Review Date:_____

Adaptation Team Comments:	
Adaptation Team Approval:	

Questions?

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Adaptation of TI-CBT: Step 3 continued

Step	Description
Step 1: Assessment	Steps 1 and 2 have been completed; no action is required by study sites.
Step 2: Decision	
Steps 3-8 will be completed prior to the Randomized Trial.	
Step 3: Administration	• Administration will involve identifying components of the Youth and Caregiver Intervention Manuals that may be adapted to support local context through community stakeholder engagement. • Components identified will be delivered in Focus Groups to the target population (youth and caregivers) in each country having participating sites.

Focus Groups

Part 3: Sites Administer adapted TI-CBT

a) **Community Engagement:** Protocol team works with local site, community and youth advisory boards, and other key stakeholders to review the intervention for relevance and applicability to the cultural context.

b) **Focus Group (n = 5 - 8 youth & 5 - 8 caregivers per site or country)**: Youth living with HIV 15-19 years of age and their caregivers enroll to receive components of the TI-CBT intervention by local clinical staff to inform the relevance, acceptability and understanding of TI-CBT delivered by IYL.

Parts 4-7 – *no enrolled participant engagement*

Part 4: **Produce** TI-CBT intervention based on information obtained in part 3 by protocol team

Part 5: **Topical** experts review TI-CBT intervention where expertise is lacking to resolve issues

Part 6: **Integrate** all final input obtained in part 3 and 5 to complete production of TI-CBT intervention by protocol team

Part 7: **Train** Indigenous Youth Leaders (IYL) at site to deliver TI-CBT intervention by protocol team and local staff

Recruitment of Youth and Caregivers

Recruitment methods may vary across sites but are generally expected to rely on outreach to youth living with HIV in care at participating study sites and local clinics. Sites will recruit from the target population for the Focus Group, Pilot Test and Randomized Trial to meet the following minimum criteria:

- At time of Focus Group, 15-19 years old
- Living with HIV as confirmed by the youth
- Signed informed consent or assent per protocol eligibility criterion 4.1.2 and Appendix III.

Focus Groups Preparation

- One youth Focus Group and one caregiver Focus Group will be conducted in Botswana, South Africa, and Zimbabwe.

- A host site within each country will conduct the Focus Groups; the host site by default is the first site within a country to receive all IRB/EC approvals, protocol registration unless otherwise indicated.

- In Malawi, due to differing local context Focus Groups be conducted at each site.

Focus Groups Preparation Continued

On a site-by-site basis, when all implementation requirements have been met, the Operations Center will issue an Implementation Notice. At each site, no Focus Group activities may be performed prior to receipt of this notice.

The full intervention is not provided in the Focus Group.

Once components for the Focus Group per country are identified by stakeholders and confirmed by the Adaptation Team, a minimum of two facilitators (e.g. adult study staff not designated to the Discussion Control Arm, local supervisor, IoR) at a host site will be trained to deliver the identified components in the youth and caregiver Focus Groups.

A site must be protocol registered, complete the implementation requirements for the Focus Group, and receive an Implementation Notice prior to proceeding with the following Focus Group activities.

Conducting the Focus Group

- Four facilitators will lead two separate Focus Groups:
  – two facilitators will lead a group of youth (up to 8 participants) and
  – two facilitators will lead a group of caregivers (up to 8 participants)

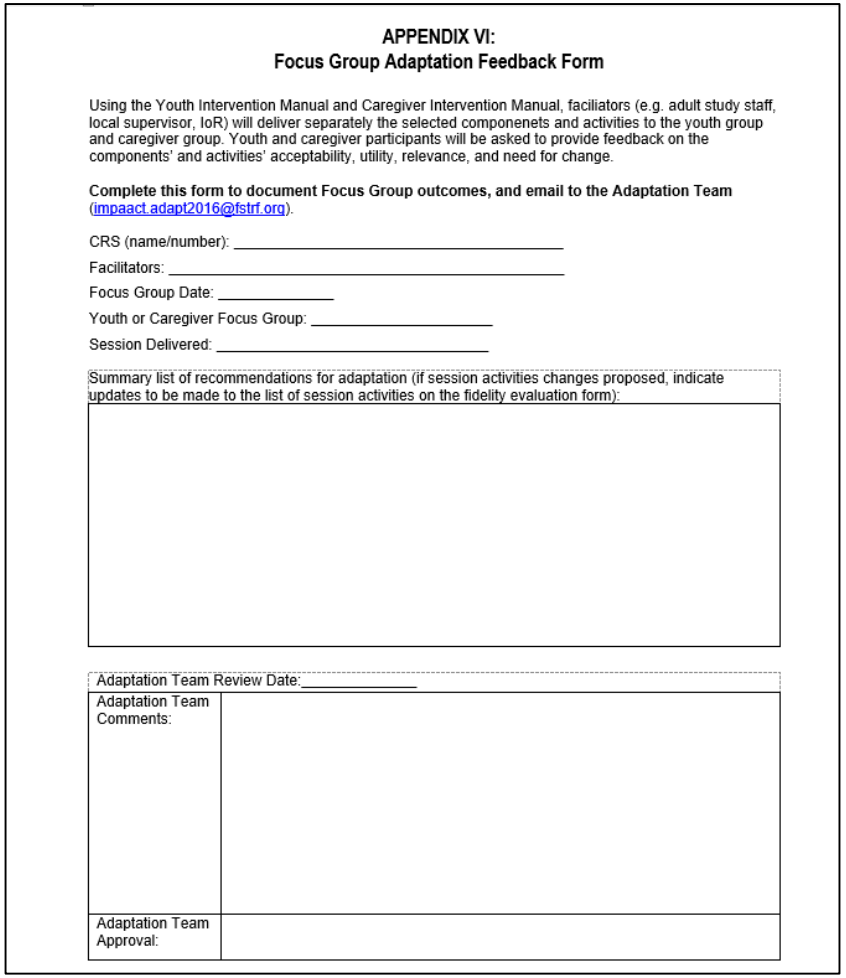
- Another site study staff member will be designated to observe and document each focus group discussion in meeting minutes to capture immediate reactions.

- After the delivery of a component, the facilitators will lead a discussion with participants about the component's acceptability, utility, relevance, and any need for change as part of the adaptation feedback from participants.

Reminder: facilitators leading the Focus Groups will not be able to lead the Discussion Control groups in the Pilot and Randomized Trial to prevent contamination.

Focus Group Adaptation Feedback Form

- Site staff email completed Focus Group Adaptation Feedback Forms to the Adaptation Team alias (impaact.adapt2016@fstrf.org)



APPENDIX VI:
Focus Group Adaptation Feedback Form

Using the Youth Intervention Manual and Caregiver Intervention Manual, faciliators (e.g. adult study staff, local supervisor, IoR) will deliver separately the selected componenets and activities to the youth group and caregiver group. Youth and caregiver participants will be asked to provide feedback on the components' and activities' acceptability, utility, relevance, and need for change.

Complete this form to document Focus Group outcomes, and email to the Adaptation Team (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Facilitators: _____

Focus Group Date: _____

Youth or Caregiver Focus Group: _____

Session Delivered: _____

Summary list of recommendations for adaptation (if session activities changes proposed, indicate updates to be made to the list of session activities on the fidelity evaluation form):

Adaptation Team Review Date:_____

Adaptation Team Comments:	
Adaptation Team Approval:	

Adaptation of TI-CBT: Steps 4-6

Step 4: Production **Step 5: Topical Experts** **Step 6: Integration**	• Select members of the protocol team will form an Adaptation Team. For adaptations which members of the Adaptation Team are not experts on, topical experts may be required to provide input. • Designated site staff to revise and finalize the Youth and Caregiver Intervention Manuals per the community stakeholder engagement, Focus Group, and topical expert feedback. • Revisions will be emailed to the designated site translators for translation and back translation. • The site translators will email the full Youth and Caregiver Intervention Manuals, with the new back translations included in each, to the Adaptation Team at impaact.adapt2016@fstrf.org for review and approval. • The Adaptation Team will distribute the final English and translated versions of the site-specific Youth and Caregiver Intervention Manuals to the respective site.

Adaptation of TI-CBT

- The Adaptation Team will review the form and discuss the feedback and recommended changes for adaptation. As needed, the Adaptation Team may request to discuss the feedback with sites by phone or email.
- Once the Adaptation Team approves requested adaptations, the site is responsible for implementing any approved changes within the associated manuals
- The sites will email any revisions to their designated site translators for translation and back translation

Recruitment of Indigenous Youth Leaders, Adult Study Staff and Local Supervisors

- Recruitment of IYL may vary across sites but are generally expected to rely on outreach to youth/young adults living with HIV, currently in care, possibly from study site and/or local clinics.
- Recruitment of adult study staff may vary across sites, but are generally expected to evaluate current staff as well as advertise for the position with preferences weighted towards those with research experience working with youth, caregivers of youth, with people living with HIV, and/or in mental health.
- Please note, new hires of family members should be approved by the IMPAACT 2016 Adaptation Team

Criteria for selecting Indigenous Youth Leaders (IYL)

APPENDIX II:
Criteria Form for Selecting Indigenous Youth Leaders (IYL)

Suggested criteria for selecting Potential IYL to lead or observe the youth group sessions listed in table below (target is a minimum of 6 IYL): complete this form for each potential IYL and email to the Adaptation Team (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Name of Potential IYL: _____

Sex (male or female): _____

Relation to clinic study staff (example daughter/son/ niece/nephew/none):

_____

Criteria	Description	Yes	No	Explanation if No
Age	… is between 21 and 30 years of age			
Clinic attendance	…Missed no more than one clinic appointment over the last 12 months			
Adherence	…Self-reports excellent ART adherence			
	…Viral load available and undetected or < 40 copies?			
Communication	….able to read and write?			
	….experience standing and teaching in front of a group (perhaps at school for a presentation?)			
Dedication	…committed to attending all training sessions and leading all intervention/discussion control sessions?			
Alcohol/Drugs	…Does **NOT** have a problem drinking alcohol or taking ilicit drugs (marijuana, cocaine, heroin, etc.)			
Mental health	…has been assessed using the same instruments as the participants			

Criteria for selecting Adult Study Staff

APPENDIX III:
Criteria Form for Selecting Adult Study Staff

Suggested criteria for selecting Potential Adult Study Staff to lead or observe the caregiver group sessions list in table below (target is a minimum of 6 adult study staff): complete this form for each potential IYL and email to the Adaptation Team (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Name of Potential Adult Study Staff: _____

Sex (male or female): _____

New hire, or currently part of IMPAACT site team?: _____

Criteria	Description	Yes	No	Explanation if No
Mental Health experience	…prior training in mental health work? (if yes please provide training experience)			
Work experience	…prior work with caregivers of youth living with HIV?			
Communication	….able to read training materials and write notes?			
	….experience standing and teaching in front of a group?			
Dedication	…committed to attending all training sessions and leading all intervention/discussion control sessions?			
Alcohol/Drugs	…does **NOT** have a problem drinking alcohol or taking ilicit drugs (marijuana, cocaine, heroin, etc.)			

Criteria for selecting Local Supervisors

APPENDIX IV:
Criteria Form for Selecting Local Supervisor

Suggested criteria for selecting Potential Local Supervisor to supervise IYL and adult study staff in their facilitation of the youth and caregiver group sessions, respectively, listed in table below (target is a minimum of 1 Local Supervisor): **complete this form for each potential Local Supervisor and email to the Adaptation Team** (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Name of Potential Local Supervisor: _____

Sex (male or female): _____

Does the Local Supervisor have credentials to serve as the on-site clinician?: _____

If yes, list credentials:_____

New hire, or currently part of IMPAACT site team?: _____

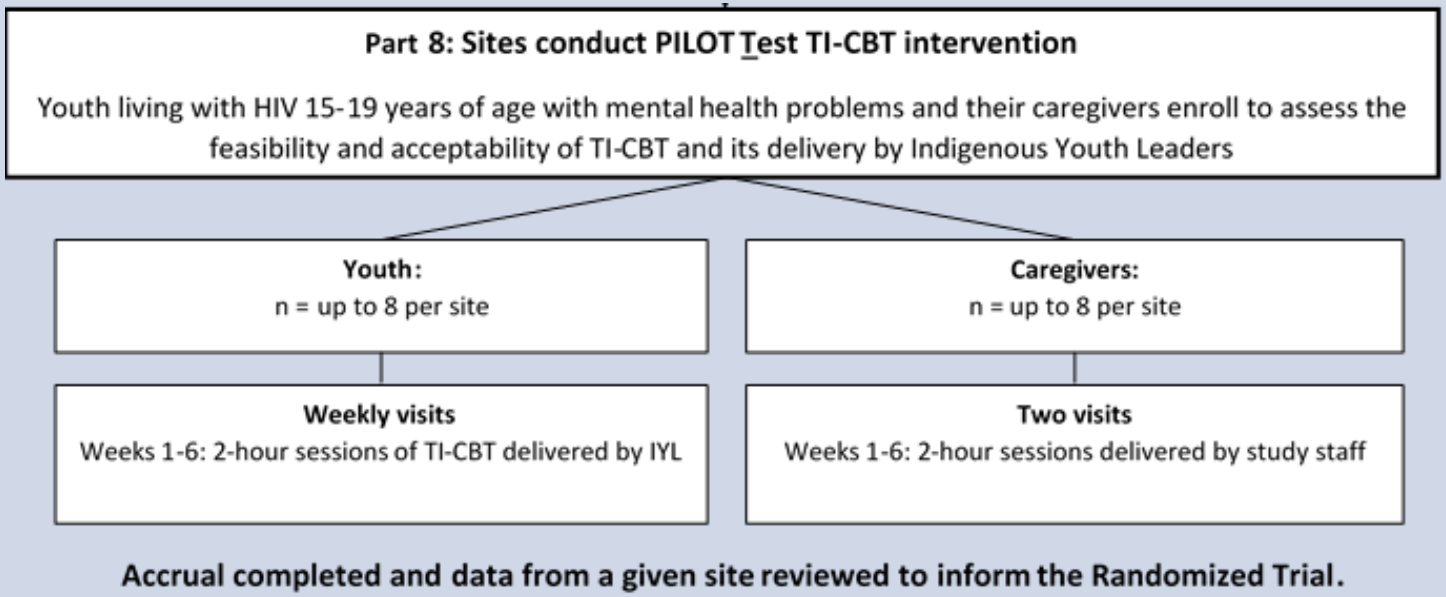
Criteria	Description	Yes	No	Explanation if No
Available	…to be onsite during group sessions at all times to assist in the event that as issue arises during group sessions that requires professional attention			
	…to be available by phone during off hours			
	…to meet weekly with the expert trainer			
	…to meet twice weekly with the IYL			
Evaluation and Mentor skills	…to help guide supervision discussions with IYL, provide support, answer questions, relate well to youth, guide IYL if issues arise, and evaluate IYL knowledge and session knowledge			

Training for Intervention Delivery: Step 7

Step	Description
Step 7: Training	• Training will involve IYL, adult study staff, and local supervisors. • Sites in Botswana, Zimbabwe, and South Africa will have one combined training per country; the two sites in Malawi may each have their own training, due to cultural variances. • Upon successful completion of training, the expert trainer and local supervisor will designate a minimum of two certified IYL and two certified adult study staff to facilitate (lead) the group sessions, and designate a minimum of one certified IYL and one certified adult study staff to observe group sessions during the Pilot Test and Randomized Trial. Should an IYL or adult study staff facilitator be unavailable to deliver a TI-CBT or Discussion Control group session, the observer designated to that study arm will take his/her place as a facilitator. • Once identified site study staff should email a list of all IYL and adult study staff with their designation (facilitator or observer) to the Adaptation Team at impaact.adapt2016@fstrf.org.

Adaptation of TI-CBT: Step 8

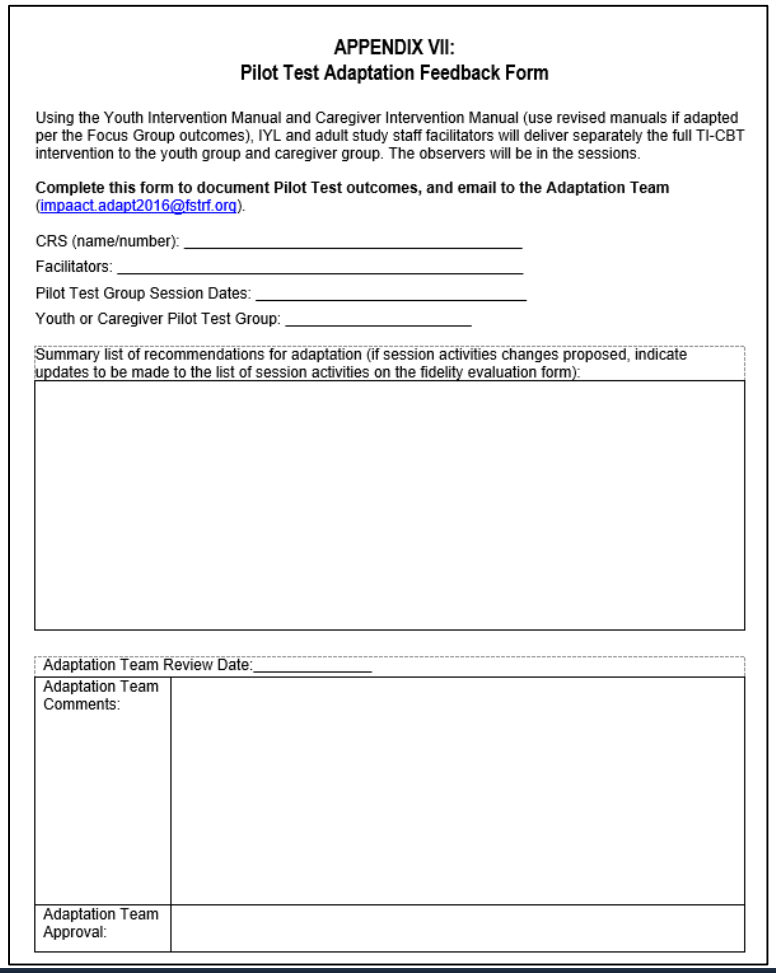
Step	Description
Step 8: Pilot Test	• For the pilot Test, IYL will deliver the complete TI-CBT intervention.



Concluding the Pilot Test

- Designated sites staff will receive site-specific acceptability and feasibility data
- Similarly to the Focus Group adaptation **study site staff are to email the Pilot Test Adaptation Feedback form to the Adaptation Team alias** (impaact.adapt2016@fstrf.org)
- The Adaptation Team will review the form and discuss the feedback and recommended changes for adaptations. As needed, the Adaptation Team may request to discuss the feedback with sites and/or additional stakeholders by phone or email
- The Adaptation Team will make a final determination of adaptations to be incorporated into the site-specific Youth and Caregiver Intervention Manuals
- The manuals will be revised and back translated as need by site staff. The Adaptation Team will distribute the final English and translated versions of the site-specific Youth and Caregiver Intervention Manuals to each respective site for implementation in the Randomized Trial.

Pilot Test Adaptation Feedback Form



APPENDIX VII:
Pilot Test Adaptation Feedback Form

Using the Youth Intervention Manual and Caregiver Intervention Manual (use revised manuals if adapted per the Focus Group outcomes), IYL and adult study staff facilitators will deliver separately the full TI-CBT intervention to the youth group and caregiver group. The observers will be in the sessions.

Complete this form to document Pilot Test outcomes, and email to the Adaptation Team (impaact.adapt2016@fstrf.org).

CRS (name/number): _____

Facilitators: _____

Pilot Test Group Session Dates: _____

Youth or Caregiver Pilot Test Group: _____

Summary list of recommendations for adaptation (if session activities changes proposed, indicate updates to be made to the list of session activities on the fidelity evaluation form):

Adaptation Team Review Date:_____

Adaptation Team Comments:	
Adaptation Team Approval:	

Similar to completion of the focus group, study site staff are asked to consider any recommended adaptations to improve intervention delivery prior to the Randomized control trial and to email the Pilot Test Adaptation Feedback form to the Adaptation Team alias (impaact.adapt2016@fstrf.org)

Questions?

IMPAACT
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Study Activation requirements for all sites

Requirements for all sites		
Study Activation Requirement	**Approval Date**	**Comments**
Preparatory Activities		
Completion of study-specific delegation of duties log for Pilot Test and Randomized Trial		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Study-Specific SOPs		
Participant accrual		• *To fulfill these requirements, sites may either prepare study-specific SOPs or add study-specific addenda (as needed) to pre-existing site SOPs.* • *The SOP for participant accrual must be submitted for IMPAACT Ops and protocol chairs review and approval; for all other SOPs, site IoR (or designee) to submit confirmation to IMPAACT Ops**
Eligibility determination		
Obtaining informed consent (including considerations for minors)		
Safety monitoring and Adverse Event Reporting		
Source documentation (to include specification of eCRFs planned to be used as source)		
Other Study-specific Materials		
Confirmation of on-site review of Manual of Procedures (MOP) and Lab Processing Chart (LPC)		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Confirmation of adapted final English and translated versions of study site-specific TI-CBT manuals on site prior to trainings: • TI-CBT Youth Intervention Manual • TI-CBT Caregiver Intervention Manual		
Confirmation of Group Session Supplies on site		
Trainings		
Indigenous Youth Leader and Adult Study Staff participation in training on delivery of the TI-CBT or discussion control group sessions		*Site IoR (or designee) to document confirmation of attendance at site**
Participation in study-specific start-up training		*To be confirmed by IMPAACT Ops*

Study Activation requirements for all sites

Requirements for all sites		
Study Activation Requirement	**Approval Date**	**Comments**
Preparatory Activities		
Completion of study-specific delegation of duties log for Pilot Test and Randomized Trial		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Study-Specific SOPs		
Participant accrual		• *To fulfill these requirements, sites may either prepare study-specific SOPs or add study-specific addenda (as needed) to pre-existing site SOPs.* • *The SOP for participant accrual must be submitted for IMPAACT Ops and protocol chairs review and approval; for all other SOPs, site IoR (or designee) to submit confirmation to IMPAACT Ops**
Eligibility determination		
Obtaining informed consent (including considerations for minors)		
Safety monitoring and Adverse Event Reporting		
Source documentation (to include specification of eCRFs planned to be used as source)		
Other Study-specific Materials		
Confirmation of on-site review of Manual of Procedures (MOP) and Lab Processing Chart (LPC)		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Confirmation of adapted final English and translated versions of study site-specific TI-CBT manuals on site prior to trainings: • TI-CBT Youth Intervention Manual • TI-CBT Caregiver Intervention Manual		
Confirmation of Group Session Supplies on site		
Trainings		
Indigenous Youth Leader and Adult Study Staff participation in training on delivery of the TI-CBT or discussion control group sessions		*Site IoR (or designee) to document confirmation of attendance at site**
Participation in study-specific start-up training		*To be confirmed by IMPAACT Ops*

Study Activation requirements for all sites

Requirements for all sites		
Study Activation Requirement	**Approval Date**	**Comments**
Preparatory Activities		
Completion of study-specific delegation of duties log for Pilot Test and Randomized Trial		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Study-Specific SOPs		
Participant accrual		• *To fulfill these requirements, sites may either prepare study-specific SOPs or add study-specific addenda (as needed) to pre-existing site SOPs.* • *The SOP for participant accrual must be submitted for IMPAACT Ops and protocol chairs review and approval; for all other SOPs, site IoR (or designee) to submit confirmation to IMPAACT Ops**
Eligibility determination		
Obtaining informed consent (including considerations for minors)		
Safety monitoring and Adverse Event Reporting		
Source documentation (to include specification of eCRFs planned to be used as source)		
Other Study-specific Materials		
Confirmation of on-site review of Manual of Procedures (MOP) and Lab Processing Chart (LPC)		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Confirmation of adapted final English and translated versions of study site-specific TI-CBT manuals on site prior to trainings: • TI-CBT Youth Intervention Manual • TI-CBT Caregiver Intervention Manual		
Confirmation of Group Session Supplies on site		
Trainings		
Indigenous Youth Leader and Adult Study Staff participation in training on delivery of the TI-CBT or discussion control group sessions		*Site IoR (or designee) to document confirmation of attendance at site**
Participation in study-specific start-up training		*To be confirmed by IMPAACT Ops*

Study Activation requirements for all sites

Requirements for all sites		
Study Activation Requirement	**Approval Date**	**Comments**
Preparatory Activities		
Completion of study-specific delegation of duties log for Pilot Test and Randomized Trial		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Study-Specific SOPs		
Participant accrual		• *To fulfill these requirements, sites may either prepare study-specific SOPs or add study-specific addenda (as needed) to pre-existing site SOPs.* • *The SOP for participant accrual must be submitted for IMPAACT Ops and protocol chairs review and approval; for all other SOPs, site IoR (or designee) to submit confirmation to IMPAACT Ops**
Eligibility determination		
Obtaining informed consent (including considerations for minors)		
Safety monitoring and Adverse Event Reporting		
Source documentation (to include specification of eCRFs planned to be used as source)		
Other Study-specific Materials		
Confirmation of on-site review of Manual of Procedures (MOP) and Lab Processing Chart (LPC)		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Confirmation of adapted final English and translated versions of study site-specific TI-CBT manuals on site prior to trainings: • TI-CBT Youth Intervention Manual • TI-CBT Caregiver Intervention Manual		
Confirmation of Group Session Supplies on site		
Trainings		
Indigenous Youth Leader and Adult Study Staff participation in training on delivery of the TI-CBT or discussion control group sessions		*Site IoR (or designee) to document confirmation of attendance at site**
Participation in study-specific start-up training		*To be confirmed by IMPAACT Ops*

Study Activation requirements for all sites continued

Requirements for all sites		
Study Activation Requirement	**Approval Date**	**Comments**
Data Management Requirements		
IMPAACT Data Management Center (DMC) approval of local data management readiness, based on confirmation of the following: • Creation of DMC portal accounts for relevant site staff with level 2 access and subject enrollment privileges • Creation of accounts in Medidata Rave for relevant site staff • Completion of required Medidata Rave eLearning courses by at least one site staff member • Participation in subject enrollment training by at least one site staff member		*To be reviewed and confirmed by IMPAACT DMC* Please email Tia (Christina) Reding at reding@fstrf.org **AND** Lindsay Miller lmiller@frontierscience.org for any DMC requirements
Translation and back-translation of study-specific questionnaires		
Participation in DMC Introductory training that includes Subject Enrollment (SES) training, introduction to Medidata Rave, other DMC utilities and guidance on best practices for data management		
Approval of CASI readiness: • Creation of accounts in CASI for relevant site staff • Paper versions of all questionnaires available for back-up • At least 1 functioning device (i.e. desktop, laptop, tablet) available for participant use – list devices available		

Study Activation requirements for all sites continued

Requirements for all sites		
Study Activation Requirement	**Approval Date**	**Comments**
Laboratory Requirements		
IMPAACT Laboratory Center (LC) approval of local laboratory site readiness, based on confirmation of the following: • Confirmation of youth HIV testing algorithms • Confirmation of access to HIV-1 RNA PCR assay at local VQA-certified laboratory • Confirmation of current IATA training certificates for at least two individuals responsible for shipping samples • DCLOT approval of laboratory readiness based on – Completion of relevant IMPAACT Critical Items from DAIDS Audit Action Plan, if applicable – Approval of protocol analyte list (PAL) – Confirmation of acceptable EQA status, (VQA) for protocol analytes for both primary and backup laboratories – Submission of current adult and pediatric reference ranges (must be reviewed, approved, and signed by Laboratory Medical Director) • Have obtained all required permits and fully executed M/STAs for shipping specimens to Monica Ghandi hair lab (LDMS lab code: 607) • Submission of current Laboratory Director's CV for Monica Ghandi hair lab (LDMS lab code: 607)		*To be confirmed by IMPAACT Laboratory Center (for NIAID sites)* Please email: Dale Dayton ddayton@impaactlabcenter.org **AND** Amy Loftis amy_james@med.unc.edu
Other Requirements		
Resolution of action items identified during study-specific training and/or other site preparatory activities		*Site IoR (or designee) to submit confirmation to IMPAACT Ops**
Approval for Study Activation of IMPAACT 2016 (Pilot Test and Randomized Trial)		*To be confirmed by IMPAACT Ops*

**For each item confirmed by the site IoR, corresponding documentation must be on file at the site and available for inspection/monitoring at any time.*

Approval for Study Activation

Once all Activation Requirements are met the Operations Center will send a Site-Specific Study Activation Notice indicating the site has met all site-specific study activation requirements, including DAIDS protocol registration, and this will be an indication to begin accrual of participants to IMPAACT 2016 for the Pilot and Randomized Trial!

Questions?

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Questions & Answers

- **Q: If a site has an Adolescent Advisory Board that could participate in the community stakeholder engagement, would the protocol team recommend having additional stakeholders participate?** A: For review of the youth intervention manual, sites can invite caregivers of youth, clinic members, and adolescent advisory board members, however the participants which participate in the community stakeholder engagement **cannot be** study participants or facilitate the study intervention. For review of the caregiver manual, sites can invite caregivers and clinic members, and again the caregivers **cannot** participate in the study intervention if they participant in the community stakeholder engagement.
- **Q: When should the community stakeholder engagement occur?** A: The engagement is part of Step 3: Administration of the ADAPT-ITT model; it must occur prior to the Focus Groups, as this process helps identify which components should be delivered in the Focus Groups, and may occur prior to IRB approval. Once the manuals have been received and minimal translation requirements of the youth and care intervention manual (translate and back translation table of contents) have been met, sites can initiate the engagement.
- **Q: Are Focus Groups audiotaped?** A: Yes, Focus Groups are audiotaped. Focus Groups may be audiotaped to help refer back to youth and caregiver participation and to guide filling out the Per Section 3.3.2 *Conducting Focus Groups and Adaptation Following Focus groups* in the adaptation guidance document, Focus Group Adaptation Feedback Form.

Questions & Answers

- **Q: If the youth and caregiver Focus Groups are held at separate times, can the same facilitators lead both groups?** A: Yes.
- **Q: Do caregiver participants in the Focus Group need to be caregivers of a youth participating in the Focus Group?** A: No, any caregiver of youth living with HIV (who is either participating or not participating in the Focus Group) may participate.
- **Q: What is the expected turnaround time for sites to incorporate adaptations into the manuals once the adaptations are approved?** A: Upon receipt of approved adaptations, sites should immediately begin incorporating adaptations so that translation and back translations of the adapted manuals can be completed as soon as possible. Once the manuals are back translated, sites may proceed to the next part of the study.
- **Q: At any point in the adaptation process, is there an external translator on the IMPAACT team to translate manuals, or will all translations be made by a local translator?** A: All translations will be made by a local translator. *Following the webinar, Ops will be distributing the manuals with instructions to include that sites will identify a local translator to translate.*

Questions & Answers

- **Q: Can the IoR also be the supervisor?** A: Yes. If time commitment of an IoR is not an issue, they would be an ideal supervisor.
- **Q: Do the weekly supervision meetings between IYL and Local Supervisors occur only during the 6-week group session intervention period, or throughout the entire study duration?** A: The weekly supervision meetings occur while the group sessions are occurring. Additionally, after the IYL and adult study staff are trained by the expert trainer, the supervisor may need to repeat portions of the training to ensure knowledge is not lost if gaps of time between the training and group sessions occur.
- **Q: When will an IYL or adult study staff be randomized to a Study Arm?** A: IYL and adult study staff will be randomized to a Study Arm before being trained by the expert trainer by the protocol adaptation team so that any perceived 'best performing' IYL or adult study staff are not designated to one arm or the other.
- **Q: Can the Malawi sites have a combined IYL and adult study staff training?** A: The chairs and operations center approve the request of the Malawi sites having a combined IYL and adult study staff training should the sites believe that separate trainings are not required due to cultural differences.