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

IMPAACT 2016

Focus Group Conduct Training

13 June 2019

Protocol Chairs: Geri Donenberg and Dorothy Dow

IMPAACT
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: **Sara Zabih**

Site Introductions

- 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

Reminder: Document this training!

Site IoRs are responsible for ensuring that study staff members are adequately trained to serve their designated site- and study-specific functions.

Per the DAIDS policy on *Requirements for Manual of Operational Procedures,* all sites must establish and follow a standard operating procedure (SOP) for personnel training and certification documentation.

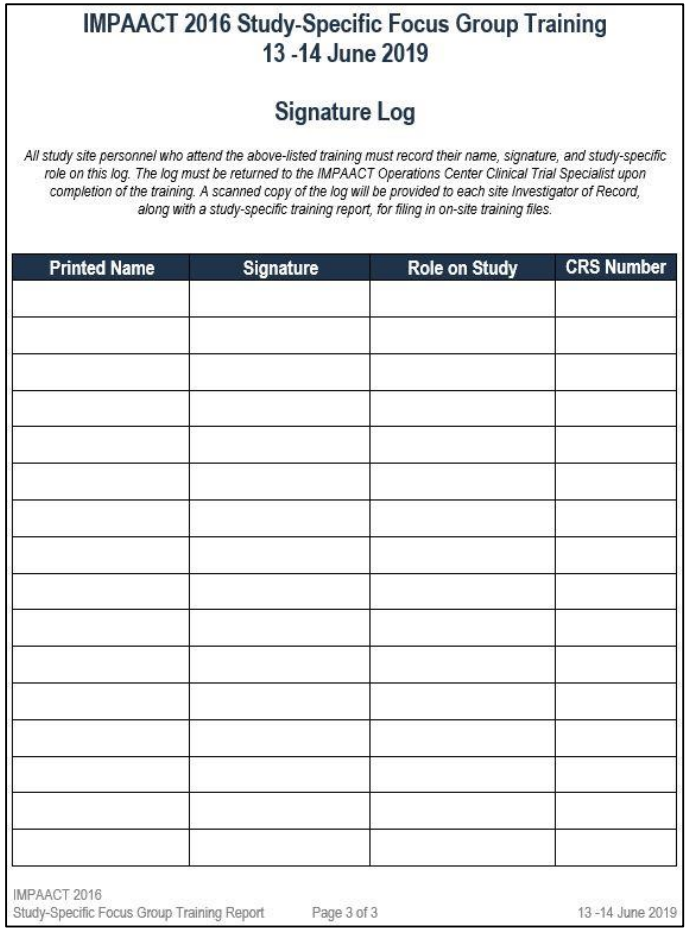
Site IoRs are responsible for documenting that each study staff member has completed study-specific training corresponding to his or her designated roles and responsibilities. This documentation must be on file at the site and available for inspection/monitoring at any time.

Reminder: Document this training!

The Ops Center will provide an email documenting that the training was conducted.

- **<u>Site personnel attending in-person training</u>: you are responsible for documenting your attendance of this in-person training**

- **<u>Site personnel separately review training materials</u>: sites are responsible for documenting individual site personnel successful review of materials if not attending in-person training**



IMPAACT 2016 Study-Specific Focus Group Training
13 -14 June 2019

Signature Log

All study site personnel who attend the above-listed training must record their name, signature, and study-specific role on this log. The log must be returned to the IMPAACT Operations Center Clinical Trial Specialist upon completion of the training. A scanned copy of the log will be provided to each site Investigator of Record, along with a study-specific training report, for filing in on-site training files.

Printed Name	Signature	Role on Study	CRS Number

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Study-Specific Focus Group Training Report Page 3 of 3 13 -14 June 2019

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.*

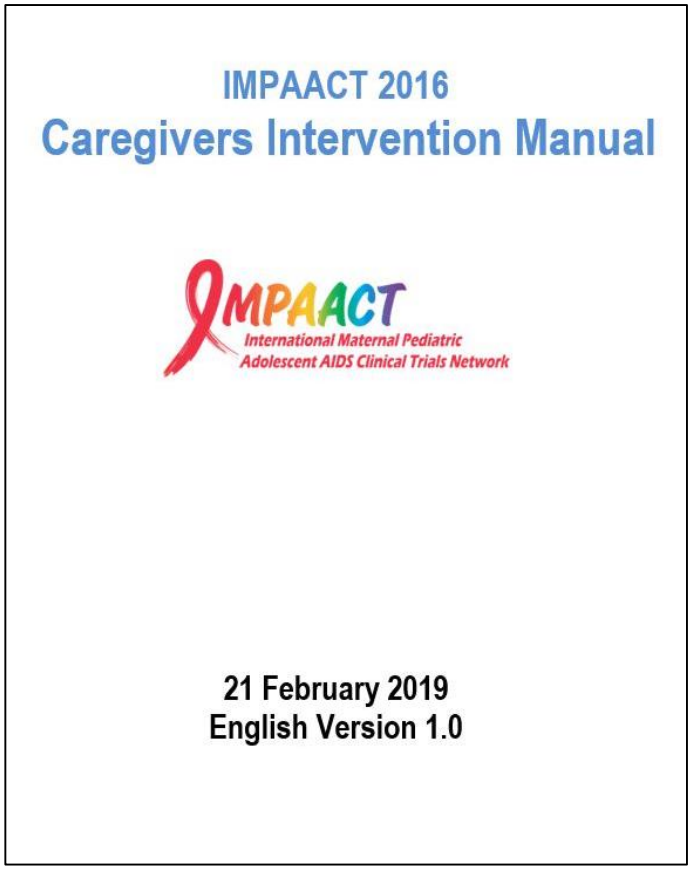
Purpose of Focus Group Training

- **Part I: Focus Group Operations**
  - Adapt Intervention Manuals
  - Reviewing Manuals with Community Stakeholder Engagement
  - Recruitment and Selection of Study-Specific Personnel
  - Implementation Notice for Focus Group
  - Recruitment of Participants for Focus Groups
  - Scheduling Focus Group Sessions
  - Conducting Focus Group Sessions
  - Participant Safety and Privacy in Focus Group Sessions
  - Concluding Focus Groups
- **Part II-A: Focus Group Overview**
  - Discuss Key Concepts
  - Adapting per site and participants needs
- **Part II-B: Practicing Youth Intervention Components**
  - Stress and Mind-Body Connection, Stress Responses
  - Connections between Thoughts-Feelings-Behaviors
  - Let Go and Open to Receive Exercise
  - Gender-based violence, Gender Roles and Expectations
- **Part II-C: Practicing Caregiver Intervention Components**
  - Hand Push Exercise
- **Part III: Site Questions and Comments from Community Stakeholder Engagement Feedback Form**
- **Part IV: Next Steps**

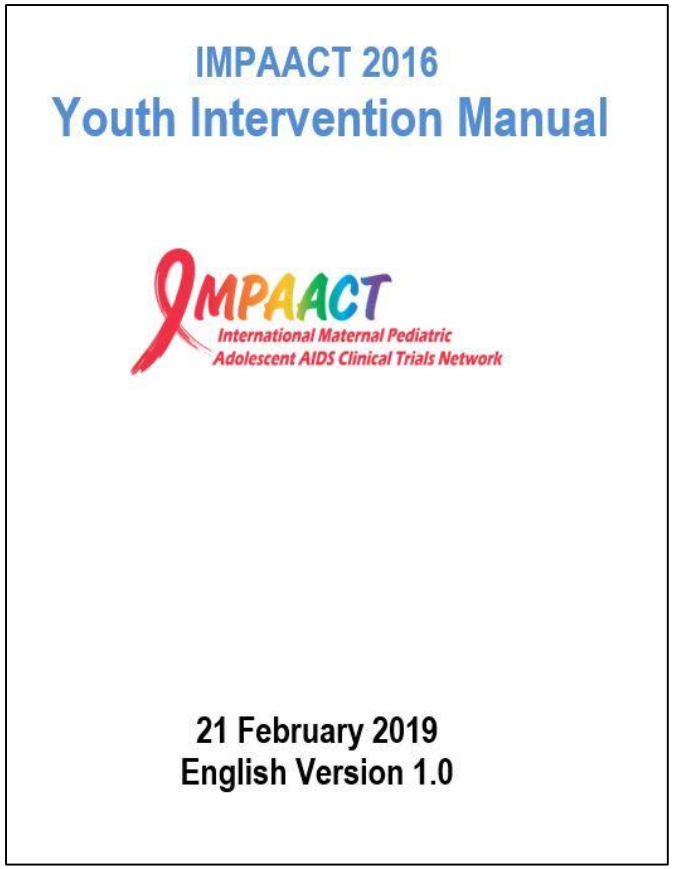
Part I:
Focus Group
Operational Guidance

Purpose: Adapt Intervention Manuals

Caregiver Intervention Manual



Youth Intervention Manual

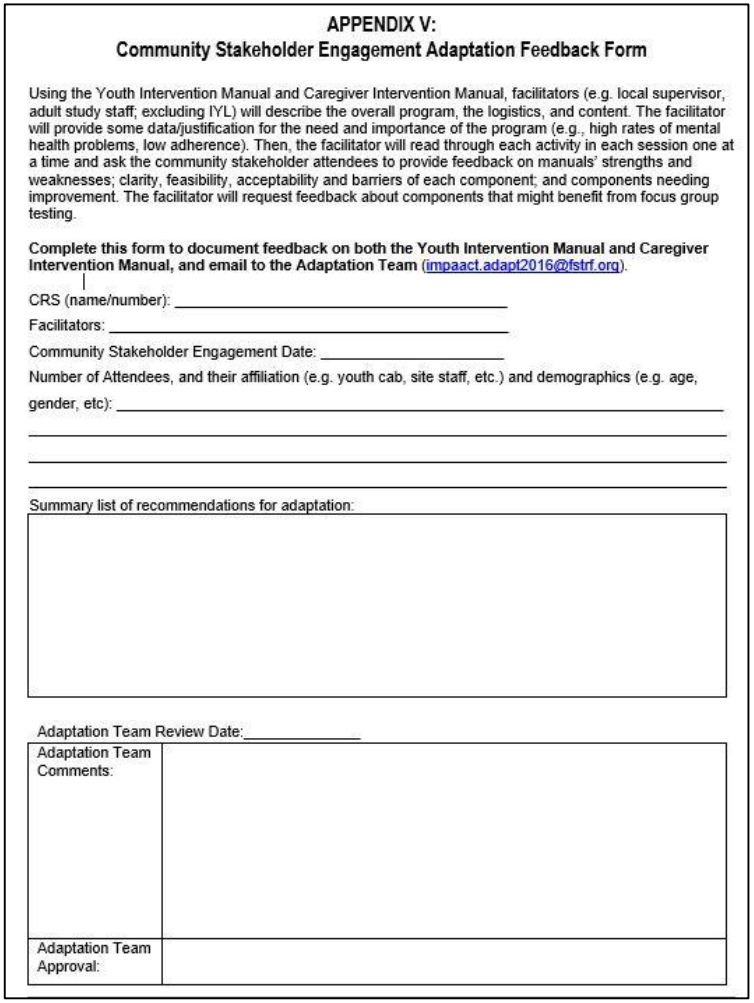


Preparing: Reviewing Manuals with Community Stakeholder Engagement

- 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:	

Preparing: Recruitment of Study-Specific Personnel

(Indigenous Youth Leaders, Adult Study Staff, and Local Supervisors)

IYL

- Recruitment 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.

Adult Study Staff

- Recruitment 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.

Local Supervisor

- Recruitment may vary across sites but are generally expected to be an individual (e.g. psychologist, nurse, IoR, other) with a working relationship with the site who is designated to supervise IYL or adult study staff.
- May also serve as the on-site study clinician

Questions should be emailed to the Adaptation Team (impaact.adapt2016@fstrf.org).

New hires of family members should be approved by the IMPAACT 2016 Adaptation Team

Preparing: Selection of Study-Specific Personnel

(Indigenous Youth Leaders and Adult Study Staff)

Indigenous Youth Leaders

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			

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.)			

Preparing: Selection of Study-Specific Personnel
(Local Supervisor)

Local Supervisor

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			

Implementation Notice for Focus Groups

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. local supervisor, IoR, but **not adult study staff designated to the Discussion Control Arm**) 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.

Recruitment of Participants for Focus Groups

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 youth reflective of the target population for Pilot Test and Randomized Trial to meet the following minimum criteria:

Youth Participants

- 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
- DOES NOT need to meet mental health criteria

Caregiver Participants

- At time of Focus Group, of legal age to provide informed consent
- May or may not currently be caring for a youth who takes part in a Focus Group; be caregivers of youth 15-19 years old living with HIV
- Signed informed consent or assent per protocol eligibility criterion 4.3.2 and Appendix III

Scheduling Focus Group Sessions

Once your site has been protocol registered and implementation notice is received it is time to conduct the focus group sessions.

- We suggest sites recruit participants as close to the focus group date as possible, to maximize participant attendance.

- Focus groups may work best on Saturday, but this will be site dependent depending on youth and caregiver schedules.

How do you plan to schedule the required Focus Group session for youth and caregivers at your site?

Conducting Focus Group Sessions

- 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)

The same two facilitators can lead the youth and caregiver groups if held at different times

- 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.

Conducting Focus Group Sessions

Role of Facilitator

- Know the intervention
- Be comfortable with intervention materials
- Facilitate group participation in all intervention activities
- Gather feedback from participants
- Provide feedback to each other and research team
- Establish strong working relationship with co-facilitator
- Be professional at all times
- Observe limits

Conducting Focus Group Sessions

Communication with Co-Facilitator

- Before beginning sessions communicate
  - styles of facilitating
  - strengths and weaknesses
  - ways would like support
  - preparation time and style

Conducting Focus Group Sessions

Communication with Co-Facilitator

- Throughout the intervention
  - Open communication
    - Direct
    - Non-judgmental
    - Accepting of feedback
  - Willingness to stretch/compromise

Conducting Focus Group Sessions

Facilitator Techniques

- Ideal Facilitator
- Tips on Facilitating

What are qualities of a good facilitator?

Conducting Focus Group Sessions

Tips on Facilitating

- Be in tune with group participants
  - Do they need a break?
  - Do they understand?
- Maintain excitement and engagement
  - Walk around when you talk
  - Maintain energy throughout session
- Get to know group participants
  - Helps give relevant examples
- Integrate previous lessons when appropriate

Conducting Focus Group Sessions

Tips on Facilitating

- Be clear
  - Use examples
  - Define words
- Use positive and corrective feedback
  - Affirmative nods
  - “Thanks for sharing” “Great point”
  - Immediately correct misinformation in non-threatening manner
  - When inappropriate behavior is shared immediately offer alternative behavior

Conducting Focus Group Sessions

Tips on Facilitating

- Be open and flexible (while sticking to the intervention)
  - Co-learn
  - Avoid being rigid (the better you know the curriculum the easier this will be)
- Be genuine
  - If you don't know say so and tell the youth you'll find out for them
  - If you make a mistake admit it and correct it
    - Good modeling for the youth
  - Ask youth to clarify what they're saying if you don't understand

Conducting Focus Group Sessions

Tips on Facilitating

- Create a safe environment
  - Assess don't assume
    - Reading level
    - Past experiences that make it difficult to participate in certain activities
  - Be in control without over-controlling
  - Don't patronize or trivialize youth experiences and contributions

Conducting Focus Group Sessions

Tips on Facilitating

- When responding to questions
  - Determine what information the caregiver and youth seem to be seeking
    - Pause if needed
  - Paraphrase the question
    - Helps check your understanding of the question
  - Respond with fact-based information
    - If presenting opinion or value state it as such

Participant Safety and Privacy in Focus Group Sessions

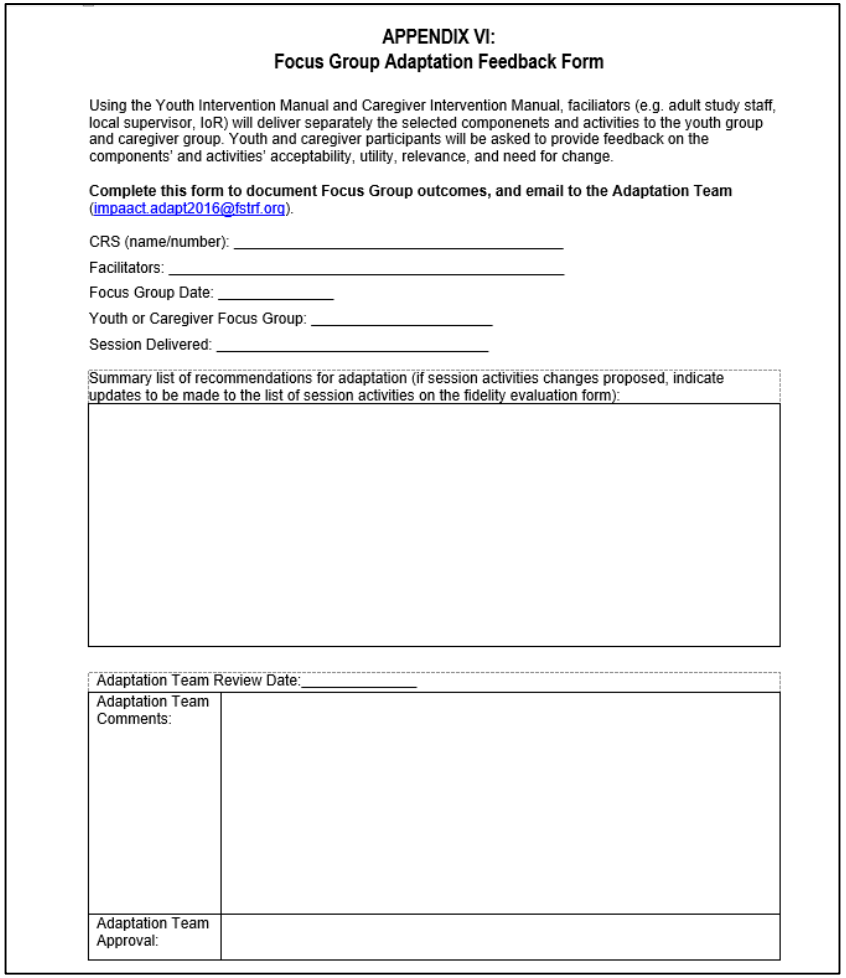
Expectations of the Focus Group:

- Participants should **turn off** cell phones
- Participants should **not** record (no pictures, no audio, and no video) or broadcast participation, especially via social media including but not limited to WhatsApp, Instagram, or Facebook groups.
- The facilitators recording via notes or audio will take care to ensure the information is kept confidential and for study purposes only.

Concluding Focus Groups

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

- Reminder: if **ANY** changes to the delivery of the intervention for the Pilot Test and Randomized Trial are needed, the proposed changes must be submitted to the adaptation team using the Adaptation Feedback Form for approval.



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 Manuals: Steps 4-6

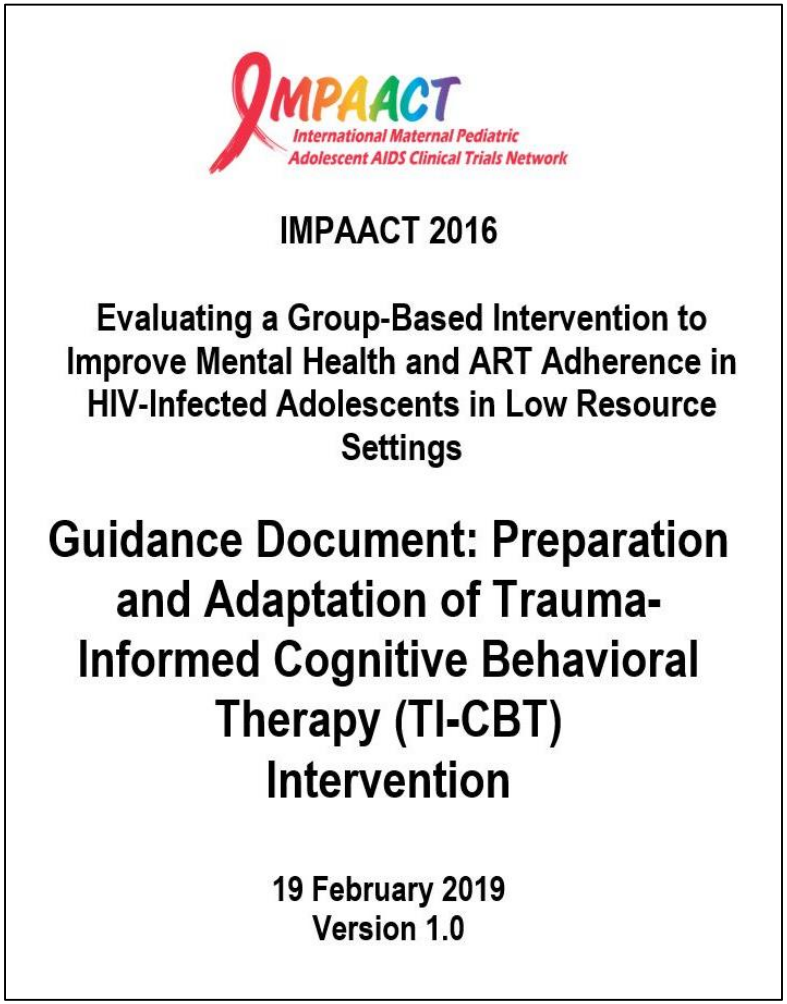
Step 4: Production
Step 5: Topical Experts
Step 6: Integration

- The Adaptation Team will review the forms from each focus group 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.
- Revisions applicable to **all sites** will be emailed by Ops to the designated site translators for translation and back translation.
- The site translators will email the revised Youth and Caregiver Intervention Manuals, as needed and per adaptation team instruction, along with the new back translation sections, to the Adaptation Team at impaact.adapt2016@fstrf.org for review and approval prior to the pilot test.
- Once the Adaptation Team approves **site-specific** changes, designated site staff will revise and finalize the Youth and Caregiver Intervention Manuals per the community stakeholder engagement, Focus Group, topical expert, and pilot test feedback.

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



Questions?

IMPAACT
International Maternal Pediatric
Adolescent AIDS Clinical Trials Network

BREAK

Please return in 10 minutes

Those planning to facilitate or supervise IYL or Adult Study Staff facilitating the discussion control group are dismissed.

Training slides 33-55 (Parts II-A, II-B, II-C, III) containing TI-CBT intervention content distributed separately for site staff planning to faciliate the Focus Groups to review to prevent contamination of the discussion control arm.

Part IV:
Next Steps

Potential Site Timeline

First Site	Last Site	Milestone
November 2018		Version 1.0 to sites
February - June 2019		Focus Group Preparations: community stakeholder engagement, manual translations, focus group training
April 2019	July 2019	Site IRB/EC Review and Approval
July 2019	Aug 2019	Focus Group • 1-day Focus Group • Review and integrate changes into intervention manuals
July 2019		Open to Accrual for Pilot Test and Randomized Trial
Sept 2019	Nov 2019	IYL/Adult Study Staff Training by Expert Trainer
Sept-Nov 2019		Regional Study Training on Pilot Testing and Randomized Trial
Nov 2019	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

Site updates on focus group implementation and activation checklist status

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**
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Requirements for sites hosting Focus Groups		
Focus Group Implementation Requirement	**Approval Date**	**Comments**
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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**
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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*

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List of Countries where CTI is required DAIDS funded sites

Name	Name
Argentina	Swaziland
Canada (depends on province)	Switzerland
India*	Tanzania
Indonesia	Uganda
Kenya	Ukraine
Malawi	Vietnam
Peru	Zambia
Philippines	Zimbabwe
South Africa	

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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*
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.*

Goodnight and thank you for your participation!

Any final questions?

IMPAACT
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