PROTOCOL TITLE:

Healthy Choices to Reduce Stigma and Improve Self-Management of Alcohol and HIV among Young Adults

PRINCIPAL INVESTIGATOR:

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	04/30/2025	Original Submission	No
2	03/01/2026	Updated measures and made minor changes to protocol language to be compliant with federal funding priorities	No

Table of Contents

1.0 Study Summary

Study Title	Healthy Choices to Reduce Stigma and Improve Self-Management of Alcohol and HIV among Young Adults
Study Design	Randomized Controlled Trial (Pilot)
Primary Objective	Test the feasibility and acceptability of the Healthy Choices intervention among young people with HIV (YPWH) in the Dominican Republic.
Secondary Objective(s)	Test to see if: (1) Intervention participants experience reductions in immediate and sustained HIV and intersectional stigmas via pre-post testing; (2) Intervention participants will experience improvements in viral burden compared to those in the control arm; and (3) Intervention participants will experience improvements in substance use compared to those in the control arm.
Research Intervention(s)/ Investigational Agent(s)	The Healthy Choices intervention
IND/IDE # (see section 5)	N/A
Study Population	Peer navigators and YPWH in the Dominican Republic
Sample Size	**Aim** 1. 2-3 focus groups (n=4-6 per focus group) with community members and 6-8 in-depth interviews with YPHW **Aim 2**. 5-8 peer navigators **Aim 3.** 45 YPWH in the RCT. All peer navigators will do an exit interview (n=5-8). We will conduct 3-6 in exit interviews with YPWH.
Study Duration for individual participants	6 months in Aim 3
Study Specific Abbreviations/ Definitions	CVC – Caribbean Vulnerable Communities Coalition HCDR – Healthy Choices Dominican Republic YPWH – young people with HIV

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives.

We propose to adapt Healthy Choices for Spanish with local contexts plus co-create implementation strategies with community advising for future scale up. We will pilot test the adapted intervention and proposed intervention strategies, using a community-led implementation approach for feasibility, acceptability, and to assess for a signal of potential effectiveness on continuum of care outcomes including antiretroviral adherence and viral load. The study has 3 aims.

Aim 1. Elucidate barriers and implementation strategies for the Healthy Choices intervention.

Aim 2. Adapt and culturally translate the Healthy Choices intervention for local contexts.

Aim 3. Pilot test Healthy Choices with implementation strategies for feasibility and acceptability.

2.2 State the hypotheses to be tested.

We will test four hypotheses, one primary and three secondary: (1) The intervention will be feasible and acceptable to YPWH (primary); (2) Intervention participants will experience reductions in immediate and sustained HIV and intersectional stigmas via pre-post testing (secondary); (3) Intervention participants will experience improvements in viral burden compared to those in the control arm (secondary); and (4) Intervention participants will experience improvements in substance use compared to those in the control arm (secondary).

3.0 Background

3.1 Describe the relevant prior experience and gaps in current knowledge.

Despite decades of research on interventions to improve HIV, substance, and stigma outcomes, there is only one intervention that improves viral burden, reduces alcohol use, and ameliorates stigma in young people with HIV (YPWH) in full-scale trials with sufficient rigor to be published in JAMA journals. Healthy Choices is a four-session behavior change communication intervention that was developmentally tailored for emerging adults to address self-management of risk behaviors and HIV with evidence of positive effect on stigma and depression, built on Motivational Enhancement Therapy, integrating Motivational Interviewing with brief cognitive-behavioral strategies. Healthy Choices can be delivered in community settings by trained community health workers. When delivered with fidelity and in adequate dose, Healthy Choices results

in reductions in substance use, HIV stigma, viral loads, and depression over follow-up compared to standard care.

In the Dominican Republic, stigmas harm YPWH, 18-29 years, particularly those using substances. The Dominican Republic is a low- to middle- income country in the Latin America and Caribbean region, is 1 of 5 countries that accounts for over 95% of Caribbean HIV infections. Results from a government-sponsored study on specific populations indicated that nearly 62% reported being stigmatized, with these experiences associated with attempted suicide, poor mental health, and substance use. Implementing evidence-based interventions that improve HIV outcomes while reducing stigma and bolstering mental well-being via non-substance reliant coping could be highly impactful. To our knowledge, there are no Spanish-language interventions that concurrently address mental health, viral suppression, and stigma, tailored for young adults who are in a developmental period marked by exploration, risk-taking, and a need for autonomy in health decision making. While the Finding Respect and Ending Stigma around HIV (FRESH) intervention was recently evaluated for feasibility in the Dominican Republic, its focus was on reducing stigma in healthcare settings among people with HIV (PWH) and their HIV healthcare providers. In contrast, Healthy Choices is community-led, focuses on young adults regardless of identity, and intervenes on substance and mental health. It is possible, after adapting and testing Healthy Choices, these two interventions, FRESH and Healthy Choices, could be layered to maximize benefit to PWH in the Dominican Republic, an underserved setting. Considering the need for stigma reduction among YPWH to improve rates of viral suppression, reduce poor mental health, and encourage healthy coping by reducing substance use, we propose to adapt Healthy Choices for Spanish with local contexts plus co-create implementation strategies with community advising for future scale up.

3.2 Describe any relevant preliminary data.

While we have conducted multiple studies that inform aspects of this trial, we highlight four, which (1) indicate high levels of stigma in the Dominican Republic, (2) describe effectiveness of the Healthy Choices intervention (HD40533, R01AA022891), (3) provide evidence of our ability to conduct stigma reduction intervention research with this team in the Dominican Republic (R21MH124083), and (4) prior experience delivering Motivational Interviewing interventions with implementation strategies in the Caribbean.

- **Healthy Choices Trials (HD40533, R01AA022891, PI: Naar, Co-I: Budhwani).** The original Healthy Choices study was a randomized controlled trial with 205 YPWH with poor antiretroviral adherence, substance use, and/or sexual risk

randomized to 4 sessions of clinic-based Healthy Choices (weeks 1, 2, 6, 10) or HIV care. Staff in 5 sites were trained in HC with ongoing fidelity monitoring. YPWH in Healthy Choices had greater reduction in depression post-intervention. Trajectory analysis found Healthy Choices increased the likelihood that YPWH would be characterized in the low- vs. the moderate substance risk group (2+ drinks/week) or high-risk group (8+ drinks/week). In the highest use groups, participation in Healthy Choices was associated with reductions in marijuana use for those in the low- and moderate-risk trajectories. Multiple linear regression models showed that the Healthy Choices group had greater viral load drop at 6 months (β=-0.36, t=-2.15, p=0.03), with a 1-log drop in viral load for YPWH on antiretrovirals. We next completed a trial of Healthy Choices using a type 1 effectiveness-implementation hybrid design. YPWH (N=183; 79.2% male; 83% Black) with detectable viral load and any alcohol use were randomized to Healthy Choices delivered by peer counselors in a community setting of their choice or in their clinic. Using growth-curve analysis, both groups had declines in viral load and reduced number of drinks in the last 30 days, and regardless of setting, Healthy Choices reduced HIV stigma. Reductions were maintained over time. In the community group, 21% achieved viral suppression at 16 weeks. This second study established that Healthy Choices could successfully be implemented in community settings by peer navigators to reduce stigma and improve HIV and substance outcomes in YPWH.

- **Motivational Interviewing Implementation Strategies (U19HD089875, R01AA022891).** Drs. Naar (Co-I) and Budhwani (PI) have led in multiple Motivational Interviewing intervention studies and are members of the Motivational Interviewing Network of Trainers. Together, they published a pragmatic guide on how best to train youth HIV providers in Motivational Interviewing and what implementation strategies are most effective in these settings. In collaboration with the CVC, they published models of delivery with implementation strategies that work best in Caribbean contexts. Drs. Budhwani, Waters, and Naar have facilitated Motivational Interviewing in collaboration with BCC in Jamaica, St. Lucia, and the Dominican Republic. Considering our team's success in Motivational Interviewing with strategies tailored for local contexts, Healthy Choices, a Motivational Interviewing-based intervention with strategies is ideal to test for stigma reduction in the Dominican Republic.

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Strikingly few interventions address stigma alongside the management of HIV and alcohol in young people with HIV (YPWH). Studies have repeatedly shown that YPWH and have difficulties with self-management as evidenced by high rates of consumption of alcohol and other drugs and low rates of viral suppression compared to older adults. Yet this key population is significantly understudied. There are numerous negative synergistic effects of stigma, alcohol consumption, and poor HIV self-management on health outcomes, and emerging adults continue to have the poorest outcomes along on the HIV treatment cascade suggesting that we have failed to developmentally tailor these interventions to address stigma and improve access, uptake and outcomes among YPWH. In substance abuse research, self-management skills such as self-control, decision making, self-reinforcement, and problem solving are core competencies at the individual level that protect against problematic alcohol and drug use and are extensible to addressing internalized stigma and reducing the effects of perceived and enacted stigma, but are not fully developed until adulthood. Healthy Choices, a 4-session, 10-week communication intervention, adapted from Motivational Enhancement Therapy, integrates Motivational Interviewing tailored for YPWH with brief cognitive-behavioral skills treatment to address self-management of HIV, reduce HIV-related stigma, and multiple risk behaviors. Healthy Choices can be delivered in clinics or community settings by trained community health workers or peer navigators. Healthy Choices is the only intervention that has been, to our knowledge, tailored for YPWH and demonstrated improvements in viral load, alcohol, and stigma trajectories in a full-scale, multi-site randomized trial.

4.0 Study Endpoints

4.1 Describe the primary and secondary study endpoints.

The primary study endpoint is completion of data collection after 6 months of enrollment.

4.2 Describe any primary or secondary safety endpoints.

If participants experience undue stress or discomfort during their sessions, they will be given the option to unenroll from the study and leave the session.

5.0 Investigational Test Articles or Products

5.1 List and describe any article or product that may be evaluated in the research; see the following IMPORTANT NOTES:

- *Test articles or products include:*
  - *Drug or pharmaceutical products;*

- *Devices, including in vitro diagnostic devices;*
- *Biological agents such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues and recombinant therapeutic proteins;*
- *Combination products (drugs/devices/biologics);*
- *Dietary supplements or food;*
- *Software or apps (whether or not "off-the-shelf") used for any health-related purpose;*
- *Any other test article or product; and,*
- *Any article or product that, even if not being evaluated in the research, is not used in accordance with its FDA-approved or cleared label, labeling, intended use, indications for use, or notice*

- *When used in research, the articles and products referred to above are regulated. The scope and nature of regulation and thus IRB review as well as documentation requirements are differentiated based upon how the articles and products may be used, so in the sections below be certain to provide detailed information about each article and product used for a research purpose.*
- *In addition to pharmacologics, some foods, biological products and dietary supplements may also be regulated, as is or as "drugs". To see how all of these may be regulated by FDA, see our FDA-related algorithms, accessible on our Decision Trees web page; scroll down to "FDA-regulated Products and Test Articles" and click on one or more of our FDA-related algorithms.*
- *The term "device" is now construed by the FDA broadly, and may include ANY instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, accessory* ***or software/applications ("apps")****, including off-the-shelf electronic devices or software/apps. Electronic devices and software and apps may be construed as a regulated "device" when those are used for a health-related purpose. To see how devices and/or software/apps may be regulated by the FDA, see our Device algorithm, accessible on our Decision Trees web page; scroll down to "FDA-regulated Products and Test Articles" and click on our FDA Device algorithm.*

N/A

5.2 *Handling: If the research involves use of a drug, device, biological agent, combination product, dietary supplement or food, or software/app, whether or not the article or product is the object of the study or being evaluated, describe your plans to store, handle, and administer those articles or products so that they will be used only on subjects and be used only by authorized investigators.*

- *If the control of the article or product used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the*

Control of Investigational Drugs, etc.), also reference that SOP in this section and provide a copy under Local Site or Study Documents of the RAMP IRB workspace.

N/A

5.3 *If the drug is investigational (has an FDA-documented IND) or the device has an FDA-documented IDE or abbreviated IDE (non-significant risk device), approved or cleared by the FDA, include the following information:*

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following, and provide official documentation of FDA approval (e.g., IND/IDE number) or clearance as well as approved or cleared labels and labelling (to include descriptions of intended use and indications for use):*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

- *IF there is no documentation of FDA approval or clearance by the FDA, then enter a statement to that effect, including a statement explaining whether and how such approval or clearance is in-process.*

N/A

5.4 *For any test article or product without an advance, FDA-documented IND, IDE or abbreviated IDE, as well as for any article or product that is not, based upon study parameters, used in accordance with its FDA-approved or cleared label, labeling, intended use, indications for use, or notice, you must—in the Local Site or Study documents section of the RAMP IRB workspace—provide a copy of the article or product's label, labeling and any other documentation that includes information about the article or product's intended use and indications for use. The IRB may require documentation in other circumstances.*

N/A

6.0 Procedures Involved

6.1 Describe and explain the study design.

Aim 1. Elucidate barriers and implementation strategies for the Healthy Choices intervention.

Overview: Conduct 2-3 focus groups (n=4-6 per focus group) with community members to identify barriers that must be addressed during implementation and strategies to bolster interventionists' fidelity in delivering Healthy Choices. Conduct 6-8 in-depth interviews with YPWH to understand their priorities and concerns related to the intervention. Use Rapid Qualitative Analysis to efficiently collate key recommendations. In Aim 1, we will begin the Exploration phase in which we examine barriers and considerations for adapting and implementing Healthy Choices in the Dominican Republic to reduce stigma in YPWH.

Recruitment: Please see Recruitment and Retention Plan.

Peer navigators at our CBOs have already agreed to participate. Our five CBOs' peer navigators can participate in focus groups if they have 4+ weekly hours of YPWH contact, identify as a peer navigator, are 18+ years, and can provide informed consent. YPWH can participate in interviews if they are 18-29 years, are diagnosed with HIV, live in the Dominican Republic, and can provide informed consent. Participants will receive a $10 USD equivalent incentive for their participation in a focus group or in-depth interview.

Questions and Content: Since Healthy Choices has already been tailored for YPWH, qualitative inquiry will focus on identifying and accommodating Dominican Republic contexts with identification of potential implementation strategies. Different guides will be developed for CBO representatives and YPWH. Example questions that may be asked of both groups are "In your experience, how can be best engage YPWH?" or "Considering that we would like to engage YPWH for 6-months, what are strategies to keep youth connected to the study?" A question that may be asked of CBO representatives is, "For your specific CBO environment, what do we need to address to ensure the intervention can be embedded in routine practice," while prompts we could use with YPWH are "tell me about stigma your experiences with stigma" or "how do you cope with stigma?"

Data Management and Analysis: Interviews and focus groups will be conducted in-person and will be audio-recorded; in-person sessions will be hosted in a private space at the CVC campus in Santo Domingo. Audio files will be uploaded to an encrypted password protected server. Audio files will be transcribed into

Microsoft Word by a transcriptionist in native Spanish. Then Spanish Word files will be translated into English.

Aim 2. Adapt and culturally translate the Healthy Choices intervention for local contexts.

Overview: We will iteratively adapt the English Healthy Choices to the Spanish-language Healthy Choices for the Dominican Republic, engaging CBO partners and YPWH throughout via 2-4 collaborative, in-person, Co-Design Workshops. Train 6-8 community peer navigators as interventionists; measure and ensure competence and fidelity. Inclusion criteria will be the same as in Aim 1. In Aim 2, we will continue the Exploration phase in which we examine and address barriers and considerations for the Healthy Choices intervention in the Dominican Republic to reduce stigma in YPWH.

Adaptation: After Aim 1 data are analyzed, they will be used to inform the adaptation of English language Healthy Choices to Spanish-language Healthy Choices for the Dominican Republic. In preparation for this study, we connected with YPWH and CBO representatives who have already expressed interest in translating the name to *Opciones para la Salud*, or Choices for Health in English a derivative of Healthy Choices. Although we do not know what will emerge from the Aim 1 data, having been through the adaptation of FRESH from the United States into a version for the Dominican Republic (R21), we anticipate adaptation to relate to content primarily. Content adaptations may include adding specific modules to better accommodate the needs of YPWH experiencing stigma in the Dominican Republic. Through the conduct of this pilot study, we may uncover similar priorities since we will be serving the needs of YPWH in the same country. Non-content changes may include placing greater emphasis on masculine or feminine tones. While reviewing data for guidance on adaptation, we will examine qualitative findings for implementation strategy recommendations. Commonly used implementation strategies to support behavior and communication interventions include text messaging between sessions, phone calls, provision of resources via email, inclusion in a close WhatsApp group, stigma reduction handouts that can be given the YPWH after the completion of each session, and so on. In Aim 1 we will explain what implementation strategies are, ask for suggestions, but if we don't receive enough feedback, we will use prompts to ask about the acceptability of these implementation strategies, and others used in global health research. After intervention changes are made in English, this draft will be culturally translated to Spanish, and implementation strategies will be included yielding Version 1. Version 1 will be shared with our CBO partners and YAB. We will ask for feedback within 7 days of presenting Version 1 via a Qualtrics survey. Both groups will be asked standard questions to compare responses between groups. Each group will also be asked a set of specific questions. For example, CBOs may be asked about the burden of use and integration into existing services. YAB members may

be asked how Healthy Choices could be enhanced to better engage people like themselves or if the proposed implementation strategies will potentially work to increase engagement and promote the intervention. We will then take Version 1 feedback and create Version 2. Thereafter, we will reconvene the same groups via Zoom and present features of the revised Healthy Choices. CBO partners and YAB members will complete the same survey again. If we find characteristics of a prior version were better received, we will revert to those in the next iteration; we anticipate that 2-3 CBO representatives and 3-4 YAB members will provide feedback on each version. Once the adapted Healthy Choices is finalized, we will adapt the accompanying competency and fidelity checklists with standard patient roleplay guides to match the revised intervention. We will create and pre-record control content on diet and nutrition that matches the time used in each Healthy Choices session. We will train selected peer navigators on Healthy Choices with implementation strategies and how to incorporate it into the support of YPWH randomized to the intervention condition in Aim 3.

Training: Prior to implementation, peer navigators will be identified by our CBO partners. Ideally, these individuals will have been involved in Aims 1 and 2. Peer navigators must have at least 4 weekly hours of YPWH engagement and match YPWH in at least one domain (age, ethnicity, HIV status). Selected peer navigators will attend a 2-day workshop (about 14-hours) at the CVC campus, conducted by Dr. Balan with support of Dr. Budhwani. This training will include an introduction to study goals and timeline, orientation to stigma reduction, presentation of Healthy Choices, hand-on practice of the adapted intervention, roleplays, introduction to virtual coaching to increase competency, and an orientation to intervention fidelity. Research team members will attend, and CBO leadership will be invited to the morning of the first day. Pre-workshop competency will be evaluated using a repeated standard patient interaction and Qualtrics survey measuring knowledge about stigma, HIV, and substance use. After the workshop, the standard patient roleplay and survey will be repeated to assess pre-post improvements. Then, peer navigators will be required to complete two to four virtual coaching sessions on Healthy Choices. After each session, competency will be assessed. To deliver Healthy Choices, navigators will need to obtain a competency level of 80%+. Those unable to meet this benchmark will not be allowed to deliver Healthy Choices. To ensure the intervention is delivered with fidelity, peer navigators will participate in spot checks conducted by Dr. Balan using standard patient roleplays adapted for the adapted intervention and local contexts. Should there be attrition, we will recruit additional facilitators from our CBO network and repeat this comprehensive training process to ensure competence and fidelity to Healthy Choices.

Aim 3. Pilot test Healthy Choices with implementation strategies for feasibility and acceptability.

Overview: Complete a 2:1 randomization of 45 YPWH with 30 to Healthy Choices and 15 to a non-HIV time attention control on diet and health. Assess feasibility and acceptability, as well as preliminary pre-post evaluation of stigma, depression, substance use, and viral suppression. See randomized trial clinical flow in Figure 5. In Aim 3, we will conclude the Exploration phase and begin the Preparation phase in which we evaluate feasibility and acceptability of the adapted Healthy Choices intervention prior to full-scale testing.

Figure 5: Pilot Randomized Controlled Trial Overview

Inclusion Criteria: We will recruit YPWH from our partner clinic and through our CBO partners. Inclusion criteria is 18-29 years, diagnosed with HIV, self-reports being stigmatized in the past 6 months, lives in the Dominican Republic, and can provide informed consent. Participants will receive a $20 USD equivalent incentive for data collection pre-post each session and over follow-up. To retain YPWH, we will collect multiple communication channels with permission to reach out. Implementation strategies identified in Aim 1 and incorporated in Aim 1 will bolster retention.

Randomization: Potential participants will be referred to CVC; within 24 hours, using a 2:1 allocation to maximize feasibility testing, participants will be randomized to Healthy Choices (n=30) or the time attention control on diet and nutrition (n=15). Allocation will occur using randomized allocation using an Excel program. Participants will be properly consented in a private space before being randomized, see Protection of Human Subjects, and linked to a Healthy Choices interventionist or the CVC representative who will facilitate the control condition.

Intervention: Intervention participants will receive four Healthy Choices 30-minute sessions over 2-months. Sessions will occur in a community setting selected by the YPWH and facilitated by a trained peer navigator.

Control: Participants in the control arm will meet with a CVC staff member who will not be trained in Healthy Choices to avoid contamination. Elias will share four pre-recorded videos on diet and nutrition developed from Center for Disease Control and Prevention (CDC) publicly available materials. The control condition will be matched in frequency and duration as the Healthy Choices intervention.

Contamination: Participants discussing intervention features with control participants will not contaminate data, because the unique features can only be fully experienced by those receiving the Healthy Choices intervention.

Measures: We will collect self-reported data from YPWH post each session and then 1-, 3-, and 6- months post-completion of intervention or control. Primary outcomes will establish the feasibility and acceptability of the intervention for YPWH in the Dominican Republic. We will collect stigma, HIV, and substance use outcomes to evaluate for a signal of effectiveness. To evaluate mechanistic effects and control for confounders, we will collect data on demographics, social support, positive affect, coping, and depression.

Table 2. Measures

Construct	Time	Measures
Primary Outcomes		
Acceptability	BL	Acceptability of Intervention Measure (12 items); Enrollment ≥80%
Feasibility	1m	Feasibility of Intervention Measure (FIM, 9 items)
Secondary Outcome		
Viral Burden / Viral Load	BL, 1m, 3m, 6m	EHR Data Extraction; Self-Report
Antiretroviral Adherence	BL, 1m, 3m, 6m	Antiretroviral Adherence Questionnaire (9 items)
HIV-Related Stigma	BL, 1m, 3m, 6m	HIV Stigma Scale (43 items)
Substance Use	BL, 1m, 3m, 6m	ASSIST and AUDIT-C
Demographics and Tertiary Outcomes		
Demographics	BL	Age, nativity,, orientation, education, and income
Social Support	BL, 1m, 3m, 6m	Social Provision Scale and UCLA Loneliness Scale
Positive Affect	BL, 1m, 3m, 6m	PANAS-Positive and Confidence
Coping	BL, 1m, 3m, 6m	Coping with Discrimination Scale and Sexuality-Related Stressors
Depression	BL, 1m, 3m, 6m	Patient Health Questionnaire Scale (PHQ-9)

Measuring Viral Load: During the Informed Consent process (see Protection of Human Subjects), we will collect information on the HIV clinic where the YPWH receives care and obtain permission to contact the clinic for their most recent past viral load and viral loads at 1, 3, and 6-months post completion of the intervention or control. Viral load data will be collected in-person by Dr. Waters. See Data Safety and Monitoring for details.

Data Management: Data management will apply procedures used in our preliminary studies with data collected from YPWH pre- and post- each of the four Healthy Choices sessions. All survey data will be collected in REDCap or Qualtrics through secure link accessible

via QR code on computer, mobile device, or tablet. REDCap or Qualtrics data will be downloaded to SAS 9.4. Encrypted and protected data files containing survey data will be stored in FSU's approved secure data management system. Our analysis plan includes 3 broad steps to test hypotheses: (1) assess immediate effects by conducting a pre- and post- analysis; (2) compare outcomes from those in the intervention to control and (3) exploratory conduct mechanistic analyses of data.

Exit Interviews: We will conduct semi-structured exit interviews with all peer navigators who delivered Healthy Choices (n=5-8) and a purposively selected sample of YPWH who were randomized to the intervention arm (n=3-6). The purpose of these interviews will be assessing satisfaction, the way the intervention was experienced and perceived, burden, and ways to improve implementation in a larger trial. Similar to the interviews in Aim 1, different guides will be developed for each group. Example questions that may be asked of both groups are "What do you think about Healthy Choices?" A question that may be asked of CBO interventionists is, "Describe the burden of the intervention and how it affected workflow," while a prompt we could use with YPWH is "Tell me about your experiences with scheduling your sessions." Interviews will be conducted in-person and will be audio-recorded hosted in a private space at the CVC campus in Santo Domingo. We will use Rapid Qualitative Analysis (RQA) to extract key information. An RQA matrix will be developed; transcription, translations, data management, and analyses processes will match those detailed in Aim 1.

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.

See section 6.1.

6.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*
- *All drugs, devices, biologics, combination products (drugs/devices/biologics), dietary supplements, foods, software or apps used for any health-related purpose or any other test article or product to be used (not just evaluated) in the research and the purpose of their use, and their regulatory approval or clearance status when applicable. Also describe whether these articles or products are used (i.e., intended use; indications for use) in accordance with their labeling. If you fail to provide labeling information or regulatory approval or*

clearance status, your application may be returned for this information.

- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*

See section 6.1.

6.4 Describe what data will be collected during the study and how that data will be obtained. Note that IF the data will include any health information, refer to the IRB's HIPAA and Research Using Health Information page [link]; for instructions, see the "What To Do if the HIPAA Privacy Rule Applies to Your Research" panel, and follow any applicable instruction accordingly, including describing how the HIPAA Privacy Rule requirement will specifically be implemented in section 17 (Data Management and Confidentiality) and particularly section 19 (Provisions to Protect the Privacy Interests of Subjects) of this protocol.

See section 6.1.

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

N/A. See section 6.1.

6.6 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

N/A

7.0 Data and Specimen Banking

7.1 If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

N/A

7.2 List the data to be stored or associated with each specimen.

N/A

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

N/A

7.4 If your study is or will be funded through any U.S. National Institutes of Health (NIH) Center, Institute or Program/Office application or contract with a January 25, 2023 or subsequent receipt date, then your study is subject to the NIH Data Management and Sharing Policy and you are required to have submitted a Data Management and Sharing (DMS) Plan to accompany that funding application or contract. In that case, you must include in this section 7 a description, consistent with your DMS Plan, about how any scientific data generated through this study may be banked and used or shared for future research. Additionally, your DMS Plan submitted to NIH must also be separately provided to the IRB as follows: in the RAMP IRB workspace for this study, on the Local Site or Study-Related Documents page, in the Other attachments section, upload by adding your DMS Plan as a separate file, add a Name for the materials if desired, and select the Category (in this case Data Management and Sharing (DMS) Plan).

See this NIH notice about elements of a DMS Plan. For additional information and resources about the NIH DMS policy and related requirements, see our NIH Data Management and Sharing (DMS) web page.

We will attach the DMS plan to the submission.

8.0 Sharing of Results with Subjects

8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.

Changes in viral load suppression rate or reductions in stigma will not be reported to anyone other than the enrolled study participant.

9.0 Study Timelines

9.1 Describe:

- *The duration of an individual subject's participation in the study.*
- *The duration anticipated to enroll all study subjects.*
- *The estimated date for the investigators to complete this study (complete primary analyses)*

	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
A1: Study Start Up w/ IRB												
A1: Kickoff Meeting												
A1: Establish Youth Advisory Board (YAB)												
A1: Focus Groups												
A1: In-Depth Interviews												
A1: Rapid Qualitative Analysis												
A2: Adaptation, 2-4 Co-Design Workshops												
A2: Adaptation, Healthy Choices Versions												
A2: Training on Spanish Healthy Choices												
A3: Recruit via our Community Partners												
A3: Recruit via our Clinic Partner												
A3: Monitor Fidelity of Interventionists												
A3: Begin the Randomized Controlled Trial												
A3: Collect Follow-up Data from Participants												
A3: Collect Follow-up Data from SNS / Clinics												
A3: Analyze Data for Outcome												
A3: Study Conclusion and Wrap-Up												
A3: Dissemination of Findings												
A1-A3. Ongoing Capacity Building												
A1-A3. Ongoing YAB Meetings												

Aim 1. One-time in-depth interview or survey.

Aim 2. 2-day workshop for peer navigators.

Aim 3. 6 months

10.0 Inclusion and Exclusion Criteria

10.1 Describe how individuals will be screened for eligibility.

Individuals will complete an online screener to check for inclusion eligibility. Eligibility will be determined from self-reported data.

10.2 Describe the criteria that define who will be included or excluded in your final study sample.

Aim 1. Peer navigators at our CBOs have already agreed to participate. Peer navigators can participate in focus groups if they have 4+ weekly hours of YPWH contact, identify as a peer navigator, are 18+ years, and can provide informed consent. YPWH can participate in interviews if they are 18-29 years, are diagnosed with HIV, live in the Dominican Republic, and can provide informed consent.

Aim 2. Prior to implementation, 5-8 peer navigators will be identified by our CBO partners. Ideally, these individuals will have been involved in Aims 1 and 2. Peer navigators must have at least 4 weekly hours of YPWH engagement and match YPWH in at least one domain (age, HIV status). Peer navigators must also complete a 2-day workshop and 2-4 virtual coaching sessions on Healthy Choices.

Aim 3. Participants must be 18-29 years, diagnosed with HIV, self-reports being stigmatized in the past 6 months, lives in the Dominican Republic, and can provide informed consent. Exit interviews will be conducted on all peer navigators and purposively selected participants in the intervention arm of the study.

10.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

No, we will not be including any of the specialized populations above.

11.0 Vulnerable Populations

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information.*

N/A

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally.

Aim 1. 2-3 focus groups (n=4-6 per focus group) with community members and 6-8 in-depth interviews with YPHW

Aim 2. 5-8 peer navigators

Aim 3. 45 YPWH in the RCT. All peer navigators will do an exit interview (n=5-8). We will conduct 3-6 in exit interviews with YPWH.

12.2 *If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)*

N/A

13.0 Recruitment Methods

13.1 *Describe when, where, and how potential subjects will be recruited. If recruitment will involve a non-FSU site, describe whether site approval for recruitment is required, and attach documentation of site approval.*

Note and Instruction: If you plan to use ResearchMatch for recruitment purposes, certain requirements apply; refer to our ResearchMatch Recruitment Instructions template in RAMP IRB [link] and carefully follow the instructions. Contact the FSU OCRA (https://ocra.fsu.edu/ or https://ocra.fsu.edu/study-support-services/recruitment/) to learn more about using ResearchMatch. This specific note and instruction is provided for your convenience and informational purposes only, and does not constitute an endorsement or an approval of any of the products or services of ResearchMatch.]

All recruitment will be done in the Dominican Republic by the team there. In Aim 1, we will partner with our five CBOs to recruit PWH. In Aim 3, we will recruit YPWH from our partner clinic and through our CBO partners.

PWH will be recruited during events hosted by our partners agencies, clinic visits, through outreach events in catchment areas, and via our extended networks. Peer navigators at our CBOs have already agreed to participate.

13.2 *Describe the source of subjects.*

See section 13.1.

13.3 *Describe the methods that will be used to identify potential subjects.*

See section 13.1.

13.4 *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude*

re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Recruitment materials will be developed in consultation with community-based organization (CBO) partners and will be reviewed by Dr. Waters to ensure materials are aesthetically appealing to our target population. Recruitment materials include minimal text, are written at a grade school reading level, state that monetary incentives are available for data collection associated with this study and will have IRB contact information at Florida State University (FSU) and Caribbean Vulnerable Communities Coalition (CVC). We will submit recruitment materials, once developed, to both IRBs prior to use.

13.5 *Describe as applicable whether and how subjects will be paid, earn course or other credits, reimbursed or provided with any financial or other incentive, token or gift for taking part in the research. Include a description and schedule of the total amount or value as well as the timing of any payments, credits, reimbursement or other incentive, token or gift. Indicate how if at all any amount is pro-rated for research visit or activity completion, and whether and how subjects' refusal to answer any question or subjects' withdrawal from or discontinuing taking part in the study or any study activity will reduce or preclude subjects from earning part or all of such any payment, credit, reimbursement or other incentive, token or gift.*

Also describe the proposed method (how, by whom, form etc.) of payment/disbursement. While payment should not be contingent upon completion of the entire study, a proportion or progressive partial payment as an incentive for completion of the study is acceptable.

Refer to this FSU Procurement Services page to obtain information regarding use of gift cards: https://procurement.fsu.edu/how-buy/shopping-guide.

Refer to FSU Controller's Office for information about the use of cash payments for human subject incentive payments.

Aim 1. Participants will receive a $10 USD equivalent incentive for their participation in a focus group or in-depth interview.

Aim 2. Trainees will not be incentivized for this intermediary step.

Aim 3. Participants will receive a $10 USD equivalent incentive for each data collection.

Describe as applicable whether and how student subjects will be provided with course or other academic credit for taking part in the study. Include a description about whether student subjects' refusal to answer any question or withdrawal from or discontinuing taking

part in the study or any study activity will reduce or preclude student subjects from earning part or all of such credit.

N/A

14.0 Withdrawal of Subjects

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

We will monitor adverse events. An adverse event (AE) is any reaction, side effect or untoward event that occurs during the course of the study. Adverse events are categorized as serious or non-serious, as related to or not related to study activities, and as expected or unexpected. For the purpose of the present project, clinically insignificant events will be excluded from any type of AE documentation. Serious adverse events (SAEs) are defined as deaths, life-threatening events, permanently or substantially disabling events, congenital anomalies, events requiring hospitalization or prolonging hospitalization, or events that require intervention to prevent permanent impairment or damage. All reports of AEs will be reported by the Contact PI to the FSU and CONABIOS IRBs. SAEs related to study participation will trigger an immediate meeting of PI, Dr. Budhwani. Additional meetings will be arranged as needed following any emergent AE issues. The participant will discontinue participation in the trial following an AE or SAE. Upon discontinuation, Dr. Budhwani will fill the End of Study Form (EOS), study SAE/AE form as well as the Problem Report provided by FSU and report to the FSU and CONABIOS IRBs as mandated. Each ongoing SAE or AE must be followed up until resolved or stabilized.

14.2 Describe any procedures for orderly termination.

Please see above.

14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

If a participant withdraws from the study, per the protocol submitted to the NIH, their data will be included in the analysis, unless they explicitly request its removal. Participants may withdraw from the study any time by a simple verbal or written request.

15.0 Risks to Subjects

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and

economic risks. For each of these risks, describe in detail how the risks will be minimized.

A number of procedures will be taken to minimize risk to the participants. The consent procedures will explicitly state that participation in the research is voluntary and that surveys and interviews will include questions regarding sensitive topics such as medication adherence, drug use, stigma, and mental health. Participants will be informed of the confidentiality of their responses, as well as the limits of that confidentiality, most notably the disclosure of suicidal thoughts, suicide attempts, homicidal intentions, or abuse or neglect reported by the participant. Consent forms indicate that all individuals who disclose violence or victimization will require an evaluation by qualified personnel from our mental health network to determine the best course of action and that conditions of immediate danger or harm may require reporting or notifying appropriate authorities (e.g., send to the emergency room, notify proper legal authorities, etc.). If a participant discloses suicidal ideation or intent to harm themselves, or any abuse or homicidal intent, a behavioral health clinician will be available to assess the level of risk and to help determine the best course of action (e.g., send to the emergency room, notify proper legal authorities, etc.).

Participants might also experience discomfort or distress. We will make every effort to create a safe environment prior to conducting research or delivering interventions. All participants will be told that they do not have to answer any question they do not wish and their participation is completely voluntary.

Participants experiencing mild distress will be offered a small break or referral for support services. In the unlikely event that a participant experiences considerable distress, they will be offered a referral to voluntary clinical assessment and/or counseling. Participants will be given the names and office phone numbers of the PI and will be provided with referrals for mental health and support services.

15.2 *If information about the study's actual purpose will not be completely or accurately described to study subjects, or in any way be withheld, obscured, masked, or blinded from study subjects (e.g., you want to avoid participation bias or priming prospective subjects), you are required to describe here that you will: (a) as part of the consent process provide subjects with a statement to the effect that subjects may not be made aware of some features about the study, such as its exact purpose, study questions and materials, or subjects' responses that you would like to collect, and that subjects will be provided with additional information about the study at the end of their participation or at any time they withdraw, (b) debrief*

subjects at the end of their participation or at any time they withdraw, and (c) provide the IRB with a copy of all materials that will be used to debrief subjects.

N/A

15.3 *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*

N/A

15.4 *If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*

N/A

15.5 *If applicable, describe risks to others who are not subjects (e.g., family members, colleagues, acquaintances or other persons) but about whom subjects will or may, as part of any study activity, identify, reference or provide identifiable, private information about these other individuals).*

N/A

15.6 *Special instructions if children (individuals less than 18 years of age) will be included as subjects: Federal law at 45 CFR 46, section 46.406 permits the involvement of children as human subjects in research for which there is no prospect of direct benefit to individual child subjects, but ONLY IF the risks in the research represent only a* ***minor increase*** *over minimal risk to a child.*

Minimal risk *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of healthy children.*

If applicable (i.e., there is no prospect of direct benefit to individual child subjects), describe how the probability (e.g., likelihood) and magnitude (e.g., severity, duration, reversibility) of any harm or discomfort anticipated in the research involving children represents only a minor (i.e., slight, negligible) increment beyond minimal risk to healthy children as subjects.

N/A

Refer to the guidance for the IRB's use when considering risk levels, risk types and examples to see how your study's risks may be evaluated. *Only the IRB, not researchers, determine whether a study is minimal risk; researchers are responsible however for fully describing risks associated with study activities, procedures and interventions.*

16.0 Potential Benefits to Subjects

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

The direct benefit to participants is the added knowledge to be gained from our ability to achieve study aims. Additionally, intervention participants may experience reductions in stigma and increases in self-efficacy, motivation, and empowerment. This study will yield significant benefits to global efforts to achieve increased rates of viral suppression among PWH including PWH. Possible risks (i.e., discomfort answering questions, potential confidentiality breaches, unlikely event of abuse) are outweighed by the new knowledge gained. Our voluntary informed consent includes a statement on the anticipated benefits that may result to participants and others from the intervention and procedures.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others. Also, payment to research subjects for participation in studies is not considered a benefit so do not list payment to research subjects in this section; if a recruitment incentive will be offered, described this in section 13 under Recruitment Methods.

Participants may benefit by having an opportunity to discuss, disclose, or reflect upon concerns that are related to stigma, disclosure, mental health, and the challenges of accessing supportive HIV care in the Dominican Republic.

17.0 Data Management and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis.

Aim 1. Interviews and focus groups will be conducted in-person and will be audio-recorded; in-person sessions will be hosted in a private space at the CVC campus in Santo Domingo. Audio files will be uploaded to an encrypted password protected server. Audio files will be transcribed into Microsoft Word by a transcriptionist in native Spanish. Then Spanish Word files will be translated into English. Due to the directive nature of this Aim, specifically to identify adaptation considerations, cultural nuances, and implementation strategies to bolster Healthy Choices delivery, Rapid Qualitative Analysis (RQA)88 will be used to extract key information needed for decision making. An RQA matrix will be developed considering adaptation needs. English language transcripts will be reviewed and matrices will be populated by two independent coders with PI (Budhwani) oversight and YAB engagement throughout the process. If members of the YAB express interest in learning about RQA or qualitative methods for intervention science, Budhwani (PI) will

conduct a Zoom capacity building session on the topic. RQA findings will directly inform the adaptation detailed and planned in Aim 2.

Aim 3. This unique small R01 mechanism is for pilot studies; thus, the research proposed will not be able to achieve statistical power. Our proposed sample reflects the limitations of the budget and time. Sample size for a full randomized controlled trial designed to detect a small-to-medium effect size of the Healthy Choices intervention in a 1:1 intervention-to-control trial ratio, assuming 80% power and α=0.05, would require 130 YPWH in each arm, using G*power 3.2 program (t-test: "Difference between two independent means"). Assuming an 85% retention rate, a full randomized controlled trial could need to randomize over 300 YPWH. For this pilot trial, we will recruit a 15% sample from the estimated sample size needed for a full randomized controlled trial in a 2:1 intervention-to-control ratio. This ratio will ensure sufficient information is obtained to assess the primary aim of intervention feasibility, while still having adequate numbers in the control arm to estimate group differences. Consequently, the sample size for this pilot trial will consist of a total of 45 YPWH, with 30 randomized to the Healthy Choices intervention arm and 15 to the time attention control arm.

We will conduct semi-structured exit interviews with all peer navigators who delivered Healthy Choices (n=5-8) and a purposively selected sample of YPWH who were randomized to the intervention arm (n=3-6). The purpose of these interviews will be assessing satisfaction, the way the intervention was experienced and perceived, burden, and ways to improve implementation in a larger trial. Similar to the interviews in Aim 1, different guides will be developed for each group. Example questions that may be asked of both groups are "What do you think about Healthy Choices?" A question that may be asked of CBO interventionists is, "Describe the burden of the intervention and how it affected workflow," while a prompt we could use with YPWH is "Tell me about your experiences with scheduling your sessions." Interviews will be conducted in-person and will be audio-recorded hosted in a private space at the CVC campus in Santo Domingo. We will use Rapid Qualitative Analysis (RQA) to extract key information. An RQA matrix will be developed; transcription, translations, data management, and analyses processes will match those detailed in Aim 1.

17.2 Describe any procedures that will be used for quality control of collected data.

The DSMB will act in an advisory capacity to the PI to monitor participant safety, evaluate the progress of the study, review procedures for maintaining the confidentiality of data, quality of data

collection, and analyses, with support from all Co-Investigators. The DSMB will meet twice annually, by video conference to review study progress, data quality, and participants' safety.

17.3 Describe the steps that will be taken to secure the data (e.g., information security and privacy training, authorization of access, authentication for access, password protection, encryption, physical and administrative controls, certificates of confidentiality (or "CoC"; see our CoC link), and separation of identifiers and data) during storage, use, transmission and sharing.

Surveys: All survey data will be collected in REDCap or Qualtrics through secure link accessible via QR code on computer, mobile device, or tablet. QR codes will be updated for each new round of data collection. REDCap or Qualtrics data will be downloaded after each data collection time point. Encrypted and protected data files containing survey data will be stored in FSU's Institutional Review Board (IRB) approved secure data management system.

EMR data: Using the electronic health records (EHR) extraction protocol from our pilot studies, we will secure viral loads for all Aim 3 YPWH participants aligned with data collection time points. In the Dominican Republic, clinics report HIV outcomes monthly to the Servicio Nacional de Salud (SNS); thus, data extraction from the SNS is efficient and will be centralized. This protocol included the following steps: (1) Inform the SNS via email that HIV data will be needed for our participants in two weeks; remind the SNS that all data must be separated into two files, one with identifying information and one with HIV continuum of care outcomes linked by a unique patient ID generated by the SNS. (2) The day before the data is due, inform the SNS via email that Dr. Waters will come to the office to pick up the data. In this step, confirm the pickup date, time, and contact. (3) The SNS will provide Dr. Waters with data in two password-protected, encrypted Excel files on an external drive. (4) Within 24 hours, Dr. Waters will upload files from the external drive to an FSU secure server. Files, including patient health records, will not be shared via email. (5) Dr. Waters will inform Dr. Budhwani (Contact PI) and Dr. Wang (Biostatistician) that the data has been uploaded. The Contact PI and biostatistician will confirm that the data is complete and the files are intact (not corrupted and accessible). (6) After successful upload, per SNS request, the external drive will be erased for use in the next data collection.

Qualitative data: In-depth interviews will be audio recorded; recordings and transcriptions will be uploaded to an encrypted password-protected FSU server.

17.4 Describe how data or specimens will be handled study-wide: e.g.,

- *Who will extract data or link data/specimens?*

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have or otherwise be provided with access to the data or specimens, including for future research or data sharing?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How will data or specimens will be transported?*
- *When will identifiers, linking keys or data be destroyed or disposed.*

See section 17.3. Only the PI and the biostatistician will have keys to files containing identifiable information. Additional access to data may be granted to other researchers to conduct specific secondary analyses. Still, when data can be shared, the data will be completely de-identified and only linked to a study-assigned participant ID.

17.5 *Note: If your study is or will be funded through any U.S. National Institutes of Health (NIH) Center, Institute or Program/Office application or contract with a January 25, 2023 or subsequent receipt date, then your study is subject to the NIH Data Management and Sharing Policy and you are required to have submitted a Data Management and Sharing (DMS) Plan to accompany that funding application or contract. In that case, you must include in this section 17 a description, consistent with your DMS Plan, about how any scientific data generated through this study may be managed and protected. Additionally and as instructed in section 7.4, your DMS Plan submitted to NIH must also be separately provided to the IRB as follows: in the RAMP IRB workspace for this study, on the Local Site or Study-Related Documents page, in the Other attachments section, upload by adding your DMS Plan as a separate file, add a Name for the materials if desired, and select the Category (in this case Data Management and Sharing (DMS) Plan).*

See this NIH notice about elements of a DMS Plan; for element 5 specifically pertaining to human research participants, refer to our NIH Data Management and Sharing Plan Template for Element 5 (external link; also located in RAMP, under the IRB, Library and Templates tabs [RAMP IRB link]). For additional information and resources about the NIH DMS policy and related requirements, see our NIH Data Management and Sharing (DMS) web page.

See above sections and DMS Plan.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required for any study that may involve: (1) any harm or discomfort for which the probability or magnitude is greater than those that may be ordinarily encountered by healthy persons in daily life or during the performance of routine physical or psychological examinations or test; (2) a clinical trial; (3) a FDA-regulated product(s) (e.g., drugs, devices, biologics, nutritional supplements or combination products); and/or (4) is funded by any federal department or agency.

18.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.*
- *What data are reviewed, including safety data, untoward events, and efficacy data.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the data.*
- *The frequency or periodicity of review of cumulative data.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that trigger an immediate suspension of the research.*

See our Clinical Trials web page at https://www.research.fsu.edu/research-offices/ohsp/clinical-trials/ to obtain more information and instructions about this and other requirements for clinical trials.

This study involves human subjects; it will comply with federally mandated human subjects regulations. Oversight of research procedures will be conducted by the IRB at FSU. Annual continuing reviews will be submitted to FSU. The study will include a Data Safety Monitoring Board (DSMB) to offer additional protections and oversight, as mentioned previously. Please see the Data Safety and Monitoring document, submitted with this protocol for further details.

19.0 Provisions to Protect the Privacy Interests of Subjects

Before completing this section, refer to the special instructions below about use of study participants' health information.

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

We have addressed the steps that will be taken to mitigate these risks in this protocol (Section 15).

19.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

All information used in enrollment and recruitment describing the research activities will include a detailed description of the content and expected participation of the respondent, such that the respondent is aware of the nature of the questions to be included in the surveys. Informed consent documents will inform research participants of the need to keep answers to questions confidential. Participants will have the option to refuse to answer or skip any questions on the surveys that they are uncomfortable answering. They will also be informed about the limits of confidentiality including, but not limited to, the disclosure of suicidal thoughts, suicide attempts, homicidal intentions, or abuse or neglect reported by the participant

19.3 Indicate how the research team is permitted to access any sources of information about the subjects.

Outcomes data used for research studies will be released only in deidentified fashion. Research team members using the study-related data will not link the participant to identifying information or learn of his or her identity. All study personnel are required to renew Human Subjects trainings annually, or in accordance with their site regulatory mandates. No data will be accepted from or distributed to investigators or study staff if regulatory training is not current or if site regulatory approval has lapsed. Requests for study-related datasets will be submitted to the investigative team and DSMB (when necessary). Copies of study documents will be kept on file with the Principal Investigator.

19.4 Special instructions if you plan to obtain, collect or use health information.

Research use of certain health information may be subject to additional federal legal requirements. Among these is the HIPAA Privacy Rule (Title 45 of the U.S. Code of Federal Regulations, parts 160-164). When such health information constitutes Protected

Health Information (PHI), then as a criterion of approval of your study, the IRB must determine that you:

- *obtain an individual's Authorization to use/disclose their PHI; and/or,*
- *be granted—by the covered entity from which PHI will be obtained—a Waiver or Alteration of the Authorization requirement; and/or,*
- *be approved through a Data Use Agreement to use or disclose of PHI in a Limited Data Set; and/or,*
- *certify that use or disclosure of PHI is only to prepare a research protocol or to conduct research on decedents.*

Refer to the IRB's HIPAA and Research Using Health Information page [link] for additional information; for instructions, see the "What To Do if the HIPAA Privacy Rule Applies to Your Research" panel. Then in this section of the protocol, describe the steps that will be taken to satisfy the above HIPAA Privacy Rule requirements.

N/A

19.5 Special instructions if you plan to collect, use, disclose or process personal data from or about individuals who are located in a European Union (EU)/European Economic Area (EEA) member country.

The General Data Protection Regulation (GDPR) is a data privacy law that protects the privacy and security of individuals who are located in an EU/EEA country. The GDPR includes significant (more than what researchers may generally expect in the U.S.) restrictions on the use and disclosure of an individual's personal data and establishes responsibilities of persons or entities that collect, use, disclose or process such personal data. The GDPR may apply whether or not the study team is physically located in the EU/EEA. Refer to our GDPR in Research web page for more detailed information and instructions.

If the GDPR applies to your study, then describe the additional GDPR-related steps that will be taken to protect the personal data of individuals who are located in the EU/EEA, including providing a statement to the effect that applicable GDPR-related requirements will be followed by the study team and that the HRP-502EEA - TEMPLATE - EEA NOTICE AND CONSENT form will be used to provide the GDPR-required notice and obtain the GDPR-required consent.

N/A

20.0 Compensation for Research-Related Injury

This section is required for any study that may involve: (1) any harm or discomfort for which the probability or magnitude is greater than those that may be ordinarily encountered by healthy persons in daily life or during the performance of routine physical or psychological examinations or test; (2) a clinical trial; (3) a FDA-regulated product(s) (e.g., drugs, devices, biologics, nutritional supplements or combination products); and/or (4) is funded by any federal department or agency:

20.1 Describe what specific arrangements and referrals will be made in the event a subject experiences a research related injury.

N/A beyond the measures that will be taken in the risk section of this protocol.

20.2 Describe the available compensation in the event of research related injury.

N/A

20.3 Provide a copy of contract language, if any, relevant to compensation for research-related injury.

N/A

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

N/A

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe:

- *Where will the consent process take place*
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
- *Any process to ensure ongoing consent.*
- *Whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, describe:*
  - *The role of the individuals listed in the application as being involved in the consent process.*
  - *The time that will be devoted to the consent discussion.*
  - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
  - *Steps that will be taken to ensure the subjects' understanding.*

FSU study personnel will not be consenting participants. All consenting will be done by the Dominican Republic team, who will have IRB approval.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent*

All consent forms will be in Spanish. All study materials will be reviewed by our research partners in the Dominican Republic to ensure written material is translated correctly.

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not, describe whether and how consent of the subject will be documented in writing.

FSU study personnel will not be consenting participants. All consenting will be done by the Dominican Republic team, who will have IRB approval for this piece in the DR.

23.2 If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

N/A

23.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script.)

N/A

24.0 Setting

24.1 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*

Recruitment will occur in our partner CBOs, with Dr. Waters (MPI) leading the process at the CVC.

- *Identify where research procedures will be performed.*

  All research procedures will be done in the Dominican Republic or virtually.

- *Describe the composition and involvement of any community advisory board.*

  Dr. Budhwani will form a Data and Safety Monitoring Board (DSMB) at the beginning of Year 1. This board will include Consultant, Dr. Wang (biostatistician), as well as 1-2 HIV researchers, and 1-2 community members from the Dominican Republic. PI will be responsible for ensuring participants' safety on a daily basis. In the event of AEs, including SAEs, study personnel will be trained to report such events immediately to the PI; PI will be responsible for further reporting of these events, in accordance with established procedures, to the IRBs and the NIH, and informing the study's DSMB (either at a regularly convened meeting or sooner by ad hoc video conference). The DSMB will act in an advisory capacity to the PI to monitor participant safety, evaluate the progress of the study, review procedures for maintaining the confidentiality of data, quality of data collection, and analyses, with support from all Co-Investigators. The DSMB will meet twice annually, by video conference to review study progress, data quality, and participants' safety. In addition, Consultant, Dr. Wang will conduct interim analyses that examine differences in demographic characteristics and key study variables. Results will be communicated to the team via email. Video conference meetings will be arranged to address data integrity and participant safety issues that require immediate attention.

  Our DSMB will operate independently and is charged with the mission of reviewing and advising on procedures to monitor the safety of participants. The DSMB will ensure that all activities comply with the highest ethical standards. Specific responsibilities of the DSMB include the following:

  - Review interim data for appraisal of study-related adverse events.
  - Evaluate compliance with recruitment and retention guidelines set forth by the study.
  - Guide study adherence to proposed protocol.
  - Review adverse study-related events or occurrences that may compromise confidentiality of study data.

- Review any ethical considerations that may arise during the course of the study.
- Make all associated recommendations for study improvement to PI in a timely fashion.

- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization.*

    None noted; any relevant considerations will be addressed in the local (DR) IRB review.

  - *Local scientific and ethical review structure outside the organization.*

    CONABIOS in the Dominican Republic.

  - *For international research, refer to our FAQ #12 (Do requirements differ for international research compared to research conducted in the U.S.?) under Specific Questions on our FAQ page.*

    We will comply with all governing policies of the Dominican Republic and those required by the National Institutes of Health, as a USA federal funding agency.

- *Describe non-FSU site approval to conduct research at any non-FSU site or location and attach approval documentation. If no such approval was required, so state and be prepared to provide documentation. Studies involving non-FSU sites, institutions or agencies, such as TMH, CRMC, FAMU, state agencies and other organizations, may require those sites' IRB, research review or other approvals. Before submitting your studies for FSU IRB review, you must contact such sites to ascertain their review requirements (including as may be applicable payment of their IRB review fees, such as for TMH) and comply accordingly. The FSU IRB may require documentation of such site contact.*

  We will receive IRB approval from CONBIOS in the Dominican Republic. Letters of approval will be submitted to the FSU IRB prior to engaging any participants.

- *Collaborations involving TMH are subject to specific requirements; click here for important TMH IRB-related*

submission information and instructions. For these and other collaborations, visit the FSU Office for Clinical Research Advancement [link] to obtain support for navigating clinical research at FSU that may involve community healthcare partners.

N/A

25.0 Resources Available

25.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions, and have the requisite qualifications and training (e.g., certification, credentialing) to perform delegated study tasks.*
- *Note that any personnel assigned significant, study-related duties (e.g., obtaining and documenting consent; collecting or analyzing identifiable, private information; collecting blood or other human specimens; providing or administering any FDA-regulated product such as drugs, devices, dietary supplements; or providing any biomedical or behavioral-related intervention) MUST BE QUALIFIED AND TRAINED—NOTWITHSTANDING STATE LAWS THAT HAVE NO SUCH OR LESSER REQUIREMENTS—TO PERFORM THOSE DUTIES. A thorough description of the assignment of those duties, qualification to perform those duties, and completion of the requisite training for performing those functions must be described here. Additionally, documentation of those assignments (e.g., a delegation of duties log) and of personnels' qualifications (e.g., curriculum vitae) and training (e.g., training completion certificate) must be uploaded under Study-Related Documents as category "CV and Other Qualification or Training").*

- *For a sample of task competency checklists, review the task competency checklists located in RAMP IRB under the IRB, Library, General tabs.*

The proposed study is part of the Principal Investigator's portfolio of scientific research; if funded by the NIH, she will commit 14% annual effort to this work and will travel to the Dominican Republic as needed to provide appropriate oversight. The Principal Investigator has longstanding collaborations with agencies CBO agencies in the Dominican Republic that have comprehensive psychological support services including therapists, counselors, and behaviorally trained prevention and outreach workers. Only those select staff with human subjects training will be allowed to recruit or enroll; these same individuals will attend (or have already attended) a comprehensive study orientation which not only cover the purpose of the study but also mandatory reporting related to mental health and when to refer for supports, including economic and health.

25.2 Provide the IRB with a complete copy of your funding application and (if funded) award notice if this study will be or is funded in whole or in part by extramural funds (e.g., grant, contract with an external sponsor). The IRB is required to evaluate congruence between the funding application/award and the IRB application. Provide copies of your application/award notice in the Study Funding Sources page of your RAMP IRB workspace for this study, using the Attach files feature when listing the Funding organization. Alternatively, provide copies of application/award notice in the Study-related or Local Site Documents page, Other Attachments section (select Category Funding Application and Award (Funding) Notice as applicable). The FSU IRB does not have access to your funding application or award, so do not refer the IRB to the grants office. IRB applications for which the complete funding application and/or award notice is missing in this section will be returned for correction.

26.0 Multi-Site Research

26.1 Study-Wide Number of Subjects
If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

All recruitment will occur in the Dominican Republic via the Caribbean Vulnerable Communities Coalition (CVC) site.

26.2 Study-Wide Recruitment Methods

- *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.*
- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*
- *If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See "WORKSHEET: Communication and Responsibilities (HRP-830)." All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
- *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.*
    - *All local site investigators conduct the study in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.*

Please see the Recruitment and Retention plan for these details. Recruitment materials have not been developed yet but will be submitted to FSU's IRB prior to use. With PI in the DR and FSU, the team will meet weekly via Zoom, communicate as needed text and call.

26.3 Describe the method for communicating to engaged participating sites (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):

- *Problems (inclusive of reportable events).*

- *Interim results.*
- *The closure of a study*

Sites have already agreed to participate. The point of contact in Dominican Republic, Dr. Waters, will communicate with sites regarding problems, results, and closure of study.

26.4 If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See "WORKSHEET: Communication and Responsibilities (HRP-830).")

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

There are no specimens in this project. Outcomes data used for research studies will be released only in deidentified fashion. Research team members using the study-related data will not link the participant to identifying information or learn of his or her identity. All study personnel are required to renew Human Subjects trainings annually, or in accordance with their site regulatory mandates. No data will be accepted from or distributed to investigators or study staff if regulatory training is not current or if site regulatory approval has lapsed. Requests for study-related datasets will be submitted to the investigative team and DSMB (when necessary). Copies of study documents will be kept on file with the Principal Investigator.

Survey data will be collected in REDCap of Qualtrics via secure link accessible by QR code on a mobile device. QR codes will be updated for each round of data collection. Data will be downloaded to Excel after each data collection. Excel files will be encrypted and password protected. Protected files containing survey data, which will be imported into statistical software, will be stored in FSU's secure data management system.