

Title: Sistas Informing Sistas on Topics about AIDS and PrEP (SISTA-P)

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IRB Protocol

# INTERVENTIONAL RESEARCH PROTOCOL

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## STUDY INFORMATION

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## 1.0 Research Design

### 1.1 Purpose/Specific Aims

Ending the HIV epidemic in the United States will require effective strategies to address the striking and persistent disparities in utilization of pre-exposure prophylaxis (PrEP) for HIV prevention.<sup>1</sup> PrEP is a highly effective HIV prevention medication<sup>2</sup> that may be especially useful for women, as it can circumvent gendered barriers to other HIV prevention methods.<sup>3</sup> CDC estimates suggest that among women who could benefit from PrEP,<sup>4</sup> only 10% linked to PrEP in 2019.<sup>5</sup> Further, there are deep disparities among women; cisgender Black women's (BW) PrEP uptake lags far behind that of white women,<sup>6,7,8</sup> even as infections among Black women are 11 times the rate of white women. Evidence-based behavioral interventions (EBIs) to increase adult BW's PrEP use are rare, despite the demonstrable need for them. The proposed research aims to address this gap by pilot testing the delivery of Sistas Informing Sistas on Topics about AIDS and PrEP (SISTA-P), a communication and social skills training intervention to bolster PrEP uptake among Black women. Our team developed SISTA-P (1K01DA050496-01A1), a 6-session group-based HIV prevention intervention for Black women who are potentially eligible for PrEP. SISTA-P is an update and adaptation of Sisters Informing Sisters about Topics on AIDS (SISTA),<sup>9,10</sup> a widely implemented gender- and culture specific HIV prevention intervention among BW.<sup>11,12</sup> The specific aim of this study is to pilot test SISTA-P to establish feasibility and acceptability and relevance to BW.

#### A. Objectives

The proposed intervention addresses the following specific aim:

To pilot test SISTA-P to establish feasibility, acceptability, and relevance to BW.

The overall positive impact of this work will be a manualized gender and culturally specific HIV prevention intervention protocol that includes PrEP education and cultivates skills for addressing the social-structural and contextual factors that impede BW's HIV prevention broadly, and PrEP uptake specifically.

#### B. Hypotheses / Research Question(s)

We hypothesize that the SISTA-P intervention will be acceptable, feasible and relevant from the perspectives of the community-based organization, intervention facilitators and participants.

### 1.2 Research Significance

There are no published evidence-based interventions to increase BW's PrEP uptake. Whether PrEP's potential to reduce disparities in HIV incidence is realized depends on whether people who stand to benefit from it know about it, have access to it, perceive it as viable, and can successfully navigate individual (i.e., self-efficacy), social-structural (e.g., gendered relationship norms, intersectional stigma) and contextual (i.e., substance use) barriers. Although public health efforts to increase BW's PrEP uptake are underway,<sup>13-15</sup> there is a dearth of evidence-based strategies to support them. EBIs to increase condom use may offer insight into potentially effective strategies for increasing BW's PrEP uptake. The proposed research aims to leverage and cultivate BW's agency to overcome barriers to PrEP uptake.

Empirical research suggests three critical barriers to BW's PrEP uptake: partners, healthcare providers (HCP) and substance use or SU (i.e., alcohol, marijuana, pain pills, crack). Although PrEP can be used discretely, some BW express an obligation to disclose PrEP use to male partners.<sup>10,11</sup> Thus, PrEP use may be hindered by the same gendered barriers as condom use. Interventions focused on increasing BW's condom use have achieved positive effects by bolstering safer-sex communication skills.<sup>12,13</sup> However, the extent to which BW's gendered barriers to PrEP uptake can be overcome by cultivating communication skills is understudied. Through the proposed research, we are developing a behavioral intervention to increase BW's PrEP uptake that is responsive to their HIV prevention experiences, cultivates self-efficacy and communication skills, and mitigates, wherever possible, the barriers erected by substance use. The overall positive impact will be a reduction in HIV incidence among BW through increased PrEP uptake.

### 1.3 Research Design and Methods

Experienced BW facilitators will implement 3 intervention cycles (i.e., six 3.5-hour sessions, N = 8-12 BW/group), while expert panelists observe, at a community-based organization (TWC, Positive Impact Health Centers, St. John Baptist Church #5/CAMP ACE). Intervention cycles will be conducted in accordance with the *Draft SISTA-P Scripted Facilitator's Manual*. One intervention cycle will be delivered at The Women's Collective, Washington, DC. One intervention cycle will be delivered at Positive Impact Health Centers, Decatur, Ga. One intervention cycle will be delivered at St. John Baptist Church #5/CAMP ACE, New Orleans, LA. An independent contractor with expertise in PrEP delivery (i.e., a medical provider or PrEP navigator) will be hired for session 5.

This person will only present educational materials as an expert and be available for questions. This person will not collect any information and the participants will be asked not to disclose any private information, such as their names. The participants will be asked if they are comfortable with the contractor being present to provide the educational materials. Any participants who are not comfortable speaking with the consultant will be allowed to leave the room for this portion of the day. This person will not be engaged in the research activities.

Table 1 : Feasibility and Acceptability Measures

Outcome	Measures	Instrument	Benchmark for Success
<b>Recruitment:</b> Can I recruit my target population?	# enrolled per month Average time to enroll enough participants to form a cycle. Proportion of eligible screens who enroll. Proportion enrolled who attend at least 1 session.	Referral Tracking Forms (staff)	8 enrolled per month > 70% enrolled attend at least one session # screened per week
<b>Retention:</b> Can I keep participants involved?	Number in attendance at first session In-person session attendance	Process Fidelity Forms (staff)	N = 8-12 in attendance at first session Average 80% session attendance, homework completion
<b>Feasibility:</b> Can I follow-up?	Homework completion Average length of time to follow-up.	Referral Tracking Forms (staff)	< 4 months > 70% successful follow-up > 90% photo confirmation of self-reported PrEP use
<b>Fidelity:</b> Can I deliver the intervention as intended?	Session observations. Number of sessions conducted Length of sessions Number and type of materials disseminated Participant demographics Activities not implemented	Facilitator Observation Form (EP) Participant Evaluation Forms (participants) Process Fidelity Forms (staff) Pre-test Surveys (participants)	Average overall performance rating > 7.5 / 10 5 sessions conducted per cycle Sessions average 2 hours 100% assigned materials distributed, assigned activities implemented Number of Black women facilitators = 2 100% of participants are PrEP eligible BW
<b>Acceptability:</b> Is SISTA-P well received?	Ratings of facilitators, sessions, utility of materials, suggested improvements	Participant Evaluation Forms (participants)	Average acceptability rating > 7.5 / 10
<b>Relevance:</b> Is SISTA-P responsive?	Qualitative assessments	Follow-up interviews (participants)	SISTA-P addresses factors important to HIV prevention

After each session, participants and subject matter expert observers will complete brief surveys. Surveys for each session include closed and open-ended measures: six items rating how well the session conveyed core information (e.g., I am confident I can communicate more effectively [Session 3]; I have a better understanding of the effects of alcohol on making sexual choices, [Session 4]) and single-item scales to evaluate the facilitator's performance and the session overall. In open-ended measures, respondents will be prompted to elaborate on their survey responses to identify ways the session could be improved. The research team will debrief to discuss each session's material, activities, content, and delivery.

We will conduct a full cycle of SISTA-P and refine SISTA-P in accordance with the theater test results to produce Draft 2. We will conduct a second SISTA-P cycle, with a new sample (n = 8 - 12) to assess acceptability of SISTA-P Draft 2. We will conduct a second SISTA-P cycle, with a new sample (n = 8 -12) to assess acceptability of SISTA-P Draft 3. We will follow up with participants after 45-60 days to assess SISTA-P's relevance, appropriateness, and to identify any missing elements that should be included.

#### **A. Research Procedures**

Participants will complete four SISTA-P sessions, with two facilitators over the course of one week. The sessions are for up to three and a half hours and discuss HIV prevention techniques, self-esteem building, and the importance of PrEP, etc. Session topics are included in Table 2. Each session will be run by a facilitator and overseen by a technical monitor. Each discussion group will consist of 8-12 participants and each cycle will consist of one group. The sessions will take place in person at The Women's Collective at Washington D.C with the first cycle taking place in January 2024. The second cycle will take place at Positive Impact Health Centers in Decatur, GA, starting in May 2024. The third session will take place at St. John Baptist Church #5/CAMP ACE in New Orleans, LA in September through November. Participants will be asked to complete a pre-test and follow up survey and two booster sessions. They will also be asked to submit photo-confirmation of PrEP prescription to the research team via Box.com labelled with their unique identifier (see attached sample Box.com request link).

#### **B. Data Points**

We will utilize standard rating forms to obtain assessments regarding recruitment (i.e., referral tracking form), intervention fidelity (i.e., process fidelity form), facilitator performance (participant evaluation). These rating forms were developed for use in the initial development of SISTA. We will adapt them for the proposed research. Process fidelity and participant evaluation forms will be completed after *each session*. The facilitator feedback form will be administered at the end of each cycle and will include the Feasibility of Intervention Measure (FIM), Acceptability of Intervention Measure (AIM), and Intervention Appropriateness Measure (IAM).<sup>113</sup> We will administer a survey of psychometric measures to assess self-reported intermediate (e.g., attitudes, perceptions of norms, self-efficacy) and outcome (i.e., behavioral) variables prior to session 1 (i.e., baseline) and immediately following the last session (i.e., post-intervention). We will follow-up after 6-weeks, using an online (or telephone) survey, to assess the feasibility of the research design and to assess psychometric properties of key intermediate and self-reported outcome variables, in preparation for an RCT to test effectiveness.

We will assess self-reporting of PrEP uptake using the Medication Adherence Self-report Inventory (MASRI)<sup>114</sup>, which is shown to be highly correlated with Medication Event Monitoring Systems (MEMS), a medication cap that electronically records the time and date each time the bottle is opened.<sup>115</sup> Respondents who self-report utilization of oral PrEP services will also be asked to provide photo confirmation of the PrEP medication, prescription or bottle to the secure study Box.com folder to confirm that the prescription was filled. Respondents who self-report utilization of long-acting injectable PrEP will be asked to provide photo confirmation of the PrEP injection appointment (i.e., photo of appointment card) to the secure Box.com folder.

### **C. Study Duration**

The study duration is seven weeks between enrollment to completion. Participants will complete one week of four in-person sessions. Each session will last for up to three and a half hours. After four weeks, they will complete one booster session and after six weeks, they will complete one final booster session. We will collect follow-up survey data using an online survey, or via telephone.

### **D. Endpoints**

When we reach 36 follow-ups, the study will conclude.

## **1.4 Preliminary Data**

**Pilot data from this population supports the initial development of SISTA-P.** We conducted in-depth interviews with N = 30 BW potentially PrEP eligible BW 27 – 64 (mean = 44.50, sd = 14.61) who have sex with men in DC. Among them, 30% reported having sex with a casual partner and on average, respondents “never” to “sometimes” used a condom during sex with casual partners. One respondent reported condomless sex with a partner known to be living with HIV and one respondent reported a recent STI. Two respondents exchanged sex for money or drugs in the past 12 months. All respondents were enrolled in Medicaid. Many respondents described histories of problem substance use, including sedatives (17%), painkillers (41.7%), cocaine/crack (25%), stimulants (4.2%), club drugs (16.7%), hallucinogens (16.7%), heroin (16.7%).

Our team conducted formative research to adapt and develop SISTA-P. We conducted formative qualitative interviews (N = 30) with adult (27-64), potentially PrEP eligible cisgender Black women who have sex with men in DC. Results of this research demonstrated histories of substance use and trauma (e.g., sexual violence) that shaped perceptions of low perceived risk for HIV (i.e., relative to the past). As in previous research, awareness of PrEP was low, but consistent with the frequently voiced desire to cultivate and maintain physical and mental wellness. In the same study, women often described low levels of social support in their self-care, which was shaped by their deeply felt gender-based obligations to others (i.e., siblings, parents, children, partners, and others). Such obligations complicated women's capacity to prioritize their own self-care. As in previous research, women anticipated partner resistance to her PrEP utilization, as it would create or magnify trust-related conflict in the relationship. Still, many also voiced willingness to negotiate safer sex with partners. Finally, respondents reported receiving poor quality of care from providers in relation to HIV prevention insofar as HCP rarely discussed issues related to sexual health.

Based on these data, we established program objectives see summary of SISTA-P session) and strategies to address the barriers to HIV prevention for Black women.<sup>16</sup> We revised the SISTA logic model and developed recommendations for adaptations based on the in-depth interviews and in consultation with an expert panel comprising interventionists (i.e., Ms. Diane Jones, Ms. June Pollydore), CBO leadership and staff (Ms. Patricia Nalls, ), a technical monitor (Dr. Arlene Edwards), a master-level trainer (Ms. Dana Williams), and a women's sexual healthcare provider (Dr. Rachel Scott). The resulting intervention, SISTA-P, includes PrEP information and skills building activities, addressing partner and provider related barriers to PrEP and cultivating social and emotional support to foster self-care.

Core elements<sup>17</sup> of SISTA-P are:

(1) small group discussions, modeling and role-play that facilitate repetition, reinforcement and sequential approximation; (2) skilled BW facilitators; (3) gender and culturally specific materials to enhance pride and self-worth; (4) teaching negotiation, self-advocacy; and (5) HIV prevention relevant skills; (6) discussing gender and culture-specific barriers and facilitators to prevention; and (7) enhancing HIV prevention norms and self-efficacy.

Table 2. SISTA-P Sessions Overview

Session	Topic
1. Self-Pride & Self-Care	Social support, emotional support
2: HIV & PrEP Education	PrEP 101, 102
3: Assertiveness Skills Training	Shared decision making with providers; Self-advocacy/partner negotiation; skills building
4: Coping Skills	Navigating PrEP Stigma, Coping with negative emotions; Substance use and HIV risk and prevention; coping with rejection
5: Let's Give It A Try! (booster, 4-weeks)	Skills practice (condom, PrEP negotiation)
6: Reunited (booster, 6 weeks)	Barriers and Facilitators to HIV prevention and PrEP

**PrEP is potentially acceptable to PrEP eligible BW, but few PrEP eligible BW know about it and thus may be unprepared to navigate the complex barriers that will likely be present.** In collaboration with The Women's Collective, we conducted 10 focus groups (N=52)<sup>15</sup> with PrEP eligible BW in DC. Few had ever heard of PrEP and only one reported accurate knowledge of PrEP for HIV prevention. When educated about PrEP, women were enthusiastic, and willing to use it. Eagerness to use PrEP was tempered by the realities of their relationship dynamics, however. Women voiced an obligation to disclose PrEP use to male partners, who they anticipated would be resistant, which they feared would create or magnify relationship conflict. As in previous research, respondents also noted that healthcare providers generally do not initiate or engaged in discussions about their sexual health. *However, many women said they were willing to initiate and engage in difficult discussions with partners and providers about PrEP, highlighting the importance of the proposed work in supporting BW to self-advocate for use of PrEP for HIV prevention with partners and HCP.*

**SISTA-P components attend to building efficacy and skills necessary for navigating individual, partner and healthcare related factors in PrEP uptake.** Our survey research demonstrated that attitudes, self-efficacy, social norms are important factors in BW's PrEP uptake<sup>11,88</sup>. After learning about PrEP, women (N= 294) indicated somewhat positive intentions to use it (M= 3.39, sd = 1.29, range 1 [definitely will not] - 5 [definitely will]) in the next 12 months. There were significant and positive direct effects of self-efficacy (b= .32), perceived norms (b= .25) and attitudes (b= .20) on intentions to initiate PrEP.<sup>11</sup> HCP providers, primary sex partners and best friends were the most important normative referents influencing the decision to use PrEP.<sup>11,14</sup> While cross-sectional, these data highlight the critical importance of

partner and provider support in women's consideration of PrEP. *This research underscores and provides the rationale for the need for theory-driven group-based intervention approaches, with a focus on partner and provider factors, such as skills and efficacy for overcoming contextual constraints related to partner providers.*

While PrEP awareness was low, many acknowledged its potential utility and voiced a strong desire to cultivate and maintain physical and emotional wellness. Many respondents remarked that PrEP has the potential to play an important role in their prioritization and enactment of self-care. At the same time, BW described low levels of social support in their self-care, and deeply felt gender-based obligations to others (i.e., siblings, parents, children, partners). These obligations complicated women's capacity to prioritize their own self-care. As in our previous research, we found that BW anticipated partner resistance to using PrEP, as it could create or magnify trust-related conflict in the relationship. Still, many BW voiced a willingness to negotiate safer sex with their partners. Also, in-line with our previous research, women reported receiving poor quality of care from providers in relation to HIV prevention, with HCPs rarely discussing sexual health.<sup>89</sup> Further, several women described being treated with disrespect and/or disregard in communication interactions with HCP). Finally, many respondents were excited to learn that the interviews would contribute to the development of an HIV prevention intervention, and several voiced willingness to participate in SISTA-P.

### **1.5 Sample Size Justification**

This is a pilot study, designed to assess the acceptability and feasibility of the scripted facilitation guide. This study is not designed to assess intervention effects. We are applying the ADAPT-ITT<sup>18</sup> model as a process to adapt SISTA into SISTA-P. ADAPT-ITT was developed by leading HIV prevention intervention specialists to facilitate the adaptation of evidence based interventions (EBI).<sup>18</sup> ADAPT-ITT prescribes a structured process for EBI adaptation: formative research, EBI selection, planning and implementing adaptations, acceptability testing, participation of expert panelists and integration of advice, staff training and pilot testing. This model guides theory-grounded, empirically based adaptation that maintains the EBI's core elements. ADAPT-ITT has been used to modify HIV prevention interventions for a diverse populations<sup>19-21</sup> and several CDC-approved HIV risk reduction EBIs.<sup>21,22</sup> risk behaviors. Thus, the sample size for the theater testing (i.e., three cycles with  $n = 8 - 12$ ) is justified, based on the intervention structure (i.e., small group) and ADAPT-ITT methods (i.e., three cycles).

### **1.6 Study Variables**

#### **A. Independent Variables, Interventions, or Predictor Variables**

This is a single-arm study. All participants who are eligible and enrolled will receive the SISTA-P intervention (i.e., 4 sessions, 2 booster-sessions).

#### **B. Dependent Variables or Outcome Measures**

This acceptability and feasibility pilot study is not intended, nor powered, to detect intervention effects. Dependent variables include self-reported and photo-confirmed PrEP uptake. We are assessing uptake to assess the feasibility of collecting these measures (rather than in order to assess intervention effects).

**Table 3. Participant survey measures, sources, and reliability**

Variable	Measures
Treatment	Number of sessions attended
Demographic	Age, education, income, children, relationship status, partner risk
	<b>Independent Variables</b>
HIV knowledge	Brief HIV knowledge questionnaire <sup>119</sup> ( $\alpha = .74-.80$ ), 18-items
Perceived risk	Perceived Risk of HIV Scale <sup>120</sup> ( $\alpha = .88$ ), 8-items
Outcome expectancies	PrEP effectiveness, side-effects, cost <sup>121</sup>
Self-efficacy	PrEP uptake efficacy, 1-item; Sexual Self-control Scale <sup>121</sup> ( $\alpha = .89$ ), 9-items; Sexual Self-Efficacy Scale <sup>23,122</sup> ( $\alpha = .89$ ), 20-items, Perceived efficacy in Patient Interactions <sup>123</sup> ( $\alpha = .89$ ), 5-items
Partner norms	Interpersonal Impact Scale, <sup>23</sup> ( $\alpha = .88-.90$ ), 11-items Sexual Relationship Power Scale <sup>124</sup> ( $\alpha = .84$ ), 23 items
Negotiation skills	Direct power strategies in sexual communication <sup>23</sup> ( $\alpha = .71$ ), 24-items
Self-advocacy	Past 30 days discussion about PrEP with partner, HCP
Stigma	Internalized Substance Use Stigma <sup>125</sup> ( $\alpha = .89$ ), 6-items Experiences of Discrimination Scale <sup>126</sup> ( $\alpha = .74$ ), 7-items
Drug use	Alcohol/Drug use <sup>53</sup> – 30 Day Frequency, Lifetime Use, 13-items
	<b>Outcome Variables</b>
PrEP intention	Intentions to use PrEP in the next month, 3-items <sup>127</sup>
PrEP uptake	Self-reported prescription uptake & adherence (MASRI), <sup>115</sup> visual/photo confirmation, pill count
HIV risk	30-day number of partners, unprotected sex <sup>129</sup> , exchange sex, IDU, sex under the influence of drugs/alcohol <sup>115</sup>

## 1.7 Drugs/Devices/Biologics

### A. Schedule and Administration

N/A

### B. Drug/Device Accountability and Storage Methods

N/A

## 1.8 Specimen Collection

### A. Primary Specimen Collection

N/A

- **Types of Specimens:** N/A
- **Annotation:** N/A
- **Transport:** N/A
- **Processing:** N/A
- **Storage:** N/A
- **Disposition:** N/A

### B. Secondary Specimen Collection

N/A

- **Types of Specimens:** N/A
- **Annotation:** N/A
- **Transport:** N/A
- **Storage:** N/A

- **Disposition:** N/A

## 1.9 Data Collection

- **Primary Data Collection**
- **Location:**
  - Participants for Cycle 1 will be recruited from and complete the intervention at The Women's Collective, 1818 New York Ave NE #229, Washington, DC 20002. Washington, DC is an ideal setting for the proposed research. This setting facilitates a focus on understanding the impact of partners, HCP and SU on BW's PrEP uptake, because HIV prevalence is high and financial barriers to PrEP are relatively low. There is an HIV epidemic in the Black community in DC (3.9% prevalence).<sup>48,49</sup> Among DC women diagnosed with HIV in 2017, 9/10 were Black. Insurance coverage is high in DC (94%)<sup>50</sup> and PrEP is covered by private insurance and Medicaid. PrEP is also available at no cost to the uninsured. Gilead Sciences offers drug assistance programs and DC Health and Wellness Center offers free same-day PrEP. In all phases of the proposed research, I will collaborate with The Women's Collective (TWC), a community-based organization that provides health and social services for women of color who are living with or at risk for HIV. TWC has extensive experience with outreach, care navigation, recruitment, and EBIs, including SISTA and WILLOW.<sup>51</sup> TWC serves 2,500+ women annually for HIV prevention, including testing, outreach, intervention, and prevention case management.
  - Participants for Cycle 2 will be recruited from and complete the intervention at Positive Impact Health Centers 523 Church St., Decatur, GA, 30030. Positive Impact is well-suited as a site for the proposed research. Like DC, Atlanta is an Ending the Epidemic Priority Jurisdiction (i.e., HIV hotspot). Black people represent 47% of Atlanta residents<sup>23</sup>, but 70% of people living with HIV are Black<sup>24</sup>. This setting facilitates a focus on understanding the impact of partners, HCP and SU on BW's PrEP uptake. HIV prevalence is high and financial barriers to PrEP are relatively low. Positive Impact Health Centers provides comprehensive care through medical services, emotional wellness and recovery programs, pharmacy services, support programs, prevention, screenings, immunizations, and testing services. Positive Impact Health Centers have provided a Letter of Cooperation.
  - Participants for Cycle 3 will be recruited from and complete the intervention at St. John Baptist Church/CAMP ACE 3613 Hamburg St., New Orleans, LA. Like DC and Atlanta, New Orleans is an Ending the Epidemic Priority Jurisdiction. This setting facilitates a focus on understanding the impact of partners, HCP and SU on BWs PrEP uptake. St. John Baptist Church #5/CAMP ACE provides an array of quality educational, social, health and cultural services, including HIV testing and linkage to treatment services. St. John Baptist #5/CAMP ACE has provided a Letter of Cooperation.
- **Process of Data Collection:** The PI, who has extensive experience collaborating with CBO to recruit BW who are at risk for HIV into research, will oversee

recruitment.<sup>10,45,46</sup> Potential participants will be invited to participate in the study by staff during their routine interactions. CBO will distribute palm cards to prospective participants that direct them to the study's screening questionnaire and provide the study's contact information. The distribution of palm cards will be done during the CBO regular community outreach and engagement activities. The CBO staff will not be involved in screening, determining eligibility, or any other activities that involve the collection of prospective participant data. The CBO staff will only distribute study flyers that enable prospective participants to get in contact with study staff and/or complete the screening questionnaire. Recruitment activities will be done during the CBO's regular outreach. CBO staff will not serve as data collectors nor interviewers of potential participants. Those who agree will be provided with the study specific phone number, staffed by the project manager, and/or a link to the online self-guided eligibility-screening questionnaire, hosted via Qualtrics.<sup>52</sup> Eligible participants will generate a unique participant code and be routed to another survey to provide their name, phone number, email, availability and the contact information of a confidant who could get in touch if we are unable to reach them for scheduling. The participant generated unique identifier will be used to link the eligibility screening data with survey data and participant's identifying information (for monitoring enrollment).

- A member of the research team will coordinate with CBO to identify mutually agreeable dates and times for the study staff to conduct the research intervention. Only members of the research staff will be conducting the group sessions with these participants. The CBO staff will not be involved in research activities. They may however identify potential participants for eligibility. The project manager will contact participants to schedule the sessions, conduct informed consent procedures, and confirm the participant's unique identifier. The project manager will contact interviewees day before the scheduled sessions to provide a reminder, using their preferred method of contact. Participants will be directed to complete the follow up survey electronically through Qualtrics or by phone call with the Project Manager. We will follow-up with participants 45 days after their last intervention session to collect self-reported psychosocial and behavioral data, as well as photo-verified PrEP prescriptions and pill counts, or photo-verified appointment for the long-acting injection (i.e. appointment cards). We will use these data, along with intervention exposure and retention, self-reported mechanistic, and outcome measures to assess the feasibility and acceptability of the RCT design.
- **Timing and Frequency:** Data collection will occur prior to the sessions when participants are screened for eligibility and after the sessions when participants complete the follow-up and send photographic evidence of PrEP adherence to a secure Box.com and complete the follow up surveys. Participants will complete brief surveys to evaluate each session, immediately following each session.
- **Procedures for Audio/Visual Recording:** N/A
- **Study Instruments:** Participants will complete an eligibility screening either electronically through Rutgers Qualtrics or on the phone with the Project Manager, who will complete the Rutgers Qualtrics eligibility screening on their behalf. Participants will also complete a follow-up survey at the end of the sessions. During the sessions, facilitator will use the Session Manuals to conduct each of the four sessions and the two boosters. There is a facilitator manual for each session and booster (see attached).

- **Ethnographic Studies, Interviews, Or Observation:** N/A
- **Subject Identifiers:** No identifying information will be collected using the participant eligibility screening questionnaire. Participants who are determined to be eligible for the study and who agree, will be routed to a different survey in order to collect name and contact information (i.e., phone number, email address). Participants will generate unique identifying codes at the time of eligibility screening. The project manager will create a log linking identifying information to participant codes and will confirm the unique identifiers at the time of scheduling. All files will be password protected and stored in password protected, HIPAA compliant cloud storage (i.e., Box.com) accessible only by the project manager and the PI. The PI will delete the identifying information from the participant roster when recruitment is complete. To do so, the PI will permanently delete participant roster files and empty the trash on the device. Some eligible participants will not agree to participate. When data collection is complete, before data analysis, the program manager will permanently delete data from participants who did not consent to participate in the study, by matching the unique identifiers in the roster to eligibility screening surveys (and deleting unmatched surveys). Participants will send photo-confirmation of PrEP use to a study specific secure Box.com. Each participant will have a unique link to the folder and the folder will be labeled by their Participant ID (the first letter of their middle name, the day of the month they were born, and the first three letters of their mother's name). The program coordinator will enter photo-confirmation data into a password protected de-identified database, using study specific unique identifiers. Dr. Hull will verify accurate data entry and destroy the identifiable data immediately upon confirmation of data entry.

The participants' names, addresses, and phone numbers will be shared with Uber and the business office of the School of Communication and Information (SC&I) to coordinate travel to and from the research site.

- **Secondary Data Collection**
- **Type of Records:**
- **Location**
- **Inclusion/Exclusion**
- **Data Abstraction Form(s):**

## 1.10 Timetable/Schedule of Events

*Table 1. Proposed timetable for Cycle 1 of the intervention*

Weekday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
<b>Cycle 1 Date</b>	8- Jan	9-Jan	10-Jan	11-Jan	12-Jan	13-Jan	14-Jan
<b>Study Activity</b>	Session 1	Session 2	Session 3	Session 4			
<b>Start Time</b>	11 am	11am		11am			

<b>End Time</b>	2pm	2pm	2pm	2pm			
<b>Travel</b>	Return home via Uber						
<b>Booster 1</b>	Session 5 (week of 5-Feb)						
<b>Booster 2</b>	Session 6 (week of 19-Feb)						

Table 2. Proposed timetable for Cycle 2 and Cycle 3 of the intervention

<b>Weekday</b>	<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>	<b>Saturday</b>	<b>Sunday</b>
<b>Cycle 2 Date</b>	20 May/ 16 Sept	21 May/ 17 Sept	22 May/ 18 Sept	23 May/ 19 Sept	24 May/ 20 Sept	25 May/ 15 Oct	26 May / 4 Nov
<b>Study Activity</b>	Session 1	Session 2	Session 3	Session 4			
<b>Start Time</b>	10 am	10 am	10am	10 am			
<b>End Time</b>	1:30 pm	1:30 pm	1:30pm	1:30pm			
<b>Travel</b>	Return home via Uber						
<b>Booster 1</b>	Session 5 (June 21)						
<b>Booster 2</b>	Session 6 (July 1)						

<b>Research Timeline</b>							
	1	2	3	4	5	6	7
Recruitment (n = 8-12/cycle)							
SISTA-P Theater Testing							
Follow-Up (45 days)							
Data Analysis							
Manuscript Preparation							

## 2.0 Project Management

### 2.1 Research Staff and Qualifications

Our interdisciplinary team brings together expertise in communication science (Dr. Shawnika Hull), research to understand and address PrEP uptake among PrEP eligible Black women (Dr. Hull), community engaged research (Dr. Hull), HIV prevention service and intervention delivery (The Women's Collective, Positive Impact Health Centers), technical monitoring of intervention delivery (Dr. Arlene Edwards), and interventionist training (Ms. Dana Williams).

**Dr. Shawnika Hull** is a communication scientist at Rutgers University whose work is focused on developing and delivering communication interventions to address HIV inequities experienced by Black communities. Dr. Hull led the adaptation of SISTA to address PrEP uptake and navigate partner, provider and substance-use related barriers, in partnership with The Women's Collective (1K01DA050496-01A1).

**Dana Williams**, who is serving as an independent consultant, is a Co-Founder and Executive Director of The Community Wellness Project. As a public health consultant, she has extensive experience in writing, developing, implementing, and evaluating many HIV/AIDS/STD programs and training curriculums including Prevention Case Management, Effective-Street and Community Outreach strategies, and Community Mobilization. Ms. Williams serves as a national training partner for the Center for Disease Control, the Office of Minority Health and the Office of Women's Health and is a master-level trainer for the American Red Cross HIV/AIDS Instructor Course in both the African American and Fundamentals programs and is considered a lead trainer for the Centers for Disease Control (CDC) Capacity Building Assistance Branch for their Evidence Based Interventions (EBI's). Ms. Williams, who will lead manualization, participated in the development of the SISTA training manual and has extensive experience training interventionists to deliver SISTA.

**Dr. Arlene Edwards** is the former Centers for Disease Control SISTA Technical Monitor. Dr. Edwards is working on this project as an independent consultant. Dr. Edwards translates evidence-based HIV prevention intervention research into interventions to be implemented at community-based organizations. She ensures that HIV prevention interventions are implemented with fidelity to the original design. Dr. Edwards serves as a technical monitor for several HIV prevention interventions, including as the lead technical monitor for SISTA. Dr. Edwards and Dr. Williams participated in the development of the manualized suite of SISTA-P predecessors, including SISTA, SiHLE (focused on adolescents), WILLOW (focused on women living with HIV) and TWIST (focused on transgender women).

**Jamila Shipp** is working on this project as an independent consultant. She has extensive experience in program development, implementation, research, and evaluation of HIV/AIDS prevention programs. She specializes in underserved populations, particularly sex workers, homeless, and substance users. She has served as the chair of the California HIV planning group. Jamila holds a Master of Public Health from San Francisco State University, and a B.S. in Health Care Management from Florida Agricultural and Mechanical University.

**MJ Salas** is a graduate researcher whose interests reside at the intersection of health and critical, interpersonal communication with a focus on identity. Using transdisciplinary, mixed methods approaches, they seek to answer research questions about the health and healthcare experiences of racial, ethnic, sexual, and gender minorities. They are motivated to reduce health disparities via community-engaged, culturally tailored health interventions to affect positive change for minoritized populations and their health. In the present study, they will be involved with recruitment, data collection, study implementation, and basic data analysis and manuscript preparation.

**Lillianna Shields** is a second-year master's student at Rutgers University in the Health Communication & Information program. Her work focuses on signaling inclusivity in patient-

provider interactions to increase patient retention, as well as understanding how to better enact patient-centered care for LGBTQ+ patients and providers. She will assist with recruitment, data collection, study implementation, and basic data analysis and manuscript preparation.

**Myla Lyons** is a graduate student researcher of Applied Social Psychology examining the intersection of Black women's social positionality and subsequent HIV-related outcomes. Health behavior change and socioecological analysis is part of her doctoral work. Her contribution to this study will involve evaluation of the pilot program from these perspectives.

## 2.2 Research Staff Training

The PI will hold weekly meetings throughout the study period to discuss all issues related to intervention adaptation processes, recruitment of participants, instrument development, data collection, management, and analysis, as well as manuscript development and submission. The PI will provide guidance regarding research conduct and allocation of study resources to the accomplishment of research objectives. The PI will schedule meetings with individual team members separately as needed to supplement the weekly team meetings.

All team members based at Rutgers University will complete CITI training and protocol specific training. All independent consultants and technical monitors will complete CITI training and protocol specific training.

## 2.3 Other Resources

The proposed research will be funded through an NIH K01 grant award (1K01DA 050496-01A1).

## 2.4 Research Sites

Recruitment will take place at The Women's Collective (TWC) in Washington D.C. and at Positive Impact Health Centers in Decatur, GA (hereafter, community-based organizations [CBO]). Rutgers staff and consultants will conduct the intervention using CBO facilities (see Site Agreement Letters for TWC and Positive Impact Health Center). CBO staff will not engage in research activities.

**The Women's Collective (TWC)**, a leading community health and human service agency in Washington, DC; TWC provides prevention, care and support services, and advocates for the health and human rights of girls and women. TWC will provide space for intervention activities and assist with recruitment. TWC staff will not participate in the research activities. TWC staff will also provide referral to social and clinical services. TWC has a robust & successful Test and Link to Care program which provides integrated screening for STDs, Hepatitis C and HIV, as well as referral & linkage to prevention services including nPEP & PrEP. The program focuses on prevention education, outreach, and recruitment for targeted HIV/HEP C testing for both HIV-positive & High-Risk Negative (HRN) persons. TWC's primary target population is Black women, who account for the majority of living HIV cases among women in DC. TWC also provides clients with a comfortable and confidential space for HIV, Hepatitis C and STD screening, which meets occupational safety and environmental

regulations, includes all the critical equipment including hazardous waste disposal units and refrigerators for temperature control of testing kits and a mobile testing unit for outreach.

TWC headquarters are located at 1818 New York Avenue NE Washington. This includes two separate office spaces: one which houses the Reception, Administrative Offices, Filing and Copy Prevention Department, Care Department, additional office space for the volunteer specialist and volunteers/interns, and conference rooms. This space also has the clients' kitchen used to serve hot meals daily as well as for meetings and has resource center for clients which has computers for internet access and job searches.

The Women's Collective has spent 15 years developing an extensive service provider network. This network ensures the delivery of comprehensive services for the women and families. Our referral partners provide an array of prevention and support services, including but not limited to partner services; treatment adherence; STD, hepatitis, and TB testing and treatment; Pre-Exposure Prophylaxis (PrEP) and nPEP; health insurance navigation and enrollment; mental health counseling and services; housing; transportation services; employment services; basic education continuation and completion services.

Positive Impact Health Centers (Positive Impact) provides patient-centered HIV care and prevention services. They are the only AIDS Service Organization in Georgia to receive National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home Recognition. Positive Impact Health Centers is made up of 4 locations in metro Atlanta. Positive Impact's providers and staff work together to provide a patient-centered experience. Positive Impact offers medical care, health counseling, laboratory testing, and prescriptions. Positive Impact offers an array of preventative services, such as PrEP, and other risk reduction programs. For example, Positive Impact delivers WILLOW and TWIST, evidence-based interventions to serve women living with HIV, which are based on the original SISTA intervention (which we are adapting). Positive Impact also offers PrEP navigation services, including counseling, testing, substance abuse support, HIV/STI treatment, peer support, mental health counseling, community resources and classes.

The mission of St. John #5/Camp ACE is to increase and broaden the perspective of economically disadvantaged children, youth and families throughout the Metro New Orleans region by way of providing an array of quality educational, social, health and cultural services. St. John wholeheartedly joined in the HIV/AIDS fight 20+ years ago. Just as St. John chooses to participate in the fight against other health problems including Diabetes, Obesity, High Blood Pressure, and Cancer, just to name a few, it also understands how necessary and important it is to participate in the HIV/AIDS fight. The organization promotes and is committed to providing quality health-related services such as HIV prevention and is open to assist all people regardless of their sexual orientation, race, ethnicity, economic status, and gender. The organization promotes and is committed to providing quality health-related services such as HIV prevention and is open to assist all people regardless of their sexual orientation, race, ethnicity, economic status, and gender.

### 3.0 Multi-Center Research

N/A

## 4.0 Subject Considerations

### 4.1 Subject Selection and Enrollment Considerations

#### A. Method to Identify Potential Subjects

We will use active and passive recruitment methods and invite participants to refer others who may be eligible. The CBO staff will approach potentially eligible women through community outreach and social service activities to invite them to participate. Community health workers will provide potentially eligible participants with a palm-sized card or flyer that describes the study, the project contact information. Staff will also offer participants the opportunity to complete the eligibility screening using a tablet device, if they are already in a face-to-face context. Recruitment will also include flyers at the CBO and word-of-mouth. Eligibility screening will include self-reported HIV status and risk factors, recent drug use history, whether they are sexually active, and demographic characteristics (i.e., age, gender assigned at birth, race). Using a standardized formula, the study staff will generate a unique identifier to link contact information to eligibility screening survey responses and schedule eligible respondents for a consent discussion.

#### B. Recruitment Details

Adult (18+) cisgender BW will be eligible for inclusion as participants if they are heterosexually active, reside in Washington, DC, or Atlanta metro area (designated HIV hotspots), report at least one HIV risk factor (i.e., recent STI, sex work, inconsistent condom use, injection drug use, high risk sex partner) and are not currently using PrEP. We will recruit participants for Phase 2 through CBO routine outreach activities and by using flyers, palm cards and outreach. The rationale for including only cisgender female adults is that transgender women, youth, and transgender youth are likely to face unique barriers to PrEP uptake and require interventions that are responsive to them. Women who are living with HIV will be excluded, as the focus of the proposed research is HIV prevention.

We will use active and passive recruitment methods and invite participants to refer others who may be eligible. We will recruit potential participants through CBO HIV prevention outreach and HIV testing activities, venue-based referral and with flyers posted around metro stations, dance clubs, salons, laundromats, and convenience stores. Potential participants will be asked to complete an eligibility-screening questionnaire in-person, via telephone or online survey. Eligible participants will provide their name, phone number, email, availability and the contact information of a confidant who could get in touch if we are unable to reach them for scheduling.<sup>12</sup> This team has experience collaborating with CBO to recruit Black women who are at risk for HIV into research.<sup>25-27</sup>

#### C. Subject Screening

Participants will be screened using a short questionnaire delivered via telephone interview with the research team or using a direct link to the online screener survey, which will be hosted using Qualtrics. At the beginning of the screening session (online or telephone), participants will be provided with a brief informed consent for the screening component of the study. The informed consent will be provided at the beginning of the Qualtrics survey for those being screened online. The intervention staff will read the consent document to

individuals completing screening procedures via telephone. Participants will be notified of the study eligibility criteria at the end of the screening.

For participants who opt to conduct the screening via telephone, the project manager will read the electronic survey questions aloud and record answer options into the electronic survey, during the discussion. Since the project manager will enter response options into the electronic survey, skip patterns will be automatically activated.

At the end of the screening questionnaire, participants who consented, are eligible and willing to participate will be automatically routed to another survey to collect contact information (i.e., using survey skip patterns). Participants will be contacted by the project staff at a later time to schedule the intervention session. The eligibility screener and the intervention session may or may not be scheduled to occur on the same day.

Participants who are eligible, but unwilling to participate will receive the following message:

“Thank you for your time. As you requested, we will not contact you regarding participation in this study. Any data you provided in this survey will be removed from our database (i.e., deleted). We may use your data only to report the number of people who were eligible vs. ineligible to complete the study. We will not use your data for any other purposes. We appreciate your willingness to participate.”

Respondents who are ineligible will receive the following message:

“Thank you for taking the time to complete this study eligibility questionnaire. Based on the study criteria, you are **not eligible** to participate at this time. Any data you provided in this survey will be removed from our database (i.e., deleted). We may use your data only to report the number of people who were eligible vs. ineligible to complete the study. We will not use your data for any other purposes. We appreciate your willingness to participate. “

- **Inclusion Criteria**

Adult (18+) cisgender BW will be eligible for inclusion if they are sexually active, speak English and report at least one HIV risk factor (i.e., recent STI, sex work, inconsistent condom use, IDU, high risk sex partner) and do not currently use PrEP for HIV prevention. Although SU is not an inclusion criterion, the PI will monitor enrollment to ensure adequate proportions of SU/non-SU participants are enrolled for each phase. SU will initially be operationalized broadly as any past 30-day binge drinking, marijuana, misuse of prescription drugs and illicit SU. The rationale for including only cisgender female adults is that transgender women, youth, and transgender youth are likely to face unique barriers to PrEP uptake and require interventions that are responsive to them. Women who are living with HIV will be excluded, because for them, Truvada (PrEP) is used for treatment.

- **Exclusion Criteria**

Women who are living with HIV will be excluded, because for them, Truvada (PrEP) is used for treatment.

#### **D. Privacy Protections**

Every effort will be made to ensure confidentiality is maintained. All information will be kept in a secure folder in Rutgers Box. Participant's information will be de-identified as much as possible and all information will be stored under a secure ID number in a study database. A separate dataset used for analysis will only include de-identified variables necessary for the proposed analyses. Any presentations or publications resulting from this study will not identify any participants by name or protected health information. Only aggregate data will be presented or published.

#### **4.2 Obtaining Identifiable Information About Non-Subjects**

N/A

#### **4.3 Number of Subjects**

##### **A. Total Number of Subjects**

We will have 30 participants complete the study in its entirety. 100 potential participants are expected to be screened for the study with 35 to 40 expected to be eligible and enrolled. We have allowed for five to ten participants being unable to complete the study.

##### **B. Total Number of Subjects If Multicenter Study**

N/A

##### **C. Feasibility**

Study recruitment is expected to begin in January for Cycle 1, May for Cycle 2 and September for Cycle 3. We have extensive experience recruiting this population as evidenced by our preliminary research and ongoing collaboration with the CBO.

#### **4.4 Consent Procedures**

##### **A. Consent Process**

###### **▪ Location of Consent Process**

The project manager will conduct the consent process prior to the start of the first session, during a scheduling call.

###### **▪ Ongoing Consent**

N/A

###### **▪ Individual Roles for Researchers Involved in Consent**

The project manager will be responsible for obtaining verbal consent.

###### **▪ Consent Discussion Duration**

The consent process will be five to ten minutes in duration.

###### **▪ Coercion or Undue Influence**

The project manager and the research staff will remind participants that they are free to decline to respond to any of the questions. The research team will remind participants that their participation is completely voluntary and will in no way impact their care or relationship with any member of the study team or their care team. Participants will be encouraged to ask questions.

- **Subject Understanding**  
Each participant will be given adequate time to ask all questions about the study being conducted and to express any concerns. Research staff will also ask the participant questions about the components of the study and confidentiality to confirm their understanding. The research team will be watchful for any indications of confusion, and if apparent, will review the study and consent again.
- **Protecting Privacy**  
Every effort will be made to ensure that confidentiality is maintained. We are aware that data will contain demographic and personal health information, and consistent methods will be employed to protect the confidentiality of these data.

**B. Waiver or Alteration of Consent Process**

- **Waiver or Alteration Details**  
N/A
- **Destruction of Identifiers**  
N/A
- **Use of Deception/Concealment**  
N/A
  - a. **Minimal Risk Justification**  
N/A
  - b. **Alternatives**  
N/A
  - c. **Subject Debriefing**  
N/A

**C. Documentation of Consent**

- **Documenting Consent**  
Participants will be asked to verbally confirm their consent to the project manager. Participant's attendance at the study sessions will be recorded under their secure ID number and be considered their documentation of consent. Participants will be allowed to leave the study at any time, and thereby revoke their consent.
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**  
The project manager and the research staff will obtain verbal consent, but not document consent in writing. The project manager will provide information about the study orally, during scheduling and before the group meeting, respectively. Research staff will also provide an electronic copy of the document, if requested. The project manager and research staff will ask participants to provide a verbal response (i.e., "yes" or "no"), indicating their consent to participate in the research. Attending the intervention meetings will be considered continuing consent to participate in the research program.

**4.5 Special Consent Populations**

N/A

**A. Enrolling Minors-Subjects Who Are Not Yet Adults**

- **Parental Permission**

- N/A
- **Non-Parental Permission**  
N/A
- **Assent Process**  
N/A
- **Documentation of Assent**  
N/A
- **Reaching Age of Majority During Study**  
N/A

**B. Enrolling Wards of the State**

- N/A
- **Research Outside of NJ Involving Minors**  
N/A

**C. Enrolling Non-English-Speaking Subjects**

- N/A
- **Process for Non-English-Speaking Subjects**  
N/A
- **Short Form Consent for Non-English Speakers**  
N/A

**D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)**

- N/A
- **Assessing Adult Capacity to Consent**  
N/A
- **Selecting a Surrogate & Consent Process**  
N/A
- **Subject Assent**  
N/A
- **Selecting a Witness to the Surrogate Consent Process**  
N/A
- **Removing a Subject**  
N/A

**E. Special Consent Considerations**

As consent is done orally, participants who cannot read or write or participants who are blind can actively participate in the consent process and research intervention. Participants who are deaf can also participate, provided they provide their own interpreter.

**4.6 Economic Burden and/or Compensation for Subjects**

**A. Expenses**

All expenses related to the study will be covered by the study. The research team will call Ubers for the participants to bring them to and from the study site for each study session. Payments will be made directly to Uber.

**B. Compensation/Incentives**

After each session is completed and after each booster, the participants will receive a \$50 gift card. The participants will receive a \$50 gift card after completing the follow-up.

**C Compensation Documentation**

The research team will maintain a compensation log indicating the date and mode of delivery for gift cards, using participant identifiers to identify payees.

**4.7 Risks of Harm/Potential for Benefits to Subjects**

**A. Description of Risks of Harm to Subjects**

▪ **Reasonably Foreseeable Risks of Harm**

- ***Emotional discomfort.*** There is a chance that participants will experience emotional discomfort as a result of the discussion. However, the research will occur in the context of a women's health and social services community-based organizations. CBO focus on HIV prevention and care for women of color. The CBO have extensive experience providing support and tools to support women's efficacy in HIV prevention, including emotional and social support. Subject matter experts (i.e., Ms. Williams, Ms. Shipp, Dr. Edwards) will be directly involved in the development of the questionnaire and implementation of the research. Further, the co-facilitators will have, extensive experience engaging in focused discussions related to HIV prevention with women. Consequently, we believe that this risk is minimal. We will provide additional information and assistance with linkage to PrEP related services for all women who request it and refer women who wish to obtain PrEP to medical providers in the CBO networks. If respondents voice emotional discomfort, we will provide them with contact information for a CBO staff member (i.e., HIV prevention case manager) to be linked to appropriate services .
- ***Disclosure of personal information, including HIV risk factors and substance use.*** Eligibility screening surveys will collect private information about sexual and substance use history. HIV risk factors will be collected during the initial eligibility screening but will not be kept, except in aggregate. Participants will be asked to submit photo confirmation of PrEP prescription, or appointment for those receiving long-acting injection, to a study specific, Box.com. Each participant will have a unique submission link that connects to a folder labelled with their unique identifier. The participants' names, home addresses, and phone numbers will be shared with Uber and the SC&I business office.
- ***Risk of Harm from an Intervention on a Subject with an Existing Condition***  
We do not see any additional risks to people with psychological or physical conditions. However, the work is being conducted at a CBO who can refer them to care.
- ***Other Foreseeable Risks of Harm***  
Participants may disclose personal information during intervention sessions. However, participants must agree to a confidentiality agreement at the beginning of each session, and it will be included the consent. All handouts will be left at the CBO between sessions to ensure confidentiality is met.

- **Observation and Sensitive Information**

N/A

**B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects**

N/A

**C. Risks of Harm to Non-Subjects**

N/A

**D. Assessment of Social Behavior Considerations**

There is the possibility of emotional discomfort, social or behavioral services referred to the CBO as the study is taking place at there. CBO will refer women to services.

**E. Minimizing Risks of Harm**

***Protection against emotional discomfort.*** Participants will be reminded that they are not required to respond to any questions and are free to discontinue participation in the research at any time. The interviews and intervention sessions will be conducted at the CBO. CBO are uniquely positioned to provide HIV related social services to women in the proposed study and has extensive experience implementing the SISTA intervention. Experienced facilitators with experience working in Black women's HIV prevention will facilitate intervention sessions, focus groups and interviews. These design features facilitate rapid linkage to mental health, social, HIV prevention and related services for women in need. CBO have partnerships with a wide range of social, behavioral, and mental health service providers in the metropolitan area.

***Protection against the risk of disclosure of personal information.***

Staff-generated unique identifiers will be used to link demographic data (i.e., eligibility screening survey), contact information, and transcripts, for the purposes of scheduling, monitoring enrollment, and stratifying analyses by substance use history. The eligibility screening survey and referral forms with contact information will be kept in separate, password protected files in a password protected cloud storage space provided by the University (i.e., Box.com). The roster containing the unique identifiers and corresponding identification will be stored in a password protected encrypted file, accessible only to the PI and program manager, separate from any data files. The information shared with Uber and the SC&I business office will not be tied to any study data. Participants will be informed that their information will be shared in this way.

- **Certificate of Confidentiality**

This study is NIH funded.

- **Provisions to Protect the Privacy Interests of Subjects**

Every effort will be made to maintain confidentiality and ensure that all data is secure. All identifying information will be stored in a secure folder in Rutgers Box. Only aggregate data will be reported in presentations and published in study publications. All research staff will have completed institutional requirements for the responsible conduct of research including CITI training modules and have IRB approval for data access.

**F. Potential Direct Benefits to Subjects**

Women who participate will gain knowledge of PrEP for HIV prevention and access to services that are gender and culturally appropriate. Participants may also derive

emotional benefits from participating in research focused on preventing HIV transmission in their community through empowerment.

## **5.0 Special Considerations**

### **5.1 Health Insurance Portability and Accountability Act (HIPAA)**

We will request photo confirmation of a PrEP prescription, or photo confirmation of prescription for long-acting injectable PrEP. This may include a photo of the physical prescription, a pill bottle with the name of the prescription visible, or a photo of the participant holding the pills. We will request that participants send this photo-confirmation to a Box research folder that is unique to each participant.

Participants are asked to block their private information from the photograph. We will obtain HIV status using a data collection tool that does not include identifiable information (i.e., eligibility screener). Participants may disclose private health information during the panel sessions. We are requesting an alteration of HIPAA authorization, e.g., verbal or online confirmation.

### **5.2 Family Educational Rights and Privacy Act (FERPA)**

N/A

### **5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)**

N/A

#### **A. Special Populations**

- Pregnant Persons or Fetuses [See Toolkit HRP-412]

### **5.4 General Data Protection Regulation (GDPR)**

N/A

### **5.5 NJ Access to Medical Research Act (Surrogate Consent)**

N/A

## **6.0 Data Management Plan**

### **6.1 Data Analysis**

Sources of materials include several data collection tools. Eligibility screening surveys will also be administered using Qualtrics platform. Eligibility screening surveys will be used to obtain demographic information (i.e., age, gender, race), sexual activity, HIV status and risk factors, and substance use history. No identifying information will be collected during eligibility screening; surveys will be linked to transcripts and contact information using study specific unique identifiers. Referral form will contain contact information. Referrals will be collected using Qualtrics online data collection platform and information will be stored in password protected, secure cloud storage, accessible only to the PI and the program manager. Photo-confirmation of behavioral outcomes will be de-identified and stored in a database, using unique identifiers for tracking.

The PI will oversee data management and analysis with an approach that ensures identification of acceptability and feasibility of the intervention. Data will include demographic surveys, follow-

up surveys, photo confirmations, and brief post-session surveys. Data analysis will focus on establishing acceptability and feasibility of the intervention.

## **6.2 Data Security**

The PI will monitor staff training and conduct vis-à-vis data security. All study staff will receive CITI training in human subjects' research in social and behavioral sciences. Staff will also receive training specifically on the topic of maintaining data security during the study start-up period. All meetings will be password protected. Eligibility screening surveys will collect private, but not identifying information. Pre-interview surveys will be tracked using a staff generated unique identifier. In-depth discussions will cover sensitive and private information, including HIV risk behaviors, perceptions of partner's HIV risk, and substance use history and will not be recorded.

Staff generated unique identifiers will be used to link demographic data (i.e., eligibility screening survey), contact information, photo-confirmations of behavioral outcomes, and for the purposes of scheduling and monitoring enrollment. The unique identifier is generated using the participant's first initial of their middle name, the day of the month they were born, and the first three letters of their mother's maiden name. The eligibility screening survey, all data and contact information will be kept in separate, password protected files in a password protected cloud storage space.

## **6.3 Data and Safety Monitoring**

### **A. Data/Safety Monitoring Plan**

#### **Safety**

Communication between participants and study staff (i.e., scheduling, follow-up) will occur primarily via telephone. Participants may choose to discontinue intervention or interview participation at any time. If a participant arrives at the intervention session intoxicated, she will be asked to excuse herself from participation and CBO staff will assist her to a safe location and provided with local transportation. Other risks may arise from women attempting to engage in HIV prevention communication with partners, which may create discord in the relationship. Intervention sessions will be conducted at a CBO so that women who are in need of linkage to services related to substance use, intimate partner violence, social, physical and/or mental health.

Dr. Hull will supervise all data collection activities. All study staff will complete the Collaborative Institutional Training Initiative (CITI) Basic training course on the topic of human subjects' research in social and behavioral sciences. All data files will be kept in a password protected storage space accessed using a password-protected computer. All participants will be offered physical copies of a IRB approved informed consent document. Prior to the beginning of the first intervention session, participants will be afforded time to read the document, or the document will be read to them. The facilitator will summarize the document and offer answers to participant questions. Participants will be asked to verbally agree to continue with the research, and sign the consent form, which will be stored in a private office. Interventions sessions will be conducted in a private conference room in the CBO by a trained, experienced Black women. The facilitator will set ground rules at the beginning of each intervention session, emphasizing the importance of confidentiality in the

group discussions and activities, will protect participant's privacy. Demographic and behavioral data will be collected using a tablet computer and participant generated unique identifiers will maximize privacy. Data files will be password protected. We will collect and retain demographic and risk factor data only from participants who are eligible and agree to participate in the study.

### **Data Management, Analysis, and Quality Assurance**

Data Sources include several data collection tools. Referral forms will contain contact information. Referrals will be collected using tablet devices and information will be stored in password protected, secure cloud storage (Box.com), accessible only to the PI and the program manager. Eligibility screening surveys will also be administered using tablet devices. Eligibility screening surveys will be used to obtain demographic information (i.e., age, gender, race), sexual activity, HIV status and risk factors, and substance use history. No identifying information will be stored in eligibility survey database. A tracking database containing the unique identifiers and corresponding identification and contact information will be kept in a password protected encrypted file accessible only to the PI and program manager, separate from any data files. Brief post-session surveys will be used to evaluate whether core elements of the intervention were delivered with fidelity and to evaluate the acceptability of the content, delivery and materials. The program manager will enter photo-confirmation data into a password protected de-identified database, using study specific unique identifiers. Dr. Hull will verify accurate data entry and destroy the identifiable data immediately upon confirmation of data entry. Follow-up surveys will include psychometric measures to assess self-reported intermediate (e.g., attitudes, perceptions of norms, self-efficacy) and outcome (i.e., behavioral) variables. Follow-up surveys will be tracked using unique identifiers. No identifying information will be stored in the database. To assure the validity and integrity of the data, all study staff will receive 12 hours of training on the intervention, human subjects research and data collection tools. Recruitment and enrollment processes and data collection will be monitored and reported through regular staff meetings. As PI, Dr. Hull will supervise data analysis and monitor data management processes.

### **Reportable Events**

We will identify any potential Adverse Events, Serious Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others through regularly scheduled staff meetings. The PI will report any adverse events to the Program Officer in the annual progress report and to the Institutional IRB within 10-days of learning of the event. The PI will report Serious Adverse Events to the Program Officer and Institutional IRB within 10 days of the study team learning of the event. The PI will report Unanticipated Problems Involving Risks to Subjects or Others to the Program Officer and IRB within 10-days of learning of the event.

## **B. Data/Safety Monitoring Board Details**

### **Data Safety and Monitoring Board**

Dr. Hull will convene a data safety and monitoring board consisting of senior colleagues who are engaged in clinical trials research and have NIH funding experience. Senior colleagues will include those with expertise in communication science, public health, and biostatistics.

## **6.4 Reporting Results**

**A. Individual Subjects' Results**

Individual subjects' results will not be reported. Any reporting will summarize the data.

**B. Aggregate Results**

We will also host a townhall meeting to present the results of the proposed research to interested community members. The townhall session will be hosted at The Women's Collective. Finally, we will collaborate with TWC to identify strategies for disseminating the results of the proposed research to interested community stakeholders.

**C. Professional Reporting**

We plan to use multiple mechanisms to disseminate the results of the proposed research. Dr. Hull will ensure that the study is registered, and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy. Dr. Hull will ensure that informed consent documents for the study will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

We will submit the results of the proposed research for publication in scientific journals. We will also submit the results of the proposed research to public health and communication conferences (i.e., International Communication Association, International AIDS, American Public Health Association).

**D. Clinical Trials Registration, Results Reporting and Consent Posting**

The trial qualifies as a Clinical Trial and will be registered on clinicaltrials.gov. Per the requirements of clinicaltrials.gov, the study must also be registered through the Rutgers University account. The profile will be updated within 30 days of any IRB approved changes to recruitment status and completion status per the clinicaltrials.gov requirements. All other changes will be made at least every 12 months, except the Record Verification, which will be updated every six months per the requirements.

**6.5 Secondary Use of the Data**

The information collected about participants (or from participants) for this research will not be used by or distributed to investigators for other research.

## **7.0 Research Repositories – Specimens and/or Data**

N/A

## **8.0 Approvals/Authorizations**

A letter of agreement will be collected from The Women's Collective at D.C. detailing their participation as a recruitment site for the study intervention.

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