Title: Microenterprise Intervention to Reduce Sexual Risk Behaviors in Young Adults (EMERGE)

NCT03766165

Document Date: 23 January 2019

Johns Hopkins University Institutional Review Board (IRB)
Research Protocol

Principal Investigator (PI): Larissa Jennings Mayo-Wilson, PhD MHS
Assistant Professor, Social & Behavioral Interventions
Department of International Health
Johns Hopkins Bloomberg School of Public Health

Study Title: **Feasibility Trial to Reduce Sexual Risk Behaviors in African-American Young Adults, Aged 18 to 24, Who Are Out of School, Unemployed, and Experiencing Homelessness in Baltimore City, Maryland, United States**

Version Number / Date: Version 5 / January 23, 2019
IRB No. 00008833

Executive Summary:

The study team will conduct a two-group study to examine the feasibility of implementing an enhanced microenterprise intervention to reduce sexual risk behaviors.

- The team will enroll 40 young adults, aged 18 to 24, who are African-American, homeless, out-of-school, and unemployed or under-employed. Participants will be randomly assigned to one of two groups. The first group ("control") will receive text messages with information on job openings. The second group ("intervention") will receive text messages with information on job openings plus HIV prevention and business educational sessions, mentored apprenticeship, a start-up grant (provided in 6 payments), and HIV behavioral economics text messages.

Data will be collected for 26 weeks (week 1 to week 26).

- Participants will undergo a baseline in-person interview at the time of enrollment (week 1) and be randomized to a group after completing a 3-week run-in period (week 1 to week 3). Each group will receive the assigned activities for 20 weeks (week 4 to week 23). An endline in-person interview will be conducted in and around week 26 at 3 weeks post-intervention. The baseline and endline interviews will occur over an approximate 2-week period. Participants will also complete a weekly text message survey from enrollment (week 1) to the end of the study (week 26).

The study team will collect <u>feasibility</u> information pertaining to two primary outcomes:

- The proportion of participants in both groups who have responded to 70% or more of the weekly text message surveys at week 26; and
- The proportion of participants in the intervention group who have completed 70% or more of intervention activities (i.e., text message receipt, session attendance, grant spending, and mentor contact) at week 23.
- As secondary feasibility outcomes, the study team will collect feasibility information about the proportion of all participants who receive one or more informational text messages each week, the proportion of all participants who respond to a text message survey each week, the proportion of intervention participants who attend an educational session each week, the proportion of intervention participants who receive one or more mentor contacts each week, and the proportion of intervention participants who spend one or more grant payments each week. These are all related measures to loss-to-follow-up and retention.

The study team will also collect <u>sexual risk behavior</u> information pertaining to three primary outcomes:

- The proportion of participants in each group who report one or more unprotected sex acts in the last week and last month; and
- The proportion of participants in each group who report one or more safer sex acts in the last week and last month; and
- The proportion of participants in each group who report one or more HIV prevention care-seeking or information-seeking acts in the last week and last month.

The study team will also collect <u>economic</u> information pertaining to two primary outcomes:

- The mean number of paid hours work in a job or self-employment in the last week; and

- The mean amount of cash (U.S. dollars) earned from a job or self-employment in the last week

I. Specific Aims and Hypotheses

- **Aim 1**: To examine the feasibility of implementing an enhanced microenterprise intervention to reduce sexual risk behaviors among African-American young adults who are homeless, out of school, and unemployed (HOU).
  - **Hypothesis 1:** The study team hypothesizes that the intervention will be feasible as defined by the above (page 1) feasibility outcomes.
- **Aim 2**: To examine the preliminary efficacy of the pilot microenterprise intervention in reducing sexual risk behaviors among African-American HOU young adults.
  - **Hypothesis 2:** The study team hypothesizes that HOU participants enrolled in the intervention group will report declining and lower sexual risk behaviors as compared to HOU participants enrolled in the control group at the end of the study.
- **Aim 3**: To examine the preliminary efficacy of the pilot microenterprise intervention in improving economic outcomes among African-American HOU young adults.
  - **Hypothesis 3:** The study team hypothesizes that HOU participants enrolled in the intervention group will report improving and higher economic outcomes (employment and earnings) as compared to HOU participants enrolled in the control group at the end of the study.

The intervention is entitled the EMERGE Project, *E*ngaging *M*icroenterpris*E* for *R*esource *G*eneration and Health *E*mpowerment (K01MH107310: PI, Larissa Jennings). This is a pilot trial intended to inform a future R01 study design.

II. Background and Rationale

African-Americans young adults are disproportionately affected by the HIV epidemic: Although representing only 12% of the U.S. population, African-Americans make up nearly half (46%) of HIV diagnoses, and the rate of new HIV infections is 8.6 times higher among African-Americans compared to non-Hispanic whites [1]. African-American young adults are especially at risk and are more likely than other U.S. racial minorities to live in high poverty, high HIV prevalence urban communities [2]. For example, the Baltimore, Maryland (MD) metropolitan area is characterized by concentrated poverty in predominately African-American neighborhoods and has the 5th highest rate of new HIV infections among U.S. cities [1]. In 2012, 81% of HIV diagnoses in Baltimore were among non-Hispanic blacks, with young adults, aged 20-29, representing the highest proportion [3]. The HIV prevalence among black adult residents in Baltimore is alarmingly high at 3.2% [3], over 8 times the U.S. HIV prevalence (0.4%) and exceeding the UNAIDS definition of a "generalized" epidemic (HIV prevalence > 1%) [4],[5]. Yet, despite persistent racial disparities in HIV infection, there have been few significant intervention advances to control the epidemic in urban poor African-American settings [6].

Many economically disadvantaged populations are also at highest risk for HIV: HIV prevalence in low-income urban areas is 2 to 5 times higher than the national average, and individuals living below the poverty line are twice as likely to be infected [7]. Controlling for factors often associated with HIV (i.e., gay/bisexual men, substance abuse), HIV prevalence is 1.8 times higher among the unemployed, and 2 to 10 times higher among homeless individuals [8]. Of concern is that young adults, age 20-24, who have the highest HIV infection rates than any other U.S. age group [9], make up an increasing proportion of the urban homeless and unemployed [10]. Roughly 5.2 million U.S. youth, aged 16-24, are currently out of school and out of work [5], and over 1.7 million are homeless each year [6]. Limited economic resources can create a short-term imperative among poor youth to engage in high-risk activities to support themselves, which can increase HIV risk [10]. For young women, this may include involvement in cross-generational and transactional sex to secure food or housing [11]. Poor young men may resort to theft and the illegal drug economy to earn income [12], which are linked to adverse consequences associated with HIV transmission (i.e., substance abuse, incarceration, partner violence) [13],[14]. Limited economic resources can also lead to a loss of hope and agency that diminish

motivations to avoid exposure to future HIV infection [10]. Yet, few HIV prevention interventions have explicitly focused on economic drivers of HIV in African-American high poverty, high HIV prevalence settings. Interventions that have focused on economic drivers of HIV have almost entirely been conducted in low-income countries [15],[16]. As a result, the absence of locally-tailored interventions for African-Americans has hindered efforts to address economic vulnerabilities associated with HIV in this population [1]. Given the role that poor African-American young adults play in the U.S. HIV epidemic, reducing risky sexual behaviors in this population by developing and testing interventions that decrease economic drivers of sexual risk-taking could potentially have a considerable impact [17].

Microenterprise development may reduce risky sexual behaviors by minimizing economic stressors of HIV and motivating self-protective sexual practices. According to asset theory, increases in productive assets (i.e., business, rental property, music, books) can influence individual behaviors (including health) by motivating protective attitudes to avoid negative consequences [18]. Such assets may also minimize economic constraints and stressors that lead to risky behaviors, including time spent in high-risk survival activities [19]. Recent literature has urged studying microenterprise (i.e., businesses operating on a very small scale) as a new asset-based intervention for HIV in the U.S, given that little is known or documented on the subject [20]. Microenterprise development refers to programs that expand one's capacity to start a small business through enhanced attitudes, skills, and resources [20]. Such programs provide business education, small-scale financial investments, and technical support [21]. In public health, microenterprise is more than income generation. It aims to reduce poverty-related morbidity and mortality by empowering the poor to make economic decisions that affect health and well-being [22]. In low-income countries, microenterprise and economic empowerment programs have combined HIV education and business training, microloans, and/or savings accounts (aged 14 to 24) to improve HIV communication [23], sexual risk-taking attitudes [15], condom use [24], HIV testing [25], and number of sex partners [26]. However, at-risk African-American youth are largely omitted from the few available studies [27].

Engaging high-risk African-American youth in microenterprise strategies may reduce economic drivers of HIV more effectively than traditional HIV education, employment, and cash incentive approaches. Our prior qualitative work with African-American HOUs showed that youth were highly interested in micro-enterprise interventions and saw themselves as entrepreneurs who lacked support to channel their interests towards improved health and well-being [28]. Traditional employment options were not considered as viable poverty alleviation strategies for many youth, who desired safe and licit alternatives to risky survival strategies [28]. Owning assets can give vulnerable youth a sense of stability and enable them to expand their vision of possible and healthier opportunities [28]. In addition, the evidence suggests that the effect of cash incentives on risk behaviors is mixed and often attenuated after incentives cease [29]. Increased skills and resources for at-risk youth engaged in microenterprise may offer more sustainable, self-perpetuated incentives that target economic stressors of HIV [30]. Such assets have been shown to influence sexual risk behaviors by motivating intention and esteem to avoid negative health consequences [15]. In addition, microenterprise extends beyond income generation and targets non-cognitive skills (i.e., industriousness, perseverance, persistence) associated with behavioral success to enhance safer-sex self-efficacy and employability in lieu of risky survival strategies [31].

Behavioral economics may further enhance the delivery of HIV microenterprise interventions by economic drivers of sexual risk-taking. Behavioral economics is a field at the intersection of psychology and economics that seeks to understand decision-making in contexts of time and resource constraint [30]. Behavioral economics has been used to understand and improve decision-making in drug adherence [32], addiction [33], and obesity [34]. In this RCT study, we will use text messages aimed at reducing sexual risk behaviors among African-American young adults which are based on the behavioral economic principles of delay discounting, loss aversion, and endowment effect. *Delay discounting* is how much one devalues a reward per its delay in time [35]. Text messages informed by delay discounting will encourage participants to place higher value on the current and future benefits of HIV preventive behaviors. *Loss aversion* holds that individuals weigh losses more heavily than gains [35]. Text messages informed by loss aversion will make more salient the costs and losses associated with sexual risk behaviors. *Endowment effect* is when possessing a good increases its subjective value [36]. Text messages informed by the endowment effect will facilitate

participant views regarding their sexual health as an asset worth protecting.

III. Study Design and Measures:

3.A. Provide an overview of your study design and methods. The study design must relate to your stated aims/objectives.

3.A.1. Study Design and Measures:

Forty (n=40) African-American HOU young adults, aged 18 to 24 years old, will be randomized to one of two study groups. The first group ("control") will receive text messages with information on job openings. The second group ("intervention") will receive text messages with information on job openings plus HIV prevention and business educational sessions, mentored apprenticeship, a start-up grant (provided in 6 payments), and HIV behavioral economics text messages. The study period will be 26 weeks, comprising 3 weeks of pre-intervention assessment, 20 weeks of active intervention assessment, and 3 weeks of post-intervention assessment. Using a recruitment flyer and script, participants will be recruited on-site from one of two participating community-based organizations (CBO) in Baltimore, MD (i.e., AIRS, Inc. and YO!Baltimore). Both CBOs provide supportive residential services to homeless and unstably housed youth in Baltimore City. Study eligibility will be determined using a screening tool, and written informed consent will be obtained from all eligible study participants.

- **Aim 1**: To examine the <u>feasibility</u> of implementing an enhanced microenterprise intervention to reduce sexual risk behaviors among African-American young adults who are homeless, out of school, and unemployed (HOU).
  - **Primary (*) and Secondary (**) Outcomes for Aim 1:**
    - % participants in both groups who have responded to 70% or more of the weekly text message surveys at week 26*
    - % participants in the intervention group who have completed 70% or more of intervention activities (i.e., text message receipt, session attendance, grant spending, and mentor contact) at week 23.*
    - % all participants who receive one or more informational text messages each week **
    - % all participants who respond to a text message survey each week **
    - % intervention participants who attend an educational session each week **
    - % intervention participants who receive one or more mentor contacts each week **
    - % intervention participants who spend one or more grant payments each week **
  - **How This Will Be Measured:**
    - Feasibility data for all participants relating to receipt of and response to weekly text message surveys will be obtained from the online text messaging platform.
    - Feasibility data for intervention participants relating to attendance to educational sessions, mentor contacts, and grant spending will be measured at the end of each educational session using a session checklist. These relate to assessing loss-to-follow and retention.
  - **Conclusion Standard:**
    - The study will be determined as being feasible if:
      - $\geq$ 70% of all participants (intervention and control) respond to > 70% weekly text messages surveys following randomization; and
      - $\geq$ 70% intervention participants complete $\geq$ 70% in-person intervention activities
- **Aim 2**: To examine the <u>preliminary efficacy</u> of the pilot microenterprise intervention in reducing sexual risk behaviors among African-American HOU young adults.
  - **Primary (*) and Secondary (**) Outcomes for Aim 2:**
    - % participants in each group who report one or more unprotected sex acts in the last week and last month *
    - % participants in each group who report one or more safer sex acts in the last week and last month **

        - % participants in each group who report one or more HIV prevention care-seeking or information-seeking acts in the last week and last month **
    - **How This Will Be Measured:**
        - Weekly sexual and HIV prevention-related behavioral data will be measured using the weekly text message survey.
        - Last month sexual and HIV prevention-related behavioral data will be measured using the baseline and endline in-person interviews using a structured questionnaire.
    - **Conclusion Standard:**
        - The study will follow the enclosed analysis plan at statistical significance of $p<0.05$

- **Aim 3**: To examine the preliminary efficacy of the pilot microenterprise intervention in improving economic outcomes among African-American HOU young adults.
    - **Primary (*) Outcomes for Aim 3:**
        - The mean number of paid hours work in a job or self-employment in the last week;* and
        - The mean amount of cash (U.S. dollars) earned from a job or self-employment in the last week*
    - **How This Will Be Measured:**
        - Weekly economic data will be measured using the weekly text message survey.
        - Last month economic data will be measured using the baseline and endline in-person interviews using a structured questionnaire.
    - **Conclusion Standard:**
        - The study will follow the enclosed analysis plan at statistical significance of $p<0.05$

Intervention Summary: Participants in the intervention group will receive text messages with information on job openings in Baltimore (=1 text/per week for 20 weeks) plus: (i) business educational sessions (=1 three-hour session/per week for 20 weeks) with integrated economics-based HIV prevention education, (ii) mentored apprenticeship, (iii) cash for starting a small business ($1,100/per participant), and (iv) text messages addressing the behavioral economics of HIV (=3 texts/per week for 20 weeks). Participants in the control group will receive the same text messages with information on job openings in Baltimore only (=1 text/per week for 20 weeks). As noted above, the study period is 26 weeks: =3 weeks of pre-intervention assessment + 20 weeks of active intervention assessment + 3 weeks of post-intervention assessment.

3.A.2. Run-In Study Design:

A 3-week run-in period will be used to minimize dropouts after randomization by enabling the study team to identify participants who are likely to respond to the research project. A run-in period is defined as "a period of time prior to enrollment during which study candidates are placed on a treatment similar to one being evaluated to assess tolerance or acceptance, or to provide information on treatment compliance" [38]. It is a participatory phase of a trial between enrollment and randomization that is used to determine participants' eligibility to continue in the trial [39]. Run-in periods are recommended for randomized controlled trials (RCT) in order "to exclude subjects who would likely be poor responders if randomized because of intervention intolerance, poor compliance, or uncooperative attitudes and behaviors" [38]. "These exclusions are intended to produce an enriched randomized sample with increased response probabilities and, thereby, increased statistical power" [38]. Ultimately, run-in requirements implemented are implemented as compliance-enhancing strategies that aim to strengthen the ability of the research project to estimate true treatment effects avoid compromise due to participants drop-out or who adhere poorly to the trial protocol [38, 39]. Participation in the run-in period also offers time for participants before randomization to change their minds about taking part in the research project based on short-term experience of the potential time and effort required [39]. Run-in periods reported in published RCTs have ranged from 2 to 10 weeks in time and have included behavioral run-ins related to study activities such as using a mobile phone app, attending a meeting or specific site, discontinuing drug therapies, or wearing a pedometer [40-43]. These studies reported excluded subsets based on run-in requirements ranging from 11% to 34% of the original pre-randomization enrollment size [40-43].

In the EMERGE Project, only participants who complete all 3 of the study's run-in requirements will be eligible for random assignment to one of the two study groups. The 3 run-in requirements are: (i) complete all of the first 3 weekly text message surveys (week 1 to week 3); (ii) email a minimum 150-word intelligible statement describing the type of small business they would like to start and why to the study's email address (emergeproject.jhsph@gmail.com) by the end of week 2; and (iii) attend (by invitation only) a 30-minute group meeting in week 3 on the day of and during the time period in which the intervention's educational sessions are expected to be held each week at the CBO center. The group meeting will review the study's upcoming activities, address any challenges relating to the study's text message surveys, and pay participants for text message survey completion. Snacks will be served. Invitation to the group meeting in week 3 will be based on successful completion of the prior 2 run-in requirements. These 3 behavioral run-in requirements were chosen in order to ensure short-term tolerability to the study's primary evaluation and intervention activities, which are: (i) response to weekly text message surveys for outcome measurement; (ii) attendance to intervention in-person meetings for treatment exposure, (iii) participation in non-meeting intervention assignments also related to treatment exposure, and (iv) demonstrated English language writing capacity necessary for intervention uptake [B]. Participants will be informed of the two study groups (i.e., intervention or control) and the 3 run-in requirements for group assignment prior to study enrollment during the process of informed consent (week 0). Random assignment to one of two study groups will occur after the 3rd run-in requirement of the group meeting in week 3. Participants will be notified of group assignment by text message in week 4. Participants who are randomly assigned to the control group will then begin receiving control group text messages on HIV prevention in week 4. Participants who are randomly assigned to the intervention group will then be invited to the intervention's first educational session in week 4 at the CBO center. They will also begin receiving in week 4 intervention text messages on HIV and behavioral economics.

The expected proportion of participants who are excluded from randomization by the run-in requirements is 30%. Enrolled participants who did not successfully complete all 3 run-in requirements and are therefore not eligible for random assignment may continue to participate in the weekly text message surveys and follow-up interviews or withdraw from the study. Information on the number and characteristics of run-in failures and study non-completion will be documented in order to inform analyses of differences between randomization-eligible and ineligible participants. Participants will receive payment for participation in all run-in study activities as described in .

A. Intervention Activities:

Enrolled participants will be block randomized with a ratio 1:1 to the intervention or control arm using a treatment sequence generated in STATA Version 14. The blocking factor will be the study site from which the participant is recruited.

Participants in the intervention group will receive:

1. **One (1) text message each week for 20 weeks on job openings**. These messages will include one web-link each week of a Baltimore-based employer that has an open job listing suitable for lower-skilled young adults.
2. **Twenty (20) small business education sessions.** One 3-hour session will be conducted each week for 20 weeks at the CBO center (9am to 12noon Thursday). The educational sessions will be conducted by the study PI and study manager. The 20 session topics are listed below. Six sessions focus on HIV prevention and are intended to integrate the economic-strengthening (i.e., small business start-up) and behavioral economics components of the intervention with HIV prevention. The sessions will aim: (i) to improve participant awareness of the effects of economic disadvantage on HIV at individual and community levels in young African-Americans in Baltimore; (ii) to empower participants to identify their financial goals and sexual health goals as it relates to protecting their perceived financial and sexual assets; and to improve communication and negotiation skills for adopting safer sexual practices with sex partners, including discussing perceived financial gains and losses of these practices; (iv) to

improve awareness of available HIV prevention technologies (i.e., PreP, ARVs, condoms, HIV testing) and the costs and rewards of accessing them; to identify ways that income and other financial assets can be spent or saved to reduce HIV risk through uptake of HIV preventive practices and services (HIV 4); to emphasize how *delay discounting* tendencies to prefer rewards immediately, such as condomless sex, over rewards available at some later time, such as avoiding HIV, can influence sexual risk behaviors; to make readily in-mind and more *salient information* on ways to reduce or remove triggers to unsafe sexual practices; to empower participants to account for individual economic costs of unsafe sex (such as disease burden, lower productivity) and losing good sexual health as it relates to individuals' *loss aversion* to forfeiting owned assets.

- Introduction to EMERGE …..……..…Session 1
- Introduction to Entrepreneurship……..……..Session 2
- Developing A Micro-Business Idea……Session 3
- Developing a Micro-Business Plan and Budget……..…Session 4
- Poverty and HIV in Baltimore (HIV 1)……...Session 5
- Safer Sex Communication and Practices (HIV 2) ……..…Session 6
- Working with a Business Mentor……..…..Session 7
- Micro-Business Registration and Launch…..…….……...Session 8
- Managing Personal and Business Finances..……..…Session 9
- Behavioral Economics and Sexual Risk-Taking (HIV 3)....Session 10
- Using Your Money to Prevent HIV (HIV 4)……...……Session 11
- Expanding Your Micro-Business……..……...Session 12
- Marketing and Managing Risk……..……Session 13
- Acquiring New Skills for Your Business……..……Session 14
- Accessing HIV Prevention Technologies (HIV 5)……..….Session 15
- Avoiding Costs of Unsafe Sex (HIV 6)…..……...Session 16
- Real Baltimore Business Owners: Questions Answered…...Session 17
- Group Presentations & Feedback……..……....Session 18
- Preparing for Small Business Taxes…..……..….Session 19
- Closing and Summary…….……...Session 20

NOTE: The PPT curriculum for several sessions has been uploaded to PHIRST as an example of the content. The remaining sessions are currently being finalized.

3. **One (1) micro-business mentored apprenticeship.** The apprenticeship will comprise of a participant working a minimum of 24 hours over a period of 3 weeks (=~ 8 hours/week) with a Baltimore-based small business owner in the micro-business area selected by the participant. The participant will be paid the State of Maryland minimum wage by the small business owner/employer. The EMERGE project will facilitate introducing participants to these mentors in weeks 4 to 7 of the active intervention phase. All mentors will be oriented by the study PI prior to intervention participation.

NOTE: Mentors will be invited to attend an EMERGE educational session to meet their mentees. The PI and study manager will match mentors and participants based on participants' outlining their interests during the run-in period and first intervention meeting. All EMERGE mentors will under-go a 2-hour training session at JHSPH led by the study PI. The training session will include an overview of the project aims, timeline, grant sums, and participant profiles as well as a review of best practices for mentoring young adults and procedures for providing study progress updates to the PI and study manager. During the training, mentors will also be informed how mentor honorariums ($100/each) will be administered via the JHU accounting process.

The mentors will be Baltimore-based small business owners who are oriented by the EMERGE study. Mentors are expected to attend 3 EMERGE educational sessions to talk about their business experience and provide feedback on participant business goals. Mentors are also expected to have advising contact with the

participant at least once every two weeks by text, phone, or in-person over the duration of the 20-week active intervention period. Mentors are also expected to hire the participant at the State of Maryland minimum wage to work a minimum of 24 hours over a period of 3 weeks (=~8 hours/week) during the active intervention period.

The selection criteria for mentors will be: (1) aged 25 and older; (2) currently lives in Baltimore metropolitan area; (3) owns a registered small business doing business in Baltimore metropolitan area; (4) speaks English; and (5) is willing to participate in the EMERGE Project over the 20-week intervention period. Mentors must meet all of the above selection criteria to be eligible. Based on requests from young adults during prior formative research (2016-2017), special preference will be given to mentors who additionally are one or more of the following: (i) African-American; (ii) from other minority racial/ethnic groups; (iii) began a small business as a young adult (aged 18 to 29); (iv) are native to Baltimore City; (v) are from a disadvantaged or lower socioeconomic family or community; and (vi) have prior experience or interest working with vulnerable youth in Baltimore City.

4. **One (1) micro-business start-up grant in the amount of one thousand one hundred U.S. dollars ($1,100 USD).** The grant (repayment not required) will be deposited into a participant-owned small business checking accounts in 6 installments ($100; $200; $200; $200; $200; and $200). The grants will be used for purchasing micro-business supplies, marketing, communication, and travel (such as in selling hand-made goods and services). Grant use will be carefully monitored. Intervention participants must meet all required intervention milestones to receive each of the six installments. These milestones will include: (i) attendance to all study educational sessions to-date, (ii) completion of all weekly text message surveys to-date, (iii) development of a study-approved business plan and budget which lists the expected use of funds, (iv) submission of all expense receipts for PI-approved business purchases to-date, (iv) and submission of all monthly business checking balances to-date. Receipts and business checking statements will be submitted by text message to the EMERGE *TextIt* phone number as an mobile-phone photo. Participants who do not meet the milestone requirements will not receive the next installment. All milestones must be met within the 20-week active intervention period. The expected installment timeline is at weeks 4, 8, 12, 14, 16, and 18 of the 20-week intervention period.
5. **Three (3) text messages each week for 26 weeks on micro-business and the behavioral economics of HIV.** These messages will reinforce information presented in the EMERGE project's 20 educational sessions described above, including the 7 HIV and behavioral economics integrated sessions.

Participants in the control group will receive:

1. **One (1) text message each week for 20 weeks on job openings only.** These messages will include one web-link each week of a Baltimore-based employer that has an open job listing suitable for lower-skilled young adults.

B. Research Activities:

1. Methods to Measure Feasibility

Feasibility data for all participants relating to receipt of and response to weekly text message surveys will be obtained from the online text messaging platform. Feasibility data for intervention participants relating to attendance to educational sessions, mentor contacts, and grant spending will be measured at the end of each educational session using an educational session checklist. As part of study record keeping, we will also track number of potential participants screened, number eligible, number enrolled, number randomized after meeting run-in requirements, and number lost to follow-up after randomization. These data will be obtained from the study's screening and enrollment forms, as well based on response rates to weekly text messages, educational session, and in-person interviews (see below).

2: Methods to Measure Sexual Risk/HIV-Related Behaviors

A. In-Person Interview:

Two in-person interviews will be conducted. The interviews will be administered to all participants by the study PI and study manager using a structured questionnaire at the time of study enrollment (week 1) and at the end of the study (week 26).

B. Weekly Text Message Surveys:

All study participants will be invited to respond to one weekly text message survey during weeks 1 to 26. The text message survey will consist of 16 questions with "yes/no" and "number of times" responses. The 16 text message questions will be: (1) number of non-marital and non-cohabitating (NMNC) sex partners; (2) frequency of sex without a condom and without HIV medications with NMNC sex partners, (3) receipt of any HIV medications such as ART or PreP, (4) condom use at last sex with a NMNC sex partner, (5) frequency of oral sex only with NMNC sex partner, (6) frequency of sex without alcohol or drugs with NMNC sex partner, (7) frequency of sex while using a lubricant with NMNC sex partner, (8) ever sex while high or drunk with NMNC sex partner, (9) receipt of HIV testing in last 3 months, (10) receipt of other STI testing in last 3 months, (11) discussion of HIV testing or status with any sex partner, (12) discussion of condoms or HIV medications with any sex partner, (13) acquiring condoms or lubricants for free, (14) purchasing condoms or lubricants with money, (15) number of paid hours worked in job or self-employment in last 7 days, and (16) amount of cash (USD) earned from job or self-employment in last 7 days. We will use *TextIt* to create, push to, and receive text messages from study participants. *TextIt* is an online service for building SMS text-messaging applications. It is designed to help people who are not programmers create and modify SMS applications using the visual, interactive flow engine. The text-message campaign will be powered by a *Twillio* cloud communications platform for intervention text messaging, using the study-sponsored mobile phone number: +1 443-991-8680.

NOTE: Copies of the data collection instrument, including the recruit, screening, interview questionnaire, and text message survey are uploaded to JHSPH PHIRST online.

3.B. Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

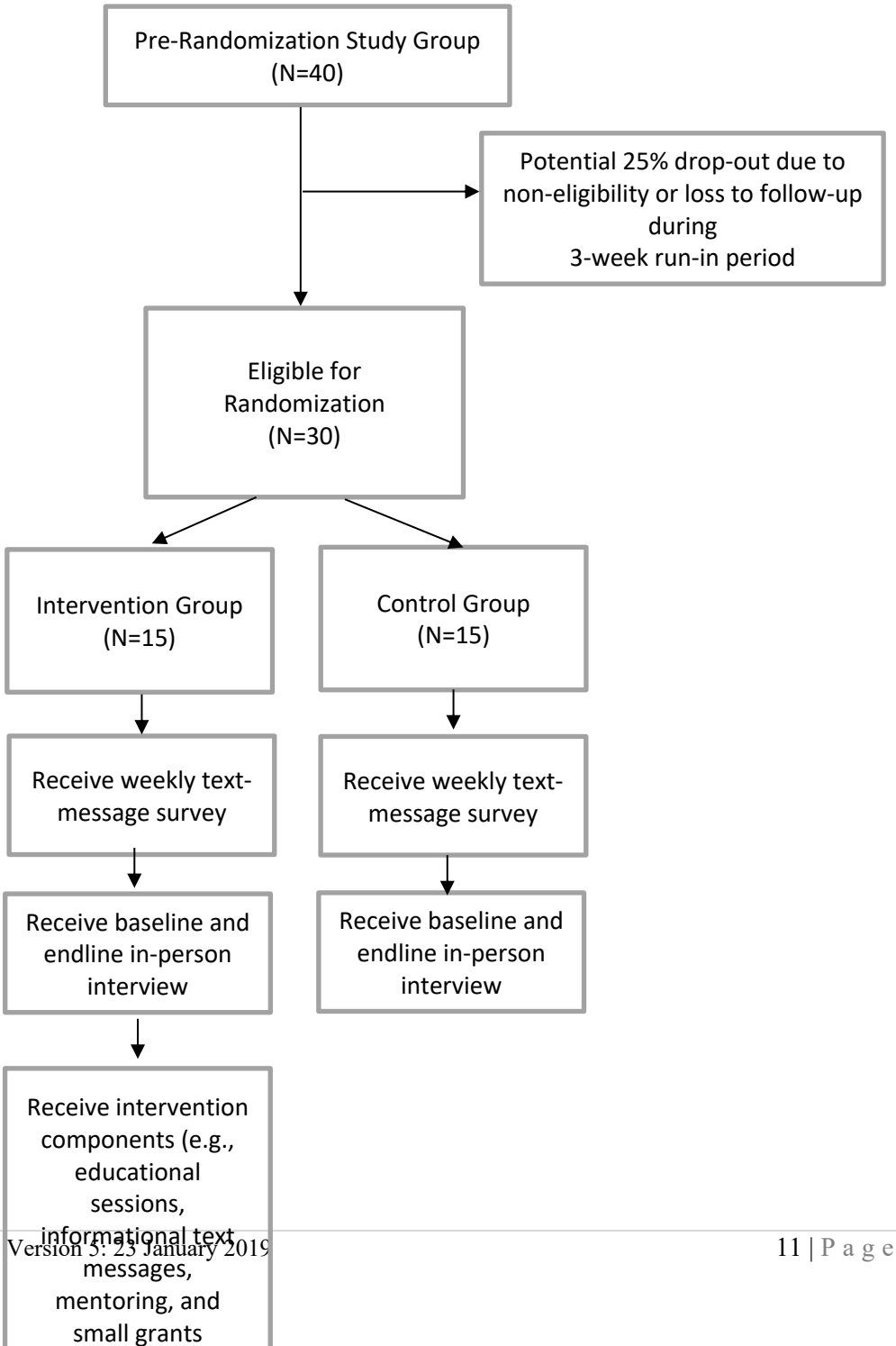
A power calculation to estimate sample size is not appropriate for a feasibility trial because the aim of the trial is not to establish efficacy. Instead, we determined that a minimum sample of 30 participants (15 in each group) would generate sufficient data to assess feasibility. This was determined with reference to good practice recommendations for feasibility studies, which recommend sample sizes of between 24 and 50 [44-46]. A maximum number of 40 African-American HOU young adults will be enrolled in the study and undergo the initial 3-week run-in period. We expect that 75% of the 40 enrolled participants (n=30) will have completed all 3 behavioral run-in requirements (see Section 3.A.2. "Run-In Study Design") and not be loss to follow-up at the end of week 3 in order to be randomized to intervention or control. Table 1 outlines the target sample size for the pilot RCT and the maximum study sample size pre- and post-randomization. Although we do not expect it, if the number of enrolled participants who are eligible for randomization is 40, all participants will be randomized to the RCT (20 participants per group). As appropriate for pilot studies, this study intends to inform the feasibility and effect sizes for designing our future R01 trial and thus is not explicitly powered to assess statistical significance. To achieve the target pre-randomization enrollment number of 40 participants, we expect to screen 60 potential young adults. The expected duration of data collection is 26 weeks from November 2018 to May 2019.

Table 1: Sample size distribution by study week, group, and total

Study Week	Study Group	CBO Sample Size		Total Sample Size
		AIRS	YO! Baltimore	
1	Maximum Pre-Randomization Enrollment Group	20	20	40

1 to 3	Randomization-Ineligible Group at End of Run-In *(based on potential 25% drop-out)*	5	5	10
3	Randomization-Eligible Group at End of Run-In	15	15	30
4 to 26	Randomized to Intervention	7	8	15
4 to 26	Randomized to Control	8	7	15
	Total Enrolled in RCT Trial	15	15	30

Figure 1: Flow Chart of Two Study Arms



3.C. Formative Work

Considerable formative research has been conducted as follows:

[1] The PI has published 3 first-author manuscripts relating to results from formative work in preparation for the proposed study. These 3 first-author manuscripts are:

- Jennings L, Lee N, Shore D, Strohminger N, Burgundi A, Conserve DF*, Cheskin LJ. U.S. minority homeless youth's access to and use of mobile phones: implications for mHealth intervention design. Journal of Health Communication 2016; Jul; 21(7):725-33. doi: 10.1080/10810730.2015.1103331.
- Jennings L, Shore D, Strohminger N, Burgundi A. Entrepreneurial development for U.S. minority homeless youth: a qualitative inquiry on value, barriers, and impact on health. Children and Youth Services Review 2015; Feb; 49: 39-47. doi:10.1016/j.childyouth.2014.12.018
- Jennings L. Do men need empowering too? A systematic review of entrepreneurial education and microenterprise development on health disparities among inner-city black male youth. Journal of Urban Health 2014; Oct; 91(5): 836-50. doi: 10.1007/s11524-014-9898-z.

[**2] These manuscripts led to and were based on the PI's JHSPH IRB-approved study (IRB 00004729), archived in PHIRST in June 2016.**

[3] Summary findings from this work showed that:

I worked closely with two CBOs who provided supportive and residential services to HOU youth in Baltimore and Washington, D.C. for approximately two years (2012-2014). We found that 90.2% of HOUs lacked full-time employment (n=41, aged 15-24), 29.3% reported ever trading sex, 90.2% knew at least one HOU peer who had ever traded sex, and 41.5% did not use a condom at last sex. Mobile phone coverage was high (78%) with high (93.8%) text message service via "text-for-free apps". Mean duration of keeping a phone (before switching) was 14.8 months. Many had a free back-up phone through federal benefits. Only 9.8% had ever received business training. The top 3 topics of interest for receiving texts and support were: income generation (93%), motivational messages ("don't give up") (81%), and HIV prevention (71%). We also found in our qualitative research: (n= 52, aged 15-24) that HOUs showed high interest in microenterprise and saw themselves as entrepreneurs lacking support to channel their interests towards improved health and licit alternatives to risky survival strategies. These findings are summarized in Jennings 2015 (cited above).

[4] Further formative data (2017):

After publishing the 3 above first-author manuscripts, the PI additionally conducted 1 primary-data formative research study approved by the JHSPH IRB, which was completed in January 2018 (IRB 00007563). The PI is currently preparing this findings to submit for manuscript publication. The goal of this study was to pilot the weekly text message survey and determine HIV-related behavioral economic and business preferences of African-American HOUs.

[5] Preliminary findings from this study (2017) show that:

I have continued wot work closely with the two CBOSs (2016-2017). We have found that participants are willing to respond to the weekly text message survey. The average response rate each week was 73% (8 out of 11 active participants). The average number of questions responded to was 9, ranging from 6 to 14, among active participants. On average, participants responded within 11 hours of the survey sent time. The text message survey was tested for 5 weeks (April to May 2017). We also conducted 40 qualitative interviews with African-American HOU young adults, aged 18-24, from March to July 2017. Youth responses to sexual discounting tasks yielded mixed results with some (dis)favoring delay for condom use and others foregoing sex altogether. Some exhibited greater difficulty in selecting delayed monetary rewards. Several youth perceived

that their peers were more likely to have unprotected sex in next 2 weeks than themselves. Youth also reported engaging in several sexual risk behaviors with few perceived gains in HIV risk or economic costs. We are integrating these findings in the text message and educational session curricula.

IV. Participants

Describe the study participants and the population from which they will be/were drawn. If you plan to include children, note their ages and whether you will include children in foster care. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

This study will enroll African-American young adults, aged 18-24, who are homeless, out-of-school, and unemployed (HOU) in Baltimore, MD. The study specifically targets individuals behaviorally, economically, and geographically at high risk for HIV.

The specific inclusion and exclusion criteria for participants are as follows:

4.A. Inclusion Criteria at Study Enrollment

Individuals will be included in the study if, at the time of enrollment, they are: African American, aged 18-24, living in Baltimore City, lacking a fixed and adequate nighttime residence, unemployed or underemployed (< 10 hours per week), out of school, has access to text-messaging mobile phone; and reporting at least one episode of unprotected sex in prior 12 months and at least one episode of unsafe sex in the prior 12 months through a personal or sexual partner HIV risk factor (i.e., multiple sexual partners, sex while high/drunk, etc.).

All of these criteria must be met for study eligibility.

4.B. Exclusion Criteria at Study Enrollment

Children aged 17 or younger will be excluded given that a separate age-specific study would be warranted and preferred. In addition, the research intervention on the relationship between sexual behaviors and economic factors is not relevant for children. Potential participants who are aged 25 or older, not currently a high-risk HOU, not African-American, not living in Baltimore, and without access to a text-messaging mobile phone. Participants who lack the capacity to provide informed consent or undergo study activities will also be excluded.

4.C. Inclusion and Exclusion Criteria for Randomization at 3 Weeks Post-Study Enrollment:

NOTE: The randomization eligibility criteria are detailed also in Section 3.A.2. “Run-In Study Design”.

Individuals will be eligible for randomization to one of two study groups (i.e., intervention or control) if, by the 3rd week of study enrollment they have complete all 3 of the study’s run-in requirements. The 3 run-in requirements are: (i) complete all of the first 3 weekly text message surveys; (ii) email a minimum 150-word intelligible statement describing the type of small business they would like to start and why to the study’s email address (emergeproject.jhsph@gmail.com) by the end of week 2; and (iii) attend (by invitation only) a 30-minute group meeting in week 3 at the CBO center. Invitation to the group meeting in week 3 will be based on successful completion of the prior 2 run-in requirements.

All of these criteria must be met for randomization eligibility.

V. Study Procedures

In this section, provide details of your procedures, particularly as they relate to human subjects.

5.A. <u>Recruitment Process</u>:

5.A.1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.

An in-person recruitment script will be provided to designated AIRS/YO!Baltimore points-of-contact to introduce potential study participants to the study and refer them to the researchers on scheduled study visit days. On those scheduled days, interested potential participants will be referred to meet with the study team in a designated private room at the AIRS/YO!Baltimore center. The researchers will use in-person contact to describe the study and invite young adults to participate through screening and written informed consent.

AIRS/YO!Baltimore staff who are part of the recruitment process will be oriented prior to the start of data collection. The orientation will consist of a 1-hour session led by the PI to review the study's introduction process, including the research purpose, recruitment script, eligibility criteria, intervention activities, and evaluation approach. The orientation will also summarize ethics for human subjects research using the JHSPH IRB field guide. Based on the orientation, designated AIRS/YO!Baltimore staff will introduce the study using the recruitment script – providing information on the study's purpose, collaborating organizations, eligibility criteria, participant activities, and compensation. An optional recruitment flyer may also be posted on the bulletin board of the AIRS/YO!Baltimore centers.

CBO staff will be trained to introduce the study using the recruitment script regarding a JHSPH study that support sexual health and business/employment goals. They will be advised not to refer publicly, such that others can overhear, any eligibility pertaining to sexual risk engagement. All participants at the CBO are unstably housed and under-/un-employed. Therefore, this will not single-out any potential individual participant

5.A.2. Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

The study team anticipate few privacy issues associated with recruitment given that recruitment itself will not put potential participants at risk. We are also contacting potential participants in a youth-friendly community center in which they are affiliated. Because these centers provide housing support services to youth and young adults, their housing status is already identified within the community center's patrons. Thus, being associated with homelessness or unstable housing, as well as experiencing financial disadvantage leading to or resulting from homelessness is not considered a privacy concern for this study.

However, personal questions will be asked as part of the screening process to determine eligibility for the study. Therefore, some privacy risks may be associated with screening, which is part of the larger recruitment and enrollment process of the study. To address this privacy risk, the following tasks will be implemented:

1. Informing participants prior to starting screening that sensitive questions will be asked.
2. Informing participants that screening responses will be kept confidential and that screening will be stopped as soon as they provide an ineligible response, so as to minimize undue risk.

5. B.Consent Process:

5.B.1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.

a. Who will obtain informed consent, and their qualification(s):

Informed consent will be obtained by the study PI or the study manager.

b. How, where, and when the consent discussion(s) will occur:

Consent discussions will occur on-site in a private room at the AIRS/YO!Baltimore centers. Copies of the informed consent documents are uploaded in the JHU PHIRST online portal. A written informed consent process will be used. The PI or the study manager will read the consent script in English, query the potential participant for understanding, and invite him/her to ask questions for further clarification. If the potential participant agrees to participant in the study, the PI or the study manager will obtain his/her signature and concurrently sign the consent script. The participant will also be given a copy of the consent script.

The written informed consent process will obtain personal identifiable information by way of the participant's signature and their mobile telephone number which is needed to receive text messages and be contacted for study follow-up interviews. As part of the informed consent process, the potential participant will be informed of the invitation:

1. To participate in a total of three (n=3) in-person interviews at weeks 1, 13, and 26, respectively;
2. To participate in one weekly text message surveys from weeks 1 to 26.
3. To be randomized to receive an intervention in one of two study groups: (a) **one study group** that will receive text messages with information on job openings in Baltimore (=1 text/per week for 20 weeks) plus: (i) business educational sessions (=1 three-hour session/per week for 20 weeks) with HIV prevention education, (ii) an employer-paid apprenticeship for a minimum of 24 hours over 3 weeks, (iii) cash for starting a small business ($1,100/per participant), and (iv) text messages on HIV prevention (=3 texts/per week for 20 weeks) or (b) **or another study group** that will receive text messages with information on job openings in Baltimore only (=1 text/per week for 20 weeks) – if they complete three "run-in tasks" within the first 3 weeks of the study.
4. To complete the three run-tasks for randomization to a study group which are: (i) responding to the first 3 text message surveys; (ii) emailing a business interest statement; and (iii) attending a group orientation meeting.

If the participate provides consent to enroll in the study, we will additionally conduct a 20-minute orientation session that consists of the following: (i) registration of the participant's mobile phone number to the EMERGE text message platform (5 minutes); (ii) walk-through of receiving and responding to the 16 text message questions to be received each week (10 minutes); and (iii) suggest ways to maximize privacy when using text messaging technology, such as deleting text messages once received or responded to, using their phone in a private location, and enabling the password protection function (5 minutes).

To maintain post-randomization retention (>85%), enrolled participants will also be asked to provide thee following information for locator purposes only: (i) a personal email address or 2nd mobile phone numbers; and (ii) the name and phone number of one adult contact. This information will be stored on a locator form accessible only to the study PI and study manager. If the participant cannot be reached, the study PI or study manager will then call and/or email the participant, call the provided contact(s), and/or inquire among CBO staff where the participant was recruited. All participant locator forms will be stored in a key-locked file cabinet in the JHSPH research office also accessible solely by key, and used only for participant locator purposes.

Given that homeless or unstably housed individuals are a vulnerable population, special attention will be given to ensure their understanding and voluntary participation. Extra time will be taken to explain the research and intervention activities to them, review study processes, and make certain that all risks and benefits of participation are clear to them. The study will also further explain that their participation is voluntary and that all data collected will be kept confidential. All potential participants will also be given an opportunity to ask questions, and no data collection will commence until his/her questions have been answered satisfactorily.

c. The process you will use to determine whether a potential participant meets eligibility criteria: A short screening process will precede study enrollment and occur prior to the administration of informed consent. The screening process is anticipated to take no more than 6 to 8 minutes to complete and will be administered by the

PI or study manager. The proposed screening tool is uploaded in the JHU PHIRST online portal. It will ask 9 questions regarding whether the potential participant is: (i) between the ages of 18 and 24; (ii) living in Baltimore; (iii) African-American; (iv) homeless or unstably housed; (v) out of school; (vi) unemployed or employed less than 10 hours per week; (vii) engaged in sex without a condom and without use any HIV preventive medications in last 12 months; (viii) engaged in at least one other personal or partner sexual risk factor; and (ix) has access to a mobile phone with text-messaging capacity. Eligibility will be based on meeting all 9 criteria, confirmed by self-report.

At the beginning of the screening process, potential participants will be informed of the expected time required to conduct the screening (about 6 to 8 minutes) as well as the nature and sensitivity of the questions to be asked. They will then be asked if they would like continue with screening. All screening tools will be retained and tabulated to document the characteristics of those who were pre-screened for the study, but did not actually meet eligibility requirements or decided not to enroll. This will also provide information on the full sample of individuals who asked about the study or were potentially eligible for participation. No identifiable information will be recorded during the screening process. Only a unique study identification number will be used. To achieve the target pre-randomization enrollment sample size of 114 participants, approximately 130 individuals will be screened for eligibility.

d. Whether you will obtain a signature from the participant or will use an oral consent process:
The study will obtain a signature from the participant as part of a written informed consent process.

e. Whether you will obtain a legally authorized representative's signature for adults lacking capacity:
No. The study will not enroll young adults lacking capacity to provide informed consent for participation in the study.

f. If children are included in the study, if and how you will obtain assent from them:
No. Children will not be included in the study. Children aged 17 or younger will be excluded from the study given that a separate age-specific study would be warranted and preferred. In addition, the research topic on the relationship between sexual behaviors and economic factors is not relevant for children.

g. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision):
Not applicable. Children will not be included in the study.

h. If you are seeking a waiver of informed consent or assent, the justification for this request:
The study team is not seeking a waiver of signed informed consent.

i. Whether you will include a witness to the consent process and why:
No. A witness to the informed consent process will not be used as the study will not enroll young adults lacking capacity to provide informed consent for participation in the study.

j. If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials:
Not applicable. The language used in the informed consent process is written.

5.B.2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Table 2: Consent Document Location and Language

Country	Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)	Languages
United States	Written Adult Consent	English

5.C.Study Implementation:

5.C.1. Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate.

Participant research and intervention procedures are summarized in Table 3 (next page).

(a) Research Procedures – For Intervention and Control Arms: The research procedures that all study participants (i.e., intervention and control arms) will undergo is described as follows. All participants will undergo a total of three (n=3) in-person interviews led by the study PI or study manager. One interview will be conducted at weeks 1, 13, and 26, respectively. The time required to complete the in-person interview will be approximately 60 to 90 minutes. Participants will also undergo one (n=1) weekly text message survey over the 26-week study period, for a total of 26 text message surveys. The text message survey will be identical each week and consist of 16 questions with yes/no or # of times responses. The time required to complete one text-messaged survey will be approximately 5 minutes. The 16-question text message survey will represent one text message contact each week. The 16 text message questions will be:

- *N=14 HIV behavioral outcomes*
    - number of non-marital and non-cohabitating (NMNC) sex partners (*)
    - frequency of sex without a condom and without HIV medications with NMNC sex partners (*)
    - receipt of any HIV medications such as ART or PreP (*, ***)
    - condom use at last sex with a NMNC sex partner(*)
    - frequency of oral sex only with NMNC sex partner (**)
    - frequency of sex without alcohol or drugs with NMNC sex partner (**)
    - frequency of sex while using a lubricant with NMNC sex partner (**)
    - ever sex while high or drunk with NMNC sex partner (**)
    - receipt of HIV testing in last 3 months (***)
    - receipt of other STI testing in last 3 months (***)
    - discussion of HIV testing or status with any sex partner (***)
    - discussion of condoms or HIV medications with any sex partner (***)
    - acquiring condoms or lubricants for free (***)
    - purchasing condoms or lubricants with money (***)
- *N=2 Economic outcomes*
    - number of paid hours worked in job or self-employment in last 7 days
    - amount of cash (USD) earned from job or self-employment in last 7 days

(b) Intervention Procedures – For Intervention Arm Only:

The intervention procedures that only participants in the intervention arm will undergo are summarized as follows:(i) 20 weekly business educational sessions with integrated economics-based HIV prevention education each lasting 3 hours; (ii) participation in an employer-paid mentored apprenticeship for a minimum of 24 hours over the course of 3 weeks; (iii) use of a micro-business start-up grant ($1,100/per participant); (iv) receipt of 3x/weekly HIV prevention text messages for 20 weeks; and (v) receipt of 1x/weekly text message with information on job openings in Baltimore for 20 weeks.

(b) Intervention Procedures – For Control Arm Only:

Participants in the control arm will only receive 1x/weekly text message with information on job openings in Baltimore for 20 weeks. They will not receive any other intervention activities.

NOTE: **A draft of the in-person questionnaire and the weekly text message survey (with available response codes) is uploaded to JHU PHIRST online.

Table 3: Summary of Research and Intervention Procedures

	Evaluation Activities			Intervention Activities				
	Baseline In-Person Interview	Endline In-Person Interview	1x/weekly Text Message Surveys	1x/weekly Business and HIV Educational Sessions (3hrs/session)	3x/weekly HIV prevention text messages	Employer-paid apprentice-ship (24 hours over 3 weeks)	Start-Up Grant ($1,100)	1x/weekly job openings text message
Week	1	26	1 to 26	4 to 23	4 to 23	12 to15	4 to 23	4 to 23
Intervention Arm	**x**	**X**	**x**	**x**	**x**	**x**	**x**	**x**
Control Arm	**x**	**X**	**x**					**x**
# Study Visits and/or Contacts	1	1	26	20	60	1	Payable to by check or gift card	26
Total Cumulative Time Required	1.5 hours	1 hour	2.2 hours	60 hours	N/A	24 hours	N/A	N/A

5.C.2. Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place.

Participant contacts are summarized in Table 3 (above).

(a) For Research (Evaluation) Activities for All Participants: There will be one in-person study contact concurrent with the time of the study enrollment (i.e., baseline interview). The expected total time for study contact will be 90 minutes in which the participant undergoes screening (=~5 minutes), informed consent (=~5 minutes), study enrollment (=~ 20 minutes), which consists of registration and orientation to the text message survey cycle, and conduct of the baseline (week 1) in-person interview (=~60 minutes). This initial study contact will take place on-site at one of the participating CBOs (AIRS/YO!Baltimore) youth centers.

After the initial study contact, there will be an additional two in-person study contacts, also at the AIRS/YO!Baltimore youth centers in which the participants will undergo an endline (week 26) in-person interview, will be approximately 60 minutes total. All participants (i.e., intervention and control) will also receive one text message contact each week for a maximum of 26 weeks, representing 26 total text messaged survey study contacts. The participant is expected to spend a maximum of 5 minutes per week (i.e., a total of 130 minutes, equivalent to 2.2 hours, over 26 weeks) reading and responding to the study's text message survey.

(b) For Intervention "Non-Research" Activities for Participants in Intervention Arm Only:

The intervention procedures that only participants in the intervention arm will undergo are summarized as follows. All intervention arm participants will under-go (a) 20 contacts during weekly educational sessions each lasting 3 hours, (b) engagement in a micro-business start-up with study grants, (c) receipt of 3x/weekly HIV prevention text messages for 20 weeks (=60 text message contacts) and 1x/weekly job openings text message for 20 weeks (=20 text message contacts); and (d) participation in an employer-paid mentored apprenticeship for a minimum of 24 hours over the course of 3 weeks.

(b) Intervention "Non-Research" Activities for Participants in the Control Arm Only:

Participants in the control arm will receive only 1x/weekly text message with information on job openings in Baltimore for 20 weeks (=20 text message contacts). They will not receive any other intervention activities.

5.C.3. Describe the expected duration of the study from the perspective of the individual participant and duration overall.

The expected duration of the study from the perspective of the individual participant will be 26 weeks with a total of 340 in-person minutes (=5.7 hours). This represents up to 90 minutes (=1.5 hours) on the day of study enrollment to complete the baseline interview, text messaging registration, and orientation, and 60 minutes (=1 hour) for the endline interview. From the perspective of the individual participant, s/he will also undergo a total of 130 minutes of text message contact (=2.2 hours) over the span of 26 weeks in responding to the weekly text-messaged survey (up to 5 minutes each). From the perspective of the research team, the expected duration of the study will be 12 months (i.e., October 2018 to September 2019): 1 month of preparation; 6 months of recruitment and data collection; 3 months of data analysis; and 2 months of writing and disseminating study results.

Given the information above, the time burden:

- For participants in the intervention group will be: 1.5 hours (baseline interview) + 1.0 hour (endline interview) + 2.2 hours (weekly text message survey)
- For participants in the control group will be: 1.5 hours (baseline interview) + 1.0 hour (endline interview) + 2.2 hours (weekly text message survey) = 4.7 hours total over 26 weeks, equivalent to 10.8 minutes per week for 26 weeks

5.C.4. Provide a brief data analysis plan and a description of variables to be derived.

Data for analyzing the study's primary feasibility and behavioral/economic outcomes will be collected via the in-person interviews at 2 time points (baseline and endline) and via the weekly text message survey at 26 time points (baseline to endline). Repeated, longitudinal data obtained from text message surveys will provide a more robust measure of changes in sexual and economic behaviors as a result of the intervention over time, as compared to traditional in-person interviews. If sufficient mobile data are obtained, we will analyze outcomes in STATA in three stages. First, we will partition the study period into exposure periods: before intervention start (pre-exposure), during the intervention (exposure), and following the cessation of the intervention (post-exposure). We will also examine any missing data patterns and, if needed, perform different analyses for data not missing at random. Two, we will estimate differences in the level and trend of weekly sexual risk behaviors and economic outcomes between the intervention and control arms over time. Third, we will estimate the level and trends in sexual risk behaviors and economic outcomes in the post-exposure period relative to the pre-exposure and exposure periods to assess sustainability. The model will be:

$Y_{ij} \mid \mu_i = \beta_0 + \beta_1*(week_i) + \beta_2*(study\ group_i) + \beta_3*(week_i*study\ group_i) + \mu_{0i} + \mu_{1i}*(week) + \varepsilon_{ij}$, where $\varepsilon_{ij} \sim N(0,\sigma^2)$, Y_{ij} is the outcome for the *i*th individual at week *j*, μ_{0i} is the subject-specific random intercept, μ_{1i} is the subject-specific random slope, $week_i$ is the time within-units factor. Change in slopes by exposure period will be analyzed using linear splines. If text message surveys are found not be a reliable or feasible method for measuring study outcomes over time, we will apply this analysis plan using the in-person interview data only and report process measures relating to feasibility, reporting, and non-reporting.

$$\begin{pmatrix}\mu_{0i}\\ \mu_{1i}\end{pmatrix} \sim N\left[\begin{pmatrix}0\\ 0\end{pmatrix}, \begin{pmatrix}\tau^2_0 & \tau_{01}\\ \tau_{01} & \tau^2_1\end{pmatrix}\right]$$

VI. Data Security and Confidentiality Protections:

6.A. Personally Identifiable Information (PII):

Please identify the Personally Identifiable Information (PII) that you may be collecting and using at any of the following stages of your study: Recruitment (R), Consent (C), and Study Implementation (S).

No personally identifiable information (PII) will be collected during the recruitment stage of the study. During the consent stage of the study, a written signature on a paper consent form will be collected as PII. During study implementation, a study enrollment form will obtain participants' names and cell phone numbers to send and receive study text messages and contact individuals regarding a follow-up in-person interview. During study implementation, a locator form will obtain a participant's email address or secondary cell phone number and the name and phone number of one adult contact. The participant locator form will be accessible only to the study PI. If a participant cannot be reached during the study period, the study PI or study manager will then call and/or email the participant, call and/or email the provided adult contact, and/or inquire among CBO staff where the participant was recruited. No other PII will be collected during consent or study implementation.

Table 1: Listing of PII Collected as Part of Study

Name, signature, initials, or other identifiable code	**C, S**
Geographic identifier: address, GPS location, etc.	None
Dates: birth, death, clinical service, discharge, etc.	None
Contact information: phone numbers, email address, etc.	**S**
ID: Social Security Number, driver's license number, etc.	None
Health record identifiers: medical record, insurance plan number, etc.	None
Account numbers	None
Device identifiers: e.g., implants	None
Internet identifiers: IP address, social media accounts	None
Biometric identifiers, including finger and voice prints	None
Audio recordings	None
Video or full face photographic images	None
Genomic/genetic data	None
Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data)	None
Other: Click here to enter text.	None

6.B. Recruitment:

Will you collect identifiers for the purpose of contacting potential participants?

No identifiers will be collected for the purpose of contacting potential participants.

6.C. Data Collection

In what form will you collect and store PII? When you respond, think of PII collected for recruitment, consent, and other study purposes.

6.C.1. Hard Copy/Paper: Yes X No ☐

If yes, please answer the following:

a. **How will the data be kept secure during transfer from study collection site to storage site?** The paper informed consent and locator forms will be returned to a locked file cabinet accessible only to the study PI at the JHSPH Wolfe Street Building on the day of study enrollment.

b. **Will the data be secured in a locked cabinet or room?Yes X No ☐**

c. **Are the data collection forms and study data stored without personal identifiers and separate from the study IDs/code? Yes X No ☐**

d. **How long after study completion will you keep the hard copy/paper forms?** The paper consent forms will be kept until two years after the end of data collection.

6.C.2. Electronic: Yes ☐ No X

6.C.3. Audiotape: Yes ☐ No X

6.C.4. Photograph/Video: Yes ☐ No X

6.D. PII De-Identification of Data Used for this Study:

When will you destroy the PII and/or the code linking the PII with the study ID?

The PII, the code linking the PII with the study ID, all paper materials, including paper informed consent forms will be destroyed two years following the end of data collection by use of an automated paper shredding device.

6.E. Data Storage and Analysis:

One of the keys to protecting PII is the proper use of tools to share and conduct your analysis. JH and JHSPH offer several options for you to consider. Please select the system that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed.

_____ **JH Virtual Desktop: IT@JH provides (for a monthly fee) a virtual Windows desktop.**

_____ **JHSPH SharePoint and File Shares: These systems provide a managed and secure platform for your research project. They also provide a built-in encrypted backup solution.**

_____ **JHSPH RedCAP or HPCC: These are departmentally managed applications.**

__X__ **JHBox: Johns Hopkins Box (JHBox) is a secure cloud-based file sharing & storage service.**

_____ **Independent Departmental Servers and Systems: These servers are typically managed by departmental or research team IT staff.**

_____ **Other: Please provide details regarding any other systems being utilized.**

6.F. Other Data Security Measures:

In addition to the details regarding data collection, please review the following questions. This additional information will be utilized to assist in the development of a comprehensive Data Security plan. This would include the systems used to analyze the data, data security contacts, and additional requirements.

1. **Do you have a designated person on your research team other than the PI who is the technical contact for a Data Security plan?Yes ☐ No** X
2. **Does your sponsor have other specific data security requirements for the study data? Yes ☐ No** X

6.G. Certificate of Confidentiality:

Will the study data stored in the United States be protected by a Certificate of Confidentiality? No

6.H. Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?

Yes ☐ No X

VII: Risks of the Study

7.A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

While we anticipate that risks to participants will be minimal, the primary potential risks associated with study participation are: (1) participant discomfort in discussing and reporting sensitive behaviors; (2) breach of confidentiality regarding sensitive behaviors; and (3) potential inconvenience related to the time required to participate in the study. These risks are described in the informed consent document. A copy of the informed consent form is uploaded to the JHU PHIRST online.

A description of these potential risks is as follows:

(i) Participant discomfort in discussing and reporting sensitive behaviors: Participants will complete interviews and text message surveys regarding sexual risk behaviors and other sensitive behaviors (i.e., economic activity). These topics may be considered sensitive by some participants, and a few may feel the psychological risk of invasion of privacy, discomfort, or anxiety in discussing and reporting on their personal behaviors. We discuss efforts to minimize these risks in Section 7.C.

(ii) Breach of confidentiality regarding sensitive behaviors: Participants may have concerns about how answering interview questions or using the text message platform may result in inadvertent disclosure of sensitive information, such as financial hardship or sexual behaviors. Such a breach could pose emotional and social risks associated with being viewed negatively by peers, community members, or authorities. We expect that the likelihood of a breach to be very small given the procedures that we will set in place to safeguard data and participant confidentiality, as described in Section 7.C

(iii) Inconvenience related to the time required to participate in the study: Participants may experience some inconvenience or fatigue related to the time spent participating in study intervention activities and evaluation activities (i.e., interviews and text message surveys) during the study period. We have designed the study to reduce any burden to the participant. These efforts are described in Section 7.C

7.B. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?

The anticipated frequency of the risks identified above is low given the safeguards described in Section 7.C. Therefore, for an individual who is participating in the study, we anticipate an adverse occurrence (related to the risks above) to occur no more than one time out of 150 (about 0.7%). If such an adverse occurrence were to happen, we expect that it would not be severe given that unfortunately financial hardship and sexual risk-taking are normative among young adults in many U.S. urban communities.

7.C. Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it.

The following steps will be taken to minimize each of the risks described above. A description of efforts to arrange for care or referral for participants who may need it is described in the last paragraph of this section.

(i) Participant discomfort in sensitive behaviors:

As part of the process of obtaining informed consent, we will explain and iterate to participants their right to decline participation in the study, start and then stop an interview, skip a question or opt-out of the text message survey, and/or start and then stop any of the intervention activities at any time during the study. During informed consent, we will also attempt to minimize potential participant discomfort by clearly communicating the study purpose and what the participant should expect to happen if s/he enrolls into the study. We will also explain the process of randomization and the potential for participants to be assigned to one of two study groups, including the run-in criteria for being eligible for randomization. The study PI and study manager have experience exercising non-judgmental and active listening, confidentiality, and building rapport to minimize discomfort for study participants. All study activities will also take place in an audibly private area at the AIRS/YO!Baltimore CBO centers, where the participant will be familiar and comfortable, but wherein others cannot overhear the responses.

(ii) Breach of confidentiality regarding sensitive behaviors:

Participant confidentiality is of utmost importance to the study. All interviews will be conducted in a place where privacy is ensured. Participants will be informed that their names will not be linked with any responses shared. All study documents will also be key-locked in file cabinets in the JHSPH research office or stored on password-protected computers to which only the minimal number of study staff necessary will have access. Furthermore, we will develop a system that prevents linking of sensitive information (i.e., sexual behaviors) to participants' personal identifiers. To this end, all documents that have patient identifiers (i.e., signed consent forms) will be managed via a "named based system" and strictly kept separate from the "ID-based system" that will include all study files that do not have personally identifying information. Study documents in one system or the other will never be filed together, and all documents will be stored in one of the two systems, but never both. We will have one form that will link participants' names to an assigned study ID. This form will not be entered into any database, and will be key-locked in a file cabinet in the JHSPH research office likewise accessible uniquely by key. Only the study PI and study manager will have access to both keys. We will not link records obtaining data to any personally identifiable information.

In the case of using text message-collected data, we will set up a system that will strictly separate the cell phone numbers entered into the system for sending out text messages and receiving text message data from the names associated with those cell phone numbers. During mobile phone registration for the study, we will additionally conduct a 20-minute orientation session with participants on use of the cell phone for the study's purposes to inform participants on how to maximize privacy when using text messaging technology. We will suggest ways to protect their privacy, such as deleting text messages once received or responded to, using their phone in a private location, enabling the password protection function, and avoiding sending responses to the wrong number. These steps will also be provided to participants via an informational sheet. We will also fully inform participants that text messages are sent via cell phone company networks, and that there is a small chance that their data could be accessed by other individuals, if someone breaks into the cell phone company's data network. However, we anticipate that this will be very unlikely.

NOTE: This study does not solely place the security burden on study participants.
Other <u>study-enacted security measures</u> relating to text messages are listed below:

1. The study will strictly separate the participant's phone number used for sending out text messages from the name associated with that phone number.
2. The study will use a text-messaging platform called TextIt.In that was chosen because it does not require handing over the participants' name, address, or other identifying data to a mobile database software company.
3. The study will delete all outgoing and incoming text messages at the end of the study and only de-identified response data will be used for analysis.
4. The study will also activate the phone number anonymization feature of TextIt.In at the end of the study. This feature is permanent and replaces each phone number with a random code that completely removes the phone number from the platform account and renders it invalid for future use.
5. The study team will inform participants during the orientation session that all text message responses are de-identified and stored on servers protected by firewalls, and that all access to those servers is permitted only through encrypted channels of TextIt.In that are FIPS-140-2 compliant.
6. In addition to the 20-minute orientation session for participants to maximize privacy, the study will bear the burden of printing and providing an informational sheet reviewing all participant best practices, such as deleting text messages once received or responded to, using their phone in a private location, and enabling the password protection function.

(iii) <u>Inconvenience related to the time required for participating in the study</u>:

We have specifically designed the study to ensure that the research burden is low. To minimize inconvenience, all interviews will be conducted during day or early evening hours at the AIRS/YO!Baltimore CBO center where or near where the participant currently lives. Participants will also be informed during the informed consent process that should the study activities become too burdensome, they have a right to decline or cease participation at any time, including refraining from answering any questions, withdrawing from the interviews or text message surveys, or other study activities. They will also be informed during the informed

consent process regarding the expected frequency and duration of study activities relevant to the study aim for which they are being recruited. In cases of severe emotional distress, participants will be referred to supportive services within the AIRS/YO!Baltimore CBOs by provision of the address and contact number. If a participant appears to experience severe distress during the interview, the interviewer per study protocol will end the interview and document the reason for non-completion.

7.D. Describe the research burden for participants, including time, inconvenience, costs, etc.

There are two types of burden in the study: (a) research burden related to evaluating outcomes; and (b) intervention burden related to educational sessions and apprenticeship.

- The research burden is low. Over the course of 26 weeks, participants will contribute to maximum of two in-person interviews (=150 minutes) and 26 text message surveys (=130 minutes) which amounts to a maximum time requirement of 280 minutes or 4.7 hours. This is about 10.8 minutes of research burden per week. To further minimize inconvenience, all data collection activities will be conducted at the AIRS/YO!Baltimore CBO where or near where the participants are living. There will be no anticipated out-of-pocket costs associated travel or accessing the study site.
- The educational intervention burden is also relatively low. Over the course of 26 weeks, participants will participate in a maximum of one 3-hour educational session (=180 minutes) for 20 weeks, totaling 3,600 minutes; plus one educational apprenticeship (=1,440 minutes) for 3 weeks at 8 hours/week. This is a total of 5,040 minutes over the course of 26 weeks, equivalent to 3.2 hours per week (=5040 divided by 60 divided by 26). It is crucially important to note that 3.2 hours per week is equivalent to 8% of the time required for a *full-time job* of 40 hours per week which the participants want to obtain. All participants will be paid for their employed time and receive payment in exchange for educational session attendance. 8% effort is less than the paid effort (burden) of similarly-aged federal work study students – who sit in 30 hours or more of class each week and have 10 to 15 hours of employed time also, each week. In addition, many potential EMERGE participants will have successfully completed GED training programs that require 20 or more hours per week. Therefore, this study voluntary participation in 3.2 hours of week is relatively low burden, as required by local colleges and universities (without pay) and as required simply for a full-time job.
- Combining the research burden and time towards educational opportunities, intervention participants can expect to be engaged up to 5,320 minutes (=5,060 + 280) over the course of 20 weeks, equivalent to 3.4 hours per week. This is comparable to the amount of leisure time spent each week at a gym, basketball practice, GED training, homework, etc.

7.E. Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.

Because sensitive questions are included in the study survey, the following measures will be done to protect participants' privacy: (i) We (the PI and study manager) will conduct all data collection activities in an audibly private room within the CBO; (ii) The interviewer will respect participant confidentiality for all questions; (iii) We will inform the participant that his/her responses will not be linked to his/her name; (iv) We will inform the participant that s/he may skip any questions that s/he is uncomfortable in answering, and that skipping or discontinuing the study will not result in any discontinuation of CBO services or penalty; and (v) We will use careful and standard language that minimizes participants' feeling an invasion of financial or sexual privacy. Further procedures to minimize potential risks of breach of confidentiality, including invasion of privacy, are summarized above in Section 7.C.

VIII.Direct Personal and Social Benefits:

8.A. Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

While there are no planned direct benefits, study participants may welcome the opportunity to discuss their opinions and experiences, including being a part of a microenterprise intervention for HIV prevention among African-American young adults. Participation in the study may also be perceived as an occasion for personal development and peer bonding. The high poverty and high HIV prevalence communities in which the study is located may also benefit in the long-term if the study results in increased economic development and lower HIV infection rates over time.

8.B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

Results from this study will provide empirical data and knowledge on how microenterprise incorporating behavioral economic text messages can work to minimize economic stressors of HIV and motivate self-protective sexual practices. This may have a considerable societal benefit as African-Americans are disproportionately burdened by HIV, and young adults have the highest HIV infections rates than any other U.S. age group. Economic vulnerability contributes to HIV risk among low-income African-American young adults. Yet, current economic-strengthening interventions have omitted U.S. racial minorities.

IX: Payment

9.A. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment", and if the study will reimburse, explain.

Participants in the baseline, midline, and endline interviews will be provided $15 USD compensation for each interview. Participants will be provided $10 USD for every 4 weekly text message surveys completed to cover their reporting time and any study-related cellular charges, in text message surveys completed during the run-in period. Payment for study participation will be provided in cash at the CBO at the end of the run-in period and at the end of the study's data collection period.

9.B. Include the possible total remuneration and any consequences for not completing all phases of the research.

The total possible remuneration for a participant for completing all phases of the research is $135 USD. This comprises of: (i) a total possible remuneration for completing all study interviews of $45 USD (=$15 USD*3 interviews); and (ii) a total possible remuneration for completing all text message surveys over the 26-week study period of $65 USD (=$2.50 for each weekly text message survey). There are no consequences for not completing all research activities.

X.Study Management

10.A. Oversight Plan:

1. Describe how the study will be managed. The study will be conducted in partnership with two Baltimore-based homeless and unstably housed youth community centers: AIRS and YO!Baltimore. AIRS was founded in 1987 in response to the AIDS epidemic and has since expanded to provide a comprehensive array of services for homeless youth ages 14-24, including transitional housing and permanent supportive housing as well as a homeless youth resource center that provides case management, emergency services, life skills education, and housing referrals. Through its community outreach program, AIRS also assists Baltimore homeless youth in accessing available food vouchers and resources, including clothing and toiletries. The organization is one of the oldest and largest homeless youth community organizations serving youth in Baltimore City and Baltimore County. YO!Baltimore was founded in 1999 in partnership with the Historic East Baltimore Community Action Coalition (HEBCAC) to address the development needs of out of school and unstably housed teens and young adults, aged 17-24, in East Baltimore. YO!Baltimore connects youth to services relating to housing, education, training, health care, and/or family support with partnering public and community-based agencies.

The responsibility of AIRS and YO!Baltimore will be to assist in the recruitment of potential study participants. These CBOs will designate a program manager who will also assist in the identification of an on-site private location for recruiting, conducting the interviews, and conducting the intervention sessions. A letter of support from AIRS and YO!Baltimore has been submitted via the JHU PHRIST online.

The JHSPH PI with support from the study manager will be responsible for conduct of all study activities, including intervention implementation, data collection, analysis, training, and financing tasks.

2. What are the qualifications of study personnel managing the project?

Dr. Jennings (PI) is an Assistant Professor, JHSPH, Department of International Health, within the Social and Behavioral Interventions (SBI) program with experience in HIV prevention and microeconomic behavioral interventions in resource-poor settings. Ms. Davoust is a Research Program Manager (Study Manager), JHSPH, Department of International Health, also within the SBI program with experience in youth and HIV prevention study management.

3. How will personnel involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website: www.jhsph.edu/irb)

Should the study engage any graduate student RAs to support data collection, analysis, or writing, they will be trained on human subjects protections by the study PI, using the JHSPH Ethics Field Training Guide. This training will focus on the study protocol and use of the data collection instruments and will occur at JHSPH in Baltimore, MD.

4. If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.

The PI will personally be on-site throughout the data collection process.

10.B. Recordkeeping

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation.

The data collection will be conducted by the study PI and the study manager. Should the study engage any graduate student RAs or other members of the study team to support data collection, those individuals will be informed and trained on the study protocol, including how to properly record and store study materials and adhere to IRB regulations. Protocol compliance will be ensured using the following methods: (i) routine review of the completed study documents and files by the study PI and study manager. These reviews will check for screening accuracy, reconciled consent documents, interview questionnaire use, and adequate transfer and storage of study files; and (ii) on-site observation of a 10% sample of conducted interviews by the study PI; (iii) mid-term meeting with all RAs to review the study records and address any protocol concerns; and (iv) review of queries posed by participants during conduct of any research activity to address any protocol concerns. Each of these planned processes will assist the study PI in ensuring that the study team follows the protocol and properly records and stores study documents.

10.C. Safety Monitoring

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role?

Risks related to participants are anticipated to be low given the non-invasive nature of the study. However, a monitoring and safety report will be used for documenting (i) any issues or problems with the study; and (ii) any adverse events occurring during the study. Given that the study will enroll a relatively small number of participants for a series of short encounters, the PI will monitor the study for adverse events and have overall responsibility for safety monitoring, including implementing and supervising procedures for protection against risks. In addition, all RAs will be trained to observe any risks to participant safety during data collection, such as risk of violence, trauma, illness, or injury. If any unanticipated safety issues occur, the study PI will immediately report back to the Johns Hopkins IRB through an adverse event report within 48 hours of receiving notification.

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following: (a) The DSMB membership, affiliation and expertise; (b) The charge or charter to the DSMB; (c) Plans for providing DSMB reports to the IRB; and (d) Describe plans for interim analysis and stopping rules, if any.

(a) DSMB Membership: Dr. Jennings will evaluate adverse events and initiate appropriate responses in conjunction with a JHU faculty member with expertise in human subject safety issues in HIV prevention behavioral trials. Together, they will comprise a two-member data safety and monitoring board (DSMB).

(b) DSMB Responsibility: The DSMB will be responsible for protecting the safety of study participants by ensuring that all study protocols are adhered to consistently, identifying procedural changes that are needed, and assessing study progress and safety outcomes.

(c) Reports to the IRB: All adverse events will be reported through an adverse event report to the IRB within 48 hours of any received notification or directly observed event.

(d) Interim Analysis: We will conduct interim analyses for the study's outcomes at 25%, 50%, 75% and 100% of the study period duration. If the interim analyses reveal adverse or serious adverse events, we will quickly inform the IRB and take appropriate steps to address the events.

7.5.5 Frequency of Data and Safety Monitoring

Data and safety monitoring will be conducted weekly throughout the study by Dr. Jennings. The DSMB will review the monitoring and safety reports every 3 months.

10.D. Reporting Unanticipated Problems/Adverse Events (AE's) to the IRB (*all studies must complete this section*): Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.

If an adverse event occurs, the PI will immediately report back to the Johns Hopkins IRB through an adverse event report within 48 hours of receiving notification. A summary of the adverse events that occurred during the previous year will also be included in the annual progress report to study sponsor, the NIH. Only adverse events that are unanticipated, pose risk of harm to participants or others, and are related to the study will be reported.

10.E. Other IRBs/Ethics Review Boards:

If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances).

Not applicable. The proposed research will not undergo review by any other IRBs or Ethics Review Boards.

10. F. Collaborations with non-JHSPH Institutions:

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

	JHSPH	AIRS	YO!Baltimore
Primary Grant Recipient	X		

Collaborator		X	X

For the following, indicate "P" for "Primary", "S" for "Secondary" (as appropriate to role and level of responsibility.) Add additional items if useful.

1.	Human subjects research ethics training for data collectors	P	S	S
2.	Day to day management and supervision of data collection	P	S	S
3.	Reporting unanticipated problems to the JHSPH IRB/Sponsor	P	S	S
4.	Hiring/supervising people obtaining informed consent and/or collecting data	P	S	S
5.	Execution of plan for data security/protection of participant data confidentiality, as described in the Data Security and Confidentiality Protections section above .	P	S	S
6.	Biospecimen processing, storage, management, access, and/or making decisions about future use	N/A	N/A	N/A

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