VCU Office of Research and Innovation

Date: Monday, March 23, 2020 10:08:04 AM Print Close

ID: MS8_HM20011245 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator:**
   Eric Benotsch
2. * **Study Title:**
   Microeconomic Intervention to Reduce HIV Transmission in Economically Disadvantaged Transgender Women
3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - ○ Yes
   - ● **No**
4. * **Please select the primary department or center that this study is being conducted under:**
   Psychology
5. **If this is associated with other VCU IRB protocols or a resubmission of a withdrawn/closed protocol, select the VCU IRB numbers assigned to those studies:**

ID	Title	PI

There are no items to display

6. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Benotsch	Eric	ebenotsch@vcu.edu	8048280133	

7. * **Select one of the following that applies to the project (selection will branch to new pages):**

   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols. See https://research.vcu.edu/human_research/guidance.htm

   - ● **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ○ Exception from Informed Consent (EFIC) for Planned Emergency Research
   - ○ Humanitarian Use of Device for Treatment or Diagnosis
   - ○ Humanitarian Use of Device for Clinical Investigation
   - ○ Emergency Use of Investigational Drug, Biologic or Device
   - ○ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
   - ○ Center or Institute Administrative Grant Review
   - ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

ID: MS8_HM20011245 View: SF2 - Federal Regulations

Federal Regulations

1. * **Is this a FDA regulated study?**

   FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future. Check Yes if the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56. Also check Yes if the study does not involve a test article but intends to provide safety or efficacy data to the FDA about an FDA regulated product.

   ○ Yes ● **No**

2. * **Is this study supported by the Department of Defense (DoD):**

   ○ Yes

   ● **No**

3. * **Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):**

   ☐ Department of Education

   ☐ Department of Justice

   ☐ Environmental Protection Agency

   ☑ **None of the above**

ID: MS8_HM20011245 View: SF2 - IRB Panel Setup

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**

   ● **VCU IRB**

   ○ Western IRB

   ○ NCI Central IRB

   ○ Other IRB

2. * **Does this protocol already have a VCU IRB study number (HM number) and is being submitted as a new study in order to transition to review by another IRB?**

   ○ Yes - transitioning from VCU IRB to an external IRB (WIRB, CIRB, Other)

   ○ Yes - transitioning from an external IRB (WIRB, CIRB, Other) to VCU IRB

   ● **No or not applicable**

ID: MS8_HM20011245 View: SF2 - Review Setup

Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**

   Bio-Medical Research

○

● **Social/Behavioral/Education (SBE) Research**

2. * **Does this study involve greater than minimal risk:**

Does this study involve greater than minimal risk:

○ Yes

● **No**

3. * **Review type requested: (subject to IRB approval):**

○ Full Board

● **Expedited**

○ Exempt

The IRB has determined that the selected Exempt and/or Expedited categories apply to this study.

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study.

4. **For Expedited Studies:**

Category 6	Research Data Collection	Involves the collection of data from voice, video, digital, or image recordings made for research purposes.
Category 7	Behavioral	Is research that will be performed on individual or group characteristics or behavior OR will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

ID: MS8_HM20011245 View: SF2 - Initial Setup Complete

Initial Setup Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS8_HM20011245 View: SF2 - Background, Rationale and Goals

Background, Rationale and Goals

1. * **Describe the study's background and significance, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

It may be easier to simply look at the uploaded document "R34 Application -- Science and References". However, I will paste some of that material below. This material uses numbered references -- see "R34 Application -- Science and References" document for the full reference.

Transgender women face persistent discrimination and structural disadvantages including high rates of unemployment, unstable housing, and poverty. Because gender identity information is not routinely collected by the U.S. Census Bureau or most national health surveys, data sources are limited to national online2,5 or mostly online1 samples, meta-analyses of convenience samples,6-7 data from the Veteran's Health Administration,8 geographically limited household prevalence studies,9 and individual studies of convenience samples, mainly from large urban centers (e.g., New York, Los Angeles, Chicago, Boston, San Francisco).10 Nevertheless, data from multiple sources consistently show high rates of stigma;11 rejection from family and others;11-12 violence directed at TGW,13 and discrimination in employment and housing.1,-2,12,14-16

Employment discrimination. In the National U.S. Transgender Survey (USTS),2 a large study of over 27,000 transgender adults in the US and the earlier National Transgender Discrimination Survey (N > 6,000; NTDS),1 employment discrimination was pervasive: 55% of TGW reported gender identity discrimination in hiring and 18% reported losing a job because of discrimination. Harassment in work settings due to gender identity (78%) and being denied a promotion (29%) were also common. In a meta-analysis of 4 smaller studies with transgender adults, Herbst and colleagues found that 35% reported job discrimination (95% CI 31.5%-39.0%).7
Unemployment. Participants in the USTS reported unemployment at three times the national rate, with racial/ethnic minority participants especially affected.2 A separate national Internet sample (N > 1200) of transgender adults reported 17% unemployment.5 While Internet studies with TGW have great geographic diversity they tend to recruit relatively affluent, well-educated, and predominantly white samples. Thus, they may represent a conservative estimate of unemployment among TGW. A meta-analysis of 13 studies reported a 23% mean unemployment rate.7 A probability sample in Massachusetts found 33% unemployment.9
Poverty. As a result of discrimination and unemployment, many TGW live in poverty.9,14,15 Transgender adults in the USTS were twice as likely to live in poverty as the general population; 30% reported annual incomes of less than $10,000.2 In our pilot work conducted in the mid-Atlantic region, 62% of TGW had annual incomes less than $15,000.18 TGW who transition after entering the workforce see their incomes fall by one-third.19

Housing discrimination and marginal housing. Housing discrimination against TGW is common and leads to homelessness or marginal housing (e.g., staying in shelters or temporarily with friends).1,2, 20-21 In the NTDS, 19% of participants were denied a place to live and 11% were evicted because of their gender identity.2 Rates of homelessness (41%) and eviction (37%) were especially high among African American TGW. Home ownership among TGW in the USTS was approximately one quarter of the national rate.1 Other studies have reported high rates of lifetime homelessness or marginal housing among TGW.20-21

TGW are at dramatically elevated risk of HIV, substance use, and psychiatric problems. Structural disadvantages in employment and housing set the stage for a range of health problems. There have been no probability studies examining HIV prevalence in TGW, despite evidence that TGW are at very high risk for HIV. A recent meta-analysis using testing data from convenience samples estimated the HIV prevalence among TGW in the US at 21.7% (95% CI: 18.4%-25.1%).6 A second meta-analysis examining HIV prevalence in TGW in the US found that, in studies conducting HIV testing, 27.7% (95% C.I.: 24.8–30.6%) tested positive.7 This meta-analysis also reported that HIV rates were consistently highest in African American TGW (56.3%; 95% C.I.: 50.1%–62.4%), relative to other racial groups. Overall, TGW are 34.2 times more likely to be living with HIV than the general US adult population.6 TGW also have high rates of undetected HIV infection.22 Research with TGW shows high rates of sexual risk behavior, including unprotected sex and sex with multiple partners.7,23-25 Prior work has identified transactional sex, including formal commercial sex work (CSW) as a crucial risk factor for HIV infection in TGW.26-28 Rates of transactional sex among TGW are high, with estimates ranging from 15% to 42%.1,2,7 Transactional sex is especially common in TGW living in poverty.2

Substance use. TGW also report high rates of substance use,29-33 with a mean of 26.7% (95% CI: 24.5-29.0%) reporting the use of illicit drugs other than marijuana.7 Additional research has documented injection risk behaviors in TGW.34 In most groups, injection risk is due to the use of illicit drugs. Among TGW, some individuals also inject hormones or inject silicone directly into the body in an effort to feminize body shape and features.35 Sharing needles during this process may be an additional HIV risk behavior for some TGW.

Psychiatric problems. Research has consistently shown that TGW are disproportionately burdened by psychiatric problems8,12,31,36-37 For example, in a recent case-control study of over 5,000 transgender veterans and 15,000 non-transgender veteran controls, transgender veterans had higher rates of psychiatric diagnoses in each of the 10 diagnostic categories examined, including depression, PTSD, panic disorder, and alcohol abuse.8 Suicide attempt rates may be 8-10 times higher among TGW as the general population.1-2, 37-39

Structural disadvantages are important drivers of HIV acquisition, substance use, and psychiatric problems in Transgender Women. Engagement in HIV risk behaviors is complex and multiply determined. However, research suggests that TGW who are unemployed, impoverished, and have unstable housing have higher rates of transactional sex and poorer health outcomes including higher rates of HIV.1,26,40-42 Quantitative research documents higher rates of CSW among unemployed TGW1,2 and qualitative studies report that many TGW tie participation in CSW directly to

financial hardship or an inability to obtain employment.34,43-45 Unstable housing is also implicated in transactional sex. In the NTDS, 15% of TGW reported having sex in exchange for a place to stay and CSW was four times more common among TGW who had experienced homelessness.1 Structural disadvantages also negatively impact mental health, elicit substance use to cope, and can therefore lead to high-risk sex even for those who do not engage in transactional sex.41-42 Unemployment, unstable housing, and CSW are associated with worse mental health among TGW,1,21,46 incarceration,1 and substance use.1,12 Several of these outcomes (e.g., HIV-positive status, incarceration history, psychiatric problems, addiction) subsequently add to stigma and discrimination experiences, becoming additional barriers to employment, a pattern termed the Stigma-Sickness slope.17

Biomedical HIV prevention approaches for Transgender Women. Pre-exposure prophylaxis (PrEP) has been shown to dramatically reduce the likelihood of HIV acquisition among high-risk groups.54 Currently, awareness of PrEP among TGW appears low55-56 but, once learning of this approach, interest among TGW is very high.57-59 PrEP may be especially empowering for TGW engaged in high-risk behavior such as CSW.57 Persons living with HIV (PLWH) can dramatically lower the likelihood of infecting a sexual partner by suppressing their viral load through adherence to an effective antiretroviral (ARV) medication regimen.60 However, studies suggest suboptimal adherence to ARV regimens in TGW.61-62 Barriers to effective biomedical HIV prevention utilization among TGW include economic barriers, lack of awareness, and stigma within medical settings.57,63 Psychiatric problems and substance use, both of which are high in TGW, predict non-adherence to ARVs in other groups64-66 and thus may play an important role in nonadherence among TGW.

Microeconomic HIV prevention interventions. Microeconomic interventions are designed to improve financial standing by increasing entrepreneurship, savings, and/or employment, thereby targeting the structural factors underlying HIV risk behaviors in economically marginalized individuals. Common microeconomic strategies include: small business loans, personal saving accounts, vocational training, financial and business training, insurance provision, career planning, and mentoring.67-68 Often these microeconomic strategies are integrated with traditional HIV education and prevention approaches. Integrated microeconomic HIV prevention interventions have been tested mostly in the developing world.3,4 Most studies have targeted economically marginalized groups including women and orphans.69 No studies have included TGW. Microeconomic interventions have been shown to increase savings and overall income while reducing income generated from participation in the underground economy.70-72 Microeconomic interventions integrated with HIV prevention have also shown utility for increasing women's perceived power in relationships,73 HIV-related communication with partners,74-75 HIV testing,74 and condom use.71,73,74,76 These interventions also reduce participation in CSW,71,76,77 number of CSW partners,71,72,77,78 unprotected sex,74,78 sexual risk-taking intentions,79 and substance use.71 Additional benefits include greater self-efficacy for work and increased self-esteem.68 Although promising, some studies have had null results or had a combination of significant and nonsignificant findings.69 A critique of some microeconomic programs that emphasize lending is that they can create a financial burden on participants to repay the loan with interest. Limitations of the existing literature include a reliance on less rigorous research designs and studies with low participation rates.69 Despite these critiques, two recent systematic reviews have concluded that microeconomic interventions, while not universally efficacious, have considerable utility in reducing HIV transmission risk behaviors, especially among cisgender female sex workers (FSW).3,4 Microeconomic interventions that are integrated with HIV prevention and education also showed greater promise than microeconomic interventions alone.3,4 Two more recent microeconomic interventions not included in those reviews—one conducted with FSW, and one with female adolescents, some of whom engaged in transactional sex—have also shown reductions in HIV risk behavior among intervention participants.76,78 The literature as a whole suggests that microeconomic interventions have the potential to break the cycle of poverty and participation in HIV risk behaviors for financial gain.3,4,68

The vast majority of the literature cited above applies to transgender women only (the exception is the VA study which aggregated across transgender groups and did not report rates of psychiatric illness separately for transgender men and transgender women).

The study is directed at transgender women and does not include transgender men because of the substantially greater likelihood of serious health consequences for transgender women. For example, according to the CDC, between 2009-2014, transgender women were more than 5 1/2 times more likely to be diagnosed with HIV than transgender men.

https://www.cdc.gov/hiv/group/gender/transgender/index.html

In our pilot work, we collected data from both groups, and transgender women were also substantially more likely to experience both behavioral risk and economic risk, relative to transgender men. For example, transgender women were almost 4 times more likely to be unemployed, twice as likely to experience marginal housing, and more than 6 times as likely to report transactional sex (e.g., commercial sex work), relative to transgender men. They also reported substantially higher rates of employment and housing discrimination. Taken as a whole, it is appropriate to focus this research on transgender women, the group at considerably higher risk.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
The intent of the study is to conduct formative research, develop, and test an integrated microeconomic intervention for transgender women (TGW) who are economically and behaviorally vulnerable to HIV acquisition and transmission.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
Aim 1: Conduct formative work with TGW and key informants to assess TGW's current status, experiences, and preferences for each of the proposed microeconomic components. Building on our preliminary data, we will design and conduct qualitative individual interviews with both TGW and key informants (e.g., NGO representatives, community financial partners) to culturally tailor and refine the proposed microeconomic intervention components and to identify and develop solutions for potential logistical barriers in intervention implementation.

   Aim 2: Develop an integrated microeconomic intervention for HIV prevention tailored for economically disadvantaged TGW which addresses multiple economic vulnerabilities in two U.S., HIV-prevalent, and resource-poor metropolitan areas. We will work with TGW in the Richmond, VA and St. Louis, MO metro areas as well as city and community partners (e.g., banks, government agencies, community-based organizations) to develop and test each of the proposed intervention components: supportive economic services, employment readiness training, financial education, gender transition financial supports, and economics-based HIV education targeting uptake of recent biomedical HIV prevention advances (e.g., PrEP). After the delivery of each module, a process measure will be administered that assesses the participants' qualitative and quantitative reactions to the material in that module.

   Aim 3: Using a randomized experimental study design, evaluate the feasibility and preliminary efficacy of the integrated microeconomic intervention for economically disadvantaged U.S. TGW in reducing economic vulnerability and HIV sexual risk-taking. We will conduct a small experimental pilot-test of the integrated microeconomic intervention versus control with n = 50 TGW per arm with assessment of objective economic and behavioral indicators of HIV risk at 3, 6, and 9 months. As this is a two-site study, in Richmond this will include a total of 50 TGW with 25 TGW per arm.

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

   In addition to the direct benefits of participation, this research is expected to yield important new information on developing HIV risk reduction interventions for people at high risk for infection. Thus, we feel that the benefits of participation far outweigh the risks.

   The summary of the NIH expert panel that reviewed this work stated:

   "The applicant proposes developing and testing a microeconomic (ME) intervention for economically disadvantaged transgender women (TGW) to keep them from engaging in risky sexual behaviors to meet their financial and gender transition needs. TGW especially those of color are more likely to be unemployed, homeless, and poor. This strong premise
undergirds the proposed intervention which will include supportive economic services, employment readiness and financial training. The application is undoubtedly innovative for being the first project of its kind to test a ME intervention for TGW. The application is well grounded in three theories and will assess the feasibility and efficacy of the ME intervention using a robust experimental design and very rigorous objective measures. This multiple PI application is well justified, with investigators who complement one another and have a good track record of previous collaboration. The committee was very supportive of this ground-breaking intervention that will likely improve the sexual health of TGW. Some weaknesses were raised, including questions regarding whether the dosage of the intervention was appropriate or excessive and the lack of sustainability of the gender transition components of the intervention. Nevertheless, these were considered minor and well within the purview of an R34 to disentangle."

5. * **Describe any potential for direct benefits to participants in this study:**
Participants in this study will be TGW, a group at substantially increased risk for contracting HIV, substance use, mental health problems, and discrimination. Participants will complete brief screening assessments, participate in qualitative interviews, complete short quantitative assessments and/or participate in the microeconomic intervention. Participants may benefit from the opportunity to examine their behaviors, attitudes, and expectations concerning risk. Participants will also have the opportunity to interact with study staff who know the population and area well, and may benefit from the opportunity to ask these knowledgeable individuals about health-related or other matters. Study staff will be able to provide participants with local referrals for testing or other services, if needed during the screening process or Aim 1 formative work. For TGW participating in the Aim 2 pilot and Aim 3 intervention, providing information about HIV testing, PrEP, and linkage to HIV care will be explicit goals of the intervention. Intervention participants will also receive information linking them to supportive services (e.g., emergency housing, TGW-friendly banking), employment readiness training, personal financial education, and gender transition cash vouchers. Lastly, our pilot research suggested that participants resorted to high-risk survival activities (i.e., selling sex or drugs) from necessity and welcomed new and positive alternatives.

6. **Upload a supporting citation list if applicable:**

ID: MS8_HM20011245 View: SF2 - Study Population

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   350

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   700

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   This will include 30 TGW (15 in each site) for qualitative interviews which we believe will be enough to achieve saturation, 20 TGW (10 in each site) for pilot testing of intervention (we believe this will match the size of the intervention group and thus is appropriate for intervention piloting), and 100 TGW (50 in each site) for the randomized controlled trial. The total number above also reflects the numbers we anticipate screening for study inclusion. This will include some individuals who are not eligible and some individuals who are eligible but choose not to participate in study activities other than completing the screening survey. For the RCT the size is justified by power analysis. We will use intent-to-treat analyses, using standard assumptions for those in the intervention group lost to follow-up. We will have .88 power to detect a medium effect size (f=.25) for repeated measures ANOVA (assuming r = .5 for outcomes over time) and .8 power to detect a medium effect size (f2 =.15 or the equivalent of partial R = .36) with three predictors for multiple regression.

4. * **List the study inclusion criteria:**
   For screening, inclusion criteria will include that the participant is a transgender woman and is 18-45 years of age.

   For TGW, full study participation, inclusion criteria will require both (i) Economic vulnerability (unemployment or underemployment [less than 20 hours/week], low income [less than the Medicaid poverty threshold], housing insecurity in the past year, or food insecurity in the past year), and (ii) Behavioral vulnerability to HIV transmission: unprotected sex in prior 6 months, transactional sex, multiple sexual partners, 1-time sexual partner, sex with a partner of unknown HIV status, sex under the influence of drugs or alcohol. Participants will be recruited if they are age 18 or older. Based on our prior work, we expect participants meeting these guidelines to be relatively young (mean age = 32, SD =10) and predominantly African American. Based on data from our pilot work, we expect around 45% of individuals screened to meet eligibility requirements.

   These are the inclusion criteria for TGW for Aims 1, 2, and 3.

   For the Aim 1 key informant interviews, inclusion criteria will be age 18 or older and able to speak English. Individuals will be recruited who either (a) have expertise with the TGW population due to their work-related activities with that group (e.g., social workers, public health professionals) or (b) have expertise with financial-based programs such as employment or housing (e.g., bankers).

5. * **List the study exclusion criteria:**
   Participants will not be recruited for screening if they show obvious signs of intoxication or cognitive impairment or cannot speak English.

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
   - ○ Included
   - ○ Excluded - safety concerns if participants are unable to communicate with the study team
   - ○ Excluded - instruments/measures only validated in English
   - ○ Excluded - no prospect of direct benefit to individual participants
   - ○ Excluded - minimal risk study
   - ● **Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]**
   - ○ Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
   TGW are at very high risk for HIV and risk behavior is frequently motivated by financial hardship (i.e., high-risk

transactional sex to meet financial or housing needs). TGW also have additional financial costs such as gender transition costs.

The study will be conducted in English. The instruments are only validated in English. We don't have bilingual personnel and don't have the resources to hire and train additional bilingual staff.

ID: MS8_HM20011245 View: SF2 - Background, Rationale & Goals Section Complete

Background, Rationale & Goals Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

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ID: MS8_HM20011245 View: SF2 - Study Procedures

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
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2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   Aim 1: Conduct formative work with TGW and key informants to assess TGW's current status, experiences, and preferences for each of the proposed microeconomic components. Building on our preliminary data, we will design and conduct qualitative individual interviews with both TGW and key informants (e.g., NGO representatives, community financial partners) to culturally tailor and refine the proposed microeconomic intervention components and to identify and develop solutions for potential logistical barriers in intervention implementation.

   Aim 2: Develop an integrated microeconomic intervention for HIV prevention tailored for economically disadvantaged TGW which addresses multiple economic vulnerabilities in two U.S., HIV-prevalent, and resource-poor metropolitan areas. We will work with TGW in the Richmond, VA and St. Louis, MO metro areas as well as city and community partners (e.g., banks, government agencies, community-based organizations) to develop and test each of the proposed intervention components: supportive economic services, employment readiness training, financial education, gender transition financial supports, and economics-based HIV education targeting uptake of recent biomedical HIV prevention advances (e.g., PrEP). After the delivery of each module, a process measure will be administered that assesses the participants' qualitative and quantitative reactions to the material in that module.

   Aim 3: Using a randomized experimental study design, evaluate the feasibility and preliminary efficacy of the integrated microeconomic intervention for economically disadvantaged U.S. TGW in reducing economic vulnerability and HIV sexual risk-taking. We will conduct a small experimental pilot-test of the integrated microeconomic intervention versus control with n = 50 TGW per arm with assessment of objective economic and behavioral indicators of HIV risk at 3, 6, and 9 months. As this is a two-site study, in Richmond this will include a total of 50 TGW with 25 TGW per arm.

3. * **Will the investigator obtain information or biospecimens for the purpose of screening, recruiting or determining the eligibility of prospective subjects?**
   - (●) **The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative.**
   - ( ) The investigator will obtain identifiable private information by accessing records.

     The investigator will obtain identifiable biospecimens by accessing stored identifiable biospecimens.

- ○
- ○ None of the above

4. * **Choose all types of recruitment materials that may be used:**
   - ☑ **E-mail invitations**
   - ☐ Phone Solicitation scripts
   - ☑ **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
   - ☐ TelegRAM announcements
   - ☑ **Website text**
   - ☐ Study-specific web sites (design and text)
   - ☑ **Social Media**
   - ☐ Psychology Research Participant Pool (SONA) study descriptions
   - ☐ Scripts for announcements made to groups
   - ☐ Other recruitment material
   - ☐ No recruitment materials

5. * **Provide a description of**
   1. How potential participants or secondary data/specimens of interest will be identified and
   2. All procedures that will be followed to carry out recruitment and screening activities (if applicable).

   Include details (as applicable) about:
   - How secondary data/specimens that meet the study's eligibility criteria will be identified (i.e. what database(s) will be queried and the search terms that will be used)
   - How potential participants will be identified and their contact information obtained
   - The timing and frequency of recruitment activities
   - Where and how recruitment procedures will be completed
   - Who will recruit or respond to potential participants
   - What and how written or verbal recruitment materials and reminders (if any) will be used
   - What screening activities will occur and how these procedures will be performed
   See the help text for additional guidance.
   Recruitment will be primarily conducted by direct contact in conjunction with our community partners. Some locations where recruitment materials will be displayed are to be determined, but these might include local clinics or other community establishments. The Health Brigade, Planned Parenthood of Richmond, the Minority Health Consortium, Nationz Foundation, and Side by Side have agreed to allow us to recruit in their spaces and/or to display recruitment posters, distribute flyers, and/or contact their members to provide them with information about the study.

   We will work with the community partners and will recruit through five methods: (1) On recruitment days we will have a study table set up and potential participants will be able to initiate a conversation with us (2) If practical and consistent with partner procedures and practices, we will approach potential participants for screening in private settings, (3) Distribution of a flyer / placement of a poster in a community setting with contact information for the study investigators, (4) online via the project's facebook page, (5) via email from our community partners to their current contacts (e.g., their own listserv).

   Participants who screen as eligible on the screening assessment will be invited to provide their name and contact information. If they choose to provide that information we will contact them shortly thereafter (e.g., within 2-3 days). If they provide both a phone number and email address, we will first attempt to call them and if that is not successful, we will email them. Individuals will be contacted by the research assistants or study investigators.

   Scripts for phone and email contact (including new scripts for Aim 3) have been uploaded.

   The RA or study investigator calling will answer any questions the participant has, and, if the participant is interested, will schedule the interview. If the interview is scheduled more than 1 day after the participant is contacted, we will ask their permission to send a reminder text/email/phone call on the day before the pilot test.

   A script for the email is:

�Hi [participant name]

My name is [writer�s name]. I am a [writer�s title] at VCU. You recently completed a short questionnaire on a tablet computer and were invited to participate in an intervention for trans women. You provided your email address so I am writing to tell you a bit about the intervention.

If you participate in this project, you will come to an intervention for trans women. The intervention focuses on multiple things, including education about resources available for trans women in Richmond, job readiness training including how to write a resume and how to do a good job interview, financial training such as how to create a budget, gender transition information such as how to style hair or apply make-up, and HIV prevention information.

Some trans women who participate will receive the intervention right away. Others will receive it in six months. Who gets it right away versus later is randomly determined. This is so we can test the effects of the intervention.

If you are randomly assigned to receive the intervention right away, you will come to six sessions on six different days. Each session will last for around 2 � hours (around 15 hours total).

If you are randomly assigned to receive the intervention in 6 months, you will come to three sessions on three different days. Each session will last for around 4 hours (around 12 hours total).

Sessions will be held at VCU or at one of our community partners.

Some participants will also receive some financial assistance for finding a job and for gender transition costs. Who receives that financial assistance will be also randomly determined.

We will audio record the intervention, including what you say when you participate, but we will keep everything you tell us confidential. The intervention is expected to last a total of around 15 hours, spread out over 6 days (2 1/2 hours per day). An incentive of $15/hour will be paid for your participation. So, if you came to 15 hours, you would receive $225 and if you come to 12 hours, you would receive $180.

If you participate, you will also be asked to complete a questionnaire four times. The first time you complete it, we will pay you $20. That amount will go up by $5 for each additional time you complete the questionnaire -- $25 for the second time (3 months later), $30 for the third time (3 months after that), and $35 the fourth time (3 months after that). If you complete all four questionnaires, we will give you an additional $50 bonus.

I�m happy to answer any questions you have. Please let me know if you�d like to learn more or if you�d like to participate in the intervention.

Regards,

[name]�

If contacted, the writer will answer any questions and, if the participant is interested, schedule the interview. If the interview is scheduled more than 1 day after the participant agrees to participate, we will ask their permission to send a reminder text/email/phone call on the day before the interview.

We also asked about other or better means to contact them. These might include being contacted via social media. In that case, we will use the email script (or as close to it as possible if there are space limitations in the social media platform�s messaging system).

We will send a reminder email, text message, or will call on the day prior to the scheduled sessions, if participant has agreed to be reminded of the appointment.

A light snack or meal may be be provided at some recruitment events and/or during the intervention sessions. For participants attending sessions, we may assist with transportation if needed (e.g., bus pas, taxi, or Uber).

6. * **Is a separate protocol document being uploaded that contains a detailed description of the study's methodology and procedures?**

   ○ Yes

   ● **No**

7. * **If a separate protocol document is NOT uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

1. A statement explaining the study design
2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
3. A description of all research measures/tests/interventions that will be used (if applicable)
4. A detailed description or list of all secondary data elements and/or secondary specimens that will be obtained and how they will be used (if applicable)
See the help text for additional guidance
Methods for Specific Aim 1:
Community Advisory Boards. We have already established community advisory board in Richmond. Our Mid-Atlantic CAB has been working with us for six years and consists of members of the transgender community and professionals working with TGW. Agencies represented include the Minority Health Consortium, Virginia Department of Health and Nationz Foundation. Several of our Mid-Atlantic CAB members (Heck, Pierce, McNulty, McMillan) co-authored articles with us describing our pilot work.25, 88-90 We have been working with the St. Louis NGO partners for 2 years. These partners consist of members of the TGW community and staff affiliated with the Missouri Department of Health, St. Louis City HIV program, and NGOs working with TGW. In our pilot work, our CAB advised us in all aspects of the work, including identification of key problems faced by the TGW community, development of qualitative and quantitative measures, and recruitment strategies. This application was developed with input from our CAB. Our CAB will play a crucial role in the project.

Screening: Participants will be recruited at community venues using in-person invitation or online. All eligibility criteria will be determined by participants' self-report via a computer-administered screening tool. We will use a password protected tablet computer for screening or password protected website. The screening survey asks questions about current and past economic and behavioral vulnerability and also includes some questions on new biomedical prevention techniques (Pre-exposure Prophylaxis) and sources of information about biomedical prevention techniques as this information will inform our intervention. For in-person recruitment, the tablet will be connected to the internet and the questions will be delivered via a Qualtrics survey. For online recruitment, participants will contact us via email or Facebook messenger and we will send them the link to the survey.

Qualitative interviews with at-risk TGW. Qualitative interviews with economically and behaviorally vulnerable TGW will be conducted in each study site (n=20; 10 in each site). Interviews will be conducted by psychology or nursing graduate student research assistants (RAs) using a semi-structured interview guide and will last 60-90 minutes. Interviewers will ask questions that assess the following content areas, guided by the theories noted above: (i) income generation goals and activities (ii) discrimination and other practical barriers (e.g., transportation, legal history) to employment, (iii) discrimination and other barriers to maintaining safe housing (iv) economic and other drivers of transactional sex, and (v) access to and affordability of gender transition services. In addition, we will describe our proposed integrated microeconomic intervention and ask about perceptions of the acceptability and utility of different intervention components, additional needed components, barriers to intervention, and methods for overcoming those barriers. We will ask about ways to identify and recruit TGW most at need for the intervention. The interview guides will be reviewed by our CAB and modified were made as needed. Participants will be paid $50 for participation.

We will also recruit a second group of TGW. These are individuals who show indications of economic and behavioral vulnerability in the past but who no longer meet criteria for either vulnerability. Our intent is to recruit 5 of these individuals in each study site (10 total). The intent of these interviews is to understand the process by which these women overcame their past economic and behavioral vulnerability. Interviews with TGW who are not currently economically or behaviorally vulnerable to HIV but who were in the past will cover these same topics (income generation, discrimination in employment and housing, transactional sex, and gender transition services) but with additional focus on the factors that enabled them to overcome economic and behavioral vulnerability to HIV transmission. The intent with these interviews is to understand how these individuals were able to access and maintain stable income, housing, and avoid HIV transmission risk behavior. We will also describe the intervention and assess their perceptions of acceptability, utility, barriers, and solutions to barriers. Based on our pilot data, we estimate that 25% of screened TGW will meet the criteria for past but not current behavioral and economic vulnerability. TGW in this group will be paid $50 for participating in the interview.

Key informant interviews. We will also conduct qualitative interviews with key informants in each study site. The key informants will consist of NGO representatives who conduct HIV prevention services with TGW in Richmond and St. Louis (n=10; 5 in each site), representatives from our community financial partners that provide financial education or housing assistance (n=10; 5 in each site). Interviews with key informants will be conducted by the PIs and study RAs in Richmond and St. Louis. Interviews with NGO or GO directors/staff will use a comparable set of questions related to TGW needs in Richmond and St. Louis related to income generation, discrimination in employment and housing, transactional sex, and gender transition services, along with a description of the integrated microeconomic intervention and questions related to its feasibility, barriers, and methods to overcome barriers. Interviews with community financial partners will be focused on services that may be available to TGW in Richmond and St. Louis, including employment and housing services. During these interviews, we will also describe the proposed intervention and assess their perceptions of feasibility, barriers, and ways to overcome their barriers. Key informants who are NGO representatives or community financial partners will be paid $25. Our CAB and study consultants have provided input on the interview guides uploaded in this amendment. The qualitative interview guides for key informants have also been reviewed by study consultants.

Recording and transcription: Interviews will be digitally recorded and transcribed for coding. Transcriptionists will be graduate and undergraduate RAs in the co-PIs' (Benotsch) lab, under the supervision of the VCU graduate RA. The co-PI's lab is equipped with professional transcription instruments. VCU undergraduate RAs have previously provided accurate transcripts of qualitative interviews. Transcripts will be compared to the original recordings and checked for accuracy by the interviewers.

Training and supervision of interviewers: Qualitative data collection will be supervised by co-investigators Jennings and Cathers, both of whom are qualitative research scientists. Prior to data collection, all interviewers will receive standardized (8 hour) training in qualitative methodology and research ethics. The training will include specific project protocols and materials to ensure that they are being rigorously and consistently implemented, including role-play rehearsal of consent procedures and the conduct of the qualitative interviews. Embedded in this training is a research ethics course devoted to informed consent, confidentiality, privacy, and research-participant boundaries. Interviewers also will be required to complete the CITI training, and to demonstrate competence with project protocols prior to conducting any field activities. Digital recordings will be sent weekly to the co-investigators for review.

Data analysis: Interview transcripts will be read by all study investigators. In addition, formal qualitative data analyses will begin once transcripts are available. Under the direction of study co-investigator (Jennings), graduate RAs at the co-I's institution will code the data. Following Spradley,91 a taxonomy of all identifiable categories and themes will be assembled in response to the study's questions of interest. Associations among categories will be interpreted and decision trails documented.92-93 All transcripts will be coded by 2 raters. Inter-rater reliabilities (kappas; intraclass correlations) will be calculated and codes with low reliabilities will be examined to resolve discrepancies and improve rater reliability. Several levels of analyses are planned. First, we will summarize the patterns of responses across the questions of interest separately for key informants and TGW. Next, these separate sources of data will be combined into an executive summary highlighting key themes within each respective site. Similarities and differences in findings emergent in the key informant versus TGW data will be noted. Feedback will be elicited from the interviewers at each site about the extent to which their site's executive summary adequately represents key themes. Disagreements will be discussed with the investigators and the reports amended if suggested by the data. Next, a global executive summary will be generated integrating the key findings from both sites. These data will provide essential information that will be used to (1) tailor the integrated microeconomic intervention; (2) identify additional venues or locales for the recruitment of TGW who are economically and behaviorally vulnerable. The executive summaries will also be shared with the CAB at each study site to elicit feedback.

Methods for Specific Aim 2: Intervention Development: To develop an integrated microeconomic intervention for HIV prevention tailored for economically disadvantaged TGW to address multiple economic vulnerabilities in HIV-prevalent resource poor communities. In Year 2, we will work with TGW communities and community partners (e.g., banks, government agencies, community-based organizations) to develop and test each of the proposed intervention components: financial training, workforce development, housing assistance, and MTF transition financial supports. We will utilize participant and community preferences for each of these intervention components based on findings from the formative research conducted in Aim 1, and based on prior successful microeconomic interventions in similar contexts.

Expected Intervention Modules: We envision the intervention modules will include the following five modules, each with the proposed content and structure as follows: (1) Module 1 – Linkage to supportive economic services: As a primary goal, the intervention will aim to expand the economically-supportive networks of participating TGW so as to enhance their ability to achieve financial stability and avoid economic stressors that increase HIV risk. Module 1 specifically introduces and links TGW to local financial assistance programs for low-income individuals. Information on the purpose, eligibility, enrollment process, scope, and contact information for the following services will be provided, as available in each of the two study sites (Richmond and/or St. Louis). Four types of services will be emphasized: (a) rental, transitional, and emergency housing placement services; (b) TGW-friendly banking services for establishing checking or savings account(s); (c) free or low-cost legal services to acquire relevant tax credits, subsidies, or temporary income; and (d) TGW-friendly vocational training and workforce development trainings. Linkages to supportive HIV preventive services will be provided in Module 5 (see below). (2) Module 2 – Employment readiness training and employment assistance program: The goal of Module 2 is to increase job skills and employment acumen in low-income TGW to improve their ability to acquire a living-wage job in the formal and licit economy. The employment readiness sessions will provide education on pre-employment skills relating to accessing occupational training, searching for a job, preparing a resume, presentation of self in terms of gender, and having a successful interview. The session will also focus on educating TGW on post-employment skills, such as maintaining employment, enhancing income potential, and responding to employment discrimination of TGW. During the session, TGW participants will also be introduced to a panel of TGW-friendly potential employers (including supportive members of the Richmond and St. Louis LGBT business groups) who will be selected by the study team in collaboration with study's CABs. The TGW-friendly potential employers will provide employer perspectives and tips for TGW new hires as well as information on HIV preventive or health promotion services provided by employers. The project will also provide an employment assistance program. For this program, we will partially fund (offsetting $4/hour for up to a 40 hours/week) a 2-month period during which participants would be hired on a temporary basis so employers have an opportunity to evaluate the participants' work. The goal with this approach is that some employers will hire participants after the end of the 2 months. (3) Module 3 – Personal financing education: The goal of Module 3 is to

improve financial autonomy of participants through improved financial information, access, and management. The financial education content will focus on topics relating to financial literacy, savings and goal-setting, budgeting, and mitigating financial insecurity. (4) Module 4 – Gender transition financial supports: As part of Module 4, the study will provide up to $600 USD in cash supports to each TGW participant to support MTF gender transition costs. These would potentially include: business-related clothing and beauty aids traditionally used by women, cosmetics, or laser hair removal. These cash supports are meant to reduce the reliance of low-income TGW on high-risk sexual behaviors to financially support their MTF gender transition costs. Financing MTF gender transition needs may also better assist TGW to avoid housing and employment discrimination as a result of improved social perception and integration, as well as improved confidence and self-esteem. The intervention's group sessions on gender transition financial supports will help TGW in developing a plan for leveraging the gender transition financial supports to improve their employability and social integration. The sessions will also link gender transition services to positive self-development which includes avoiding adverse health outcomes, such as HIV acquisition or transmission. (5) Module 5- Economics-based HIV education: The goal of Module 5 is to improve self-efficacy and uptake of HIV preventive services by directly focusing on economic determinants of HIV risk in low-income TGW. The educational content of Module 5 will include information on the array of HIV preventive technologies available to TGW (i.e., PrEP, ARV, condoms, VCT, HIV self-test kits), their financial and non-financial costs, and where and how to access TGW-friendly services in each study site. This module includes information on the purpose, eligibility, enrollment process, scope, and contact information of HIV preventive services. The session will also target and discuss TGW's perceived financial constraints and financial trade-offs to protecting against HIV – and how their access to supportive economic services (Module 1), employment gains (Module 2), personal financing skills (Module 3), and MTF transition financial supports (Module 4) can be leveraged to reduce their risk of HIV acquisition or transmission. The educational sessions will also aim to improve negotiation skills for safer sex with their sexual partners.

We anticipate this intervention dosage will also affect the study's primary economic outcomes relating to (i) formal workforce participation (ii) housing stability and (iii) financial stability and subsequently reduce economic related HIV risk behaviors such as transactional sex.
Intervention Development Procedures: The intervention development process will entail two design phases. First, we will draft intervention curricula and a trainer's manual based on information obtained during Aim 1 formative research, a review of the existing literature and educational materials from prior successful HIV prevention sessions for TGW and effective content relating to microeconomic interventions in the U.S. Secondly, we will invite the CABs and participating NGOs to advise and provide feedback on the intervention design. During this process, we will also recruit 10 economically and behaviorally vulnerable (as defined above) TGW from each of the 2 study sites (total of 20 TGW) to participate in a 3-day abbreviated session pilot (approximately 4 hours per day) of the five modules. We expect that the 3-day pilot will include an introduction to each module and an accelerated delivery of core module messages, followed by a short discussion on perceived feasibility, acceptability, and fit towards TGW's economic and HIV-related needs. We will pay each TGW test-module participant $180 for completing the 3-day session (approximately $15 per hour). After the delivery of each module, a process measure will be administered that assesses the participants' qualitative and quantitative reactions to the material in that module.

Specific Aim 3: Using a randomized experimental study design, evaluate the feasibility and preliminary efficacy of the integrated microeconomic intervention for economically disadvantaged U.S. TGW in reducing economic vulnerability and HIV sexual risk-taking.
Consistent with the program announcement, work during this stage will include testing and further refinement of the intervention manual and implementing a small-scale version of the intervention as a test-of-concept. This small scale RCT is primarily designed to assess feasibility and to estimate intervention parameters (e.g., effect sizes, attrition rates) and to perform preliminary power analyses. The trial will be registered at ClinicalTrials.gov.

Randomization. Fifty participants in each study site will be randomized to the intervention or wait-list minimal treatment control group. Assuming 80% retention, this will yield a total sample size of 80 (40 in each site). When assigning participants to treatment/control, we will use urn randomization, an adaptive randomization procedure that ensures approximately equal group sizes while approaching complete randomization.94 Adherence to the intervention and supervision of interventionists. Sessions will be conducted in private spaces at our community partner locations according to the guidelines in the treatment manual developed in Aim 2. Facilitators will follow checklists developed for each session and will complete a post-session quality assurance form after each session. All study sessions will be digitally recorded. Study investigators will listen to the first recording of each session and provide feedback to interventionists regarding adherence and quality of administration. Thereafter, study investigators will listen to 20% of all recordings (chosen randomly) and provide feedback as needed. To ensure consistency across study site, investigators will listen to audiotapes and provide feedback for both study sites. Monthly group supervision with interventionists will be conducted by the investigators.

Tracking and retention procedures: As it is common for economically marginalized individuals to move frequently and to be financially unable to maintain consistent phone service, comprehensive tracking information will be collected and updated monthly. This information will include home addresses and phone numbers, but also email addresses, social media account information (e.g., Facebook, Instagram) and contact information for individuals who would know how to reach the participants (e.g., friends, family, health care providers, emergency shelter staff). Participants will also be asked to update contact information at the end of each intervention/assessment session. To increase session attendance, we will offset transportation costs.

Assessment procedures and measures: Assessments will be conducted at baseline, 3 months post-intervention, 6 months post-intervention, and 9 months post-intervention. Graduated incentives will be used: $20 for the baseline assessment, $25 for the 3-month assessment, $30 for the 6-month assessment, and $35 for the 9-month assessment. In addition, individuals who complete all 4 assessments will receive a $50 bonus. Incentives will be prorated contingent on completion of both the objective and subjective indicator outcomes.

Primary outcomes will be economic and behavioral vulnerability to HIV, both of which will be assessed via objective and subjective indicators. Objective indicators for economic vulnerability will include verification of employment, income, housing stability, and savings. Participants will be asked to show a copy or image of a recent pay stub, lease, and bank statement. We will also conduct home visits to verify stable living arrangements and will have information from employers (e.g., hours worked) for participants who are employed through the employment assistance program. Objective indicators for behavioral vulnerability will include verification of HIV testing, verification of linkage to care, verification of enrollment in PrEP (for HIV- participants) and verification of a current prescription for ARVs (for HIV+ participants). Participants will be asked to show a copy or image of a recent physician visit statement or receipt, HIV test result, and/or medication label. Pill counts will be used to assess adherence to biomedical prevention approaches.96-98 Participants will be prompted in advance to bring objective indicators to the assessments but it will also be possible for them to provide information afterwards (e.g., by taking a photo of a bank statement or prescription label and texting it to the project or during a home visit). Subjective indicators for economic vulnerability will include self-reported employment status, hours worked, income, housing status, and savings. Subjective indicators for behavioral vulnerability will include self-reported engagement in transactional sex, number of CSW transactions and partners, unprotected anal/vaginal sex, number and type of sexual partners, and self-reported substance use in conjunction with sexual activity.

Measures. Self-report data will be collected via computer technology which reduces self-report biases.99 As with other computer-mediated assessments, the proposed method will take advantage of technology to facilitate assessment, including the use of automated skip patterns, quality control questions, and automatically using information (e.g., number of sex partners) from previous questions in relevant subsequent questions.

Sexual behavior. Participants will report information regarding sexual behavior, including the number of unprotected anal and vaginal sex acts, number of sex partners, if any partners were 1-time partners, or partners whose HIV status they did not know, or transactional partners. They will also be asked if they have been diagnosed with a sexually-transmitted infection in the prior 12 months.

Self-efficacy for workforce participation. Participants will complete an adapted version of the Occupational Self-Efficacy Scale.101 This measure has excellent internal consistency and evidence for construct validity.101

Self-efficacy for managing finances. Participants will complete an adapted version of the Financial Self-Efficacy Scale.102 This measure has excellent internal consistency and evidence of predictive utility.102

Self-efficacy for participation in biomedical prevention methods. PLHA will complete the HIV Treatment Adherence Self-Efficacy Scale, a well-validated measure of self-efficacy for ARV adherence.103 An adapted version of this same measure will assess self-efficacy for PrEP use for HIV- participants.

Self-efficacy for condom negotiation. Participants will complete the Sexual Communication Self-Efficacy Scale.104 This measure has high internal consistency and evidence for validity.104

Substance use and injection risk behaviors. Consistent with our prior work, participants will be asked separate questions concerning whether they have used a broad variety of substances in the prior 3 months. Frequency of use will be measured using a 4-point Likert-type scale (1-�none� to 4-�at least once a week�). Street names will be included. Participants will also indicate if they had used a needle to inject drugs, hormones not prescribed by a physician, or silicone and if they had shared needles with another person during the assessment period. Comparable measures have shown utility in our prior work.88-90

Mental health. Participants will complete the 18-item version of the Brief Symptom Inventory (BSI-18).105 The BSI-18 contains well-validated scales assessing symptoms of depression, anxiety, and somatic distress. Norm information is available. This measure was internally consistent in a TGW sample in our prior work.25,88

Data analysis. Due to the pilot and feasibility objectives and the size limitation of this study, emphasis of the comparative analysis of the intervention impact will focus primarily on estimation of potential mean changes associated with the intervention for planning purposes rather than confirmatory hypothesis testing. GEE models and mixed models would be ideal to use for data analysis; however, since we will be recruiting in two cities and analyzing data across four time points with a relatively small sample size (n=50 to yield final samples of 40), we will use less complex analyses for this study. Baseline characteristics of the two groups will be compared (t-tests for continuous variables, chi-square analyses for dichotomous and other categorical variables). Variables that are significantly different between the two groups at baseline will be controlled for if the sample size allows for us to do so. Two sets of primary analyses will be conducted for this small experimental trial. First, changes over time will be compared between the two groups, using repeated measures ANOVA for continuous variables (e.g., income) and McNemar�s test for dichotomous variables

(e.g., % engaged in biomedical prevention strategies of ARV use or PrEP). These mixed repeated measures ANOVAs will be conducted between the groups between baseline and each follow-up time point. We hypothesize that the integrated microeconomic intervention group will have reductions in economic and behavioral vulnerability to HIV relative to the wait-list minimal treatment control group. The second primary analysis will involve simple repeated measures ANOVAs for the integrated microeconomic intervention group only. While potential effects of maturation and history weaken our causal conclusions based on this analysis, because of the relatively small sizes of our two groups we feel it will validate our results of the mixed repeated measures ANOVA between the groups. We will use intent-to-treat analyses, using standard assumptions for those in the intervention group lost to follow-up. We will have .88 power to detect a medium effect size (f=.25) for repeated measures ANOVA (assuming r = .5 for outcomes over time) and .8 power to detect a medium effect size (f2 =.15 or the equivalent of partial R = .36) with three predictors for multiple regression. We will also compute effect sizes for use in future power analyses.

During Aim 3, we will also recruit a small number of individuals (10 total across study sites, 5 in Richmond) who report discrimination from religious organizations on the baseline assessment to participate in 60-90 minute qualitative interviews assessing those experiences. These will be digitally recorded and transcribed for qualitative analysis, similar to Aim 1. All protections used in Aim 1 will also be used here. The qualitative interview guide has been uploaded.

8. * **The IRB only reviews research procedures, so differentiate which of the study procedures are:**

   a. Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study).
   b. Alterations of routine procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.).
   c. Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
   As part of the intervention, representatives from TGW-friendly organizations will come to sessions to give presentations on their organizations and their available services. The content of these presentations will be at the discretion of the organizations' representatives and will not be driven by the intervention's protocol. These presenters would not act as representatives of the study, only representatives of their respective organizations, and would not have any further involvement in the delivery of the intervention or other aspects of the study. Thus, they are not considered to be engaged members of personnel.

   All of the other procedures described are performed exclusively for research purposes.

9. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
   Participants would have the option of not participating. Individuals would not be able to participate in the Aim 3 intervention test without participating in the research.

10. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

    Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

    Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

ID: MS8_HM20011245 View: SF2 - Project Details

Project Details

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
   - [x] **Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations**
   - [ ] Deception ((misleading participants through false or incomplete information)
   - [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
   - [ ] Placebos

- [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, and HUDs used in clinical investigations
- [ ] Washout Periods
- [ ] Expanded Access - Treatment Use of an Investigational Product
- [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
- [ ] Specimen/biological sample collection
- [ ] None of the Above

2. * **Select all of the following types of interactions that apply to this study (selections will branch):**
   - [ ] Passive Internet data collection (i.e. passively observing online behavior)
   - [x] **Active Internet data collection (i.e. using the internet to interact or intervene directly with research participants)**
   - [x] **Audio / Video recording or photographing participants**
   - [ ] Observations
   - [ ] Educational Settings/Assessments/Procedures
   - [x] **Interviews / Focus Groups / Verbal responses to questions**
   - [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
   - [ ] None of the Above
3. * **Select all types of recordings that will be made:**
   - [x] **Audio**
   - [ ] Video
   - [ ] Photographs
4. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**
   For Aim 1, we will conduct qualitative interviews of TGW and also professionals working in financial organizations as well as professional staff working with TGW governmental or nongovernmental organizations.

   For the TGW, this will include personal questions about sexual behavior, transactional sex, gender transition experiences, and discrimination.

   For Aims 2 (pilot) and 3, we will record intervention sessions for the purpose of quality control -- i.e., ensuring facilitators are adherent to the intervention protocol.
5. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**
   - [ ] Protected Health Information (PHI)
   - [ ] Secondary data/specimens NOT from a research registry or repository
   - [ ] Information/specimens from a research registry or repository (Usage Protocol)
   - [ ] Information/specimens originally collected for a previous research study
   - [ ] Publicly available information/specimens
   - [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
   - [x] **No secondary data/specimens will be used**

Behavioral Intervention Details

1. * **Describe the duration of the social/behavioral intervention:**
   For Aim 2, we will seek feedback on our proposed intervention from
   community advisory board members and will conduct a pilot test of our microeconomic intervention. This would be conducted in brief / accelerated form. We anticipate a total of 12 hours, spread out over 3 consecutive days (4 hours / day).

   After the Aim 2 pilot test of the intervention, we made modifications to the treatment manual based on feedback from the Aim 2 participants.

   Module 1 - Resources in Richmond
   Module 2 - Employment Readiness
   Module 3 - Personal Finance
   Module 4 - Gender Transition
   Module 5 - HIV Prevention

   Note that due to the heavy formatting of Module 4, it has been uploaded as a separate attachment.

2. * **Describe any potential harms or discomforts that participants could experience during the intervention:**
   Some modules will discuss topics that may be sensitive, including discrimination experiences and sexual behavior. It's possible that a participant could be uncomfortable discussing some of these experiences. We have conducted research on these topics with transgender men and women in Richmond since 2011 and in our experience, these topics have a low likelihood of leading to discomfort.

   Given the group nature of the intervention, it's not possible to guarantee confidentiality. We will take steps, such as establishing ground rules about confidentiality, that could reduce this concern; however, it is not possible to guarantee that participants will not share information outside of the group. Of course, participants are not obligated to discuss material that they wish to keep private. They have a right to skip a question which will also be formally included as a ground rule.

3. * **Will the intervention be physically invasive or painful?**
   ○ Yes
   ● **No**

4. * **Describe the impact the intervention will have on participants, including the nature and duration of any impact(s):**
   The intervention could have the effect of increasing participant knowledge regarding all of the topics discussed in the intervention, as noted above (e.g., Resources in Richmond, Employment Readiness, HIV prevention, etc.). Increased knowledge could result in some participants taking steps to improve their employment situation, or improve their health behaviors, although that is not guaranteed.

   Participants randomized to the active intervention will also receive financial assistance for workforce participation and gender transition. Specifically, we will institute an employment assistance program, which will offset part of a participant's wages. For this program, we will partially fund (offsetting $3/hour for up to a 40 hours/week) an 8-week period during which participants would be hired on a temporary basis so employers have an opportunity to evaluate the participants work. The goal with this approach is that some employers will hire participants after the end of the 2 months. So, employers would hire a participant at the normal starting wage and we would pay the employer $3/hour for every hour the participant works up to 40 hours a week for up to 8 weeks. Note that this is directly paid to the employer rather than the participant. We will also provide up to $300 for gender transition vouchers. These could be used for any reasonable gender-transition expenses, including wigs, weaves, laser hair removal, gender appropriate clothing or accessories, etc.

5. * **In the investigator's opinion, is there any reason to think that the participants will find the intervention offensive or embarrassing? Explain why or why not.**
   Whenever topics like discrimination, HIV, or sex are discussed there is some potential for embarrassment or being upset.

   In our experience, trans women in Richmond are generally comfortable with these topics.

   We've collected data including both survey data and detailed qualitative interviews from over 250 transgender adults in Richmond since 2011, including data on sex and discrimination, with no adverse events reported.

   Participants in the Aim 2 pilot test generally had very positive reactions to this material.

ID: MS8_HM20011245 View: SF2 - Active Internet Data Collection

Active Internet Data Collection

1. * **Describe the platform/technology chosen for collecting the data and transmitting data securely over the internet. Give the rationale for selecting this technology.**
   The screening survey will use Qualtrics. These individuals will be recruited in person and will take a survey on a password protected VCU tablet computer or will be sent a link to the survey after contacting us via email or Facebook messenger. Qualtrics is a platform recommended by VCU computing services because it has the needed security protections.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   Some participants, if they choose, will provide their first name and contact information. We need this information to recruit them for the Aim 3 test of the intervention. Data will be linked in the short term, but will be downloaded and delinked thereafter.

3. * **Is there an alternative method for completion of the data collection other than the internet?**
   - ○ Yes
   - ● **No**

4. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
   Participants can skip any question they choose to skip. Skipping some questions (e.g., age) may result in them not being eligible.

5. **If not including children, describe any procedures used to verify that research participants are adults.**
   We will be recruiting them in person and online. For individuals recruited in person, we will not ask for official proof of age (e.g., driver's licenses) but generally should be able to distinguish between adults and children. The screening survey asks participant's age. Individuals who enter an age under 18 will be ineligible and will immediately be routed out of the survey (i.e., answering no questions other than their age).

ID: MS8_HM20011245 View: SF2 - Costs to Participants

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - ☑ **Participants will have no costs associated with this study**
   - ☐ Study related procedures that would be done under standard of care
   - ☐ Study related procedures not associated with standard of care
   - ☐ Administration of drugs / devices
   - ☐ Study drugs or devices
   - ☐ Other

2. * **Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.**
   There will be no costs associated with the study other than time and transportation.

ID: MS8_HM20011245 View: SF2 - Compensation

Compensation

1. * **Describe any compensation that will be provided including:**
   1. **total monetary amount**
   2. **type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)**
   3. **how it will be disbursed**

Participants will be compensated $5 cash for completion of the screening survey (for all 3 Aims). Participants recruited in person will be paid $5 cash. Participants recruited online or via email will have the option of receiving a $5 gift card sent to their email address. Our psychology department fiscal staff have obtained permission in this study for TGW participants to indicate they received the $5 by only providing a first name and a signature. No other information will be needed (e.g., last name, address, social security number).

Eligible TGW who participate in the Aim 1 qualitative interviews will be compensated $50 cash (interviews are expected to take 90-120 minutes). We may provide resources for transportation costs by providing a bus pass or Uber credit (comparable to a gift card). Other key informants (NGO staff, community financial partners) who participate in the Aim 1 qualitative interviews will be paid $25 cash.

Eligible individuals who participate in the Aim 2 pilot testing of the intervention will be compensated $15 / hour. We anticipate that the pilot test will take 12 hours, so that would be $180 total compensation.

For Aim 3, eligible individuals will complete assessments at baseline, 3 months post-intervention, 6 months post-intervention, and 9 months post-intervention. Graduated incentives will be used: $20 for the baseline assessment, $25 for the 3-month assessment, $30 for the 6-month assessment, and $35 for the 9-month assessment. In addition, individuals who complete all 4 assessments will receive a $50 bonus. (maximum compensation = $160).

For Aim 3, we will ask for both subjective (self-report) and objective indicators of economic and behavioral vulnerability to HIV. Objective indicators for economic vulnerability will include verification of employment, income, housing stability, and savings. Participants will be asked to show a copy or image of a recent pay stub, lease, and bank statement. We will also conduct home visits to verify stable living arrangements and will have information from employers (e.g., hours for participants who are employed through the employment assistance program. Objective indicators for behavioral vulnerability will include verification of HIV testing, verification of linkage to care, verification of enrollment in PrEP (for HIV- participants) and verification of a current prescription for ARVs (for HIV+ participants). Participants will be asked to show a copy or image of a recent physician visit statement or receipt, HIV test result, and/or medication label. Pill counts will be used to assess adherence to biomedical prevention approaches.96-98 Participants will be prompted in advance to bring objective indicators to the assessments but it will also be possible for them to provide information afterwards (e.g., by taking a photo of a bank statement or prescription label and texting it to the project or during a home visit).

For Aim 3, all participants will be randomized to one of two groups: (1) Minimal treatment control group and (2) Full intervention group.

For Aim 3, individuals randomly assigned to the minimal treatment control group will receive an abbreviated version of the intervention, without the microeconomic components (employment assistance program, gender transition vouchers), in a 3 day workshop (4 hours per day). They will be compensated $15/hour (so $180 total if they attend 12 hours).

For individuals randomized to the full intervention (Aim 3), in order to increase the likelihood that the intervention is received at the intended dosage (15 hours), participants will be paid $15/hour for their participation. The intervention is designed to be delivered over 6 days with 2 1/2 hour sessions per day, for a total of 15 hours. Participants that attend 15 hours would receive $225. Participants will also receive up to $300 in gender transition vouchers. Some intervention modules include homework: creating a budget, creating a resume, obtaining a professional-sounding email, creating a professional sounding voicemail. For each intervention group, participants who complete the homework for that session will have their name entered into a raffle for a $20 gift card to a local vendor of the group's choosing.

We will also provide a meal at interventions sessions and may provide financial assistance for transportation costs.

For the employment assistance program, we will partially fund (offsetting $3/hour for up to a 40 hours/week) an 8-week period during which participants would be hired on a temporary basis so employers have an opportunity to evaluate the participants work. The goal with this approach is that some employers will hire participants after the end of the 2 months. So, employers would hire a participant at the normal starting wage and we would pay the employer $3/hour for every hour the participant works up to 40 hours a week for up to 8 weeks. Note that this is directly paid to the employer rather than the participant.

In addition, during Aim 3, we will recruit a small number (N = 10 total, 5 in Richmond) of participants who report discrimination from religious communities to participate in a qualitative interview. This will last around 60-90 minutes and will ask about discrimination in religious settings. Individuals who participate will receive $50.

2. **If compensation will be pro-rated, explain the payment schedule.**
   For Aim 3, compensation for assessment completion will be prorated with 50% for completion of the subjective indicators, and 50% for completion of the objective indicators.

3. * **Will Social Security Numbers be collected for compensation purposes only?**
   - (●) **Yes**
   - ( ) No

ID: MS8_HM20011245 View: SF2 - Research Plan Complete

Research Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS8_HM20011245 View: SF2 - Consent Process

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
View	Aim 2 pilot test	Written/Signed Consent by Participant	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant		Immediately prior to the first intervention session. The basics of the process will be provided over the phone prior to participants being scheduled for the first session.	Participants will have decided based on a phone conversation to participate and will be free to change their minds once they arrive for the session.	We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.	
View	Screening	None of the	Waiver of	Principal		In	The	As much	N/A

	survey - Aim 2	Above (select waiver below)	Documentation of Consent/Assent (not signed)	Investigator Co/Sub-Investigator Research Coordinator Research Assistant	community settings where TGW are recruited (e.g., clinics) or online.	incentive is quite modest $5. We will be friendly rather than coercive in our approach.	time as is practical which will depend on the setting, the time of day (e.g., if approached right as the clinic opens could be several hours, if approached shortly before the clinic closes could be a shorter period), and how long we will be recruiting in the setting. We will ensure each participant has at least 15 minutes to make a decision.
View	Aim 1 Qualitative Interview - Key Informants	None of the Above (select waiver below)	Waiver of Documentation of Consent/Assent (not signed)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant	In person, prior to the interview.	These will be professionals either (a) working with the TGW community or (b) providing economic services to individuals in the area. Interviews will be arranged by phone ahead of time. It's unlikely that such an individual would feel coerced to participate. They will be free to change their minds once they arrive for the session.	They will be contacted by phone prior to the interview and will given as much time as they need to make a decision--for example, the in-person interview will be scheduled in the future. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.
View	Aim 3 intervention	Written/Signed Consent by Participant	No Waivers Requested	Principal Investigator Co/Sub-Investigator	Immediately prior to the first intervention session. The	Participants will have decided based on a phone	We will contact them within a day or two of them

				Research Coordinator Research Assistant	basics of the process will be provided over the phone prior to participants being scheduled for the first session.	conversation to participate and will be free to change their minds once they arrive for the session.	screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.	
View	Aim 1 Qualitative Interview - transgender participants (consent form is for both previously vulnerable and currently vulnerable)	None of the Above (select waiver below)	Waiver of Documentation of Consent/Assent (not signed)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant	In person, for individuals who screened as eligible. Discussion of the research activities will occur over the phone prior to setting an appointment to meet with the person. Informed consent will occur at the in-person session, generally immediately prior to conducting the interview.	Participants will have decided based on a phone conversation to participate and will be free to change their minds once they arrive for the session.	We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.	
View	Qualitative interview assessing religious discrimination (conducted during Aim 3)	None of the Above (select waiver below)	Waiver of Documentation of Consent/Assent (not signed)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant	In person, for individuals who screened as eligible and indicated interest in participating. Discussion of the research activities will occur over the phone prior to setting an appointment to meet with the person. Informed	Participants will have decided based on a phone conversation to participate and will be free to change their minds once they arrive for the session.	We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if	N/A

	consent will occur at the in-person session, generally immediately prior to conducting the interview.	they need it.

2. Upload any consent / assent documents:

ID: MS8_HM20011245 View: SF2- Waiver of Documentation of Consent

Waiver of Documentation of Consent

Consent groups that require a waiver of documentation (i.e. consent form not signed):

Group	Types	Waivers	Roles	Roles - Other	Consent	Decision	Status Change
Qualitative interview assessing religious discrimination (conducted during Aim 3)	None of the Above (select waiver below)	Waiver of Documentation of Consent/Assent (not signed)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant		In person, for individuals who screened as eligible and indicated interest in participating. Discussion of the research activities will occur over the phone prior to setting an appointment to meet with the person. Informed consent will occur at the in-person session, generally immediately prior to conducting the interview.	We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.	N/A
Aim 1 Qualitative Interview - Key Informants	None of the Above (select waiver below)	Waiver of Documentation of Consent/Assent (not signed)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant		In person, prior to the interview.	They will be contacted by phone prior to the interview and will given as much time as they need to make a decision--for example, the in-person interview will be scheduled in the future. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.	
Aim 1 Qualitative Interview - transgender participants (consent form is for both previously vulnerable and currently vulnerable)	None of the Above (select waiver below)	Waiver of Documentation of Consent/Assent (not signed)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant		In person, for individuals who screened as eligible. Discussion of the research activities will occur over the phone prior to setting an appointment to meet with the person. Informed consent will occur at the in-person session, generally immediately prior to conducting the interview.	We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.	

Screening survey - Aim 2	None of the Above (select waiver below)	Waiver of Documentation of Consent/Assent (not signed)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant	In community settings where TGW are recruited (e.g., clinics) or online.	As much time as is practical which will depend on the setting, the time of day (e.g., if approached right as the clinic opens could be several hours, if approached shortly before the clinic closes could be a shorter period), and how long we will be recruiting in the setting. We will ensure each participant has at least 15 minutes to make a decision.	N/A

1. * **Select which of the following applies to the consent groups used in this study:**
   - ☐ (1) The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern
   - ☑ **(2) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context**
   - ☐ (3) The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

2. * **Explain how your selection above applies to this study:**
   Our intent is to make the screening survey anonymous for those who choose to remain anonymous (i.e., they will not be required to give us any identifying information). Given that we will be assessing private information (e.g., sexual behavior), having them provide a name on a consent form would appear to increase their risk. The screening survey will ask them questions about their demographic information, income, housing, and HIV risk behaviors which present no more than minimal risk of harm. Individuals who are members of groups that are at high risk of HIV, such as TGW, have become accustomed to answering questions of this sort. Many of the items in the screening assessment were used previously in our pilot work approved by this IRB, with no adverse events reported. The screening form has been reviewed by our Community Advisory Boards and they consider these items to not be invasive for this group.

ID: MS8_HM20011245 View: SF2 - Consent Plan Complete

Consent Plan Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS8_HM20011245 View: SF2 - Risks, Discomforts, Potential Harms and Monitoring

Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**

- **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
- **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
- **Research data risks (e.g. loss of confidentiality and privacy)**
- **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
- **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
- **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

See the help text for additional guidance.

Potential risks to participants in this study are negative consequences if confidentiality of information obtained in the study (including participant identity as a research participant) were violated; embarrassment, discomfort, or emotional distress in response to study assessment measures and/or sensitive discussion topics, including personal sexual behavior, substance use, past experience of discrimination or violence, and participation in transactional sex; and increased anxiety concerning HIV and personal vulnerability to HIV and other sexually-transmitted infections. We believe the steps outlined above will minimize these risks.

The PI has collected comparable information from more than 8,000 research participants (including over 200 TGW) with no adverse events reported.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
All study personnel will complete training in the ethical conduct of research with human participants. In addition to insuring that all study personnel are well-versed in research ethics, we will protect against specific risks as follows.

Confidentiality. A number of steps will be taken to protect the confidentiality of participant data and identity. The investigators have extensive experience in the safe collection, handling, and storage of sensitive and highly confidential data. All data and other project-related information will be stored in offices in locked file cabinets or password-protected computer files. Access to these files will be limited to project staff.

Screening: In person recruitment and screening will be undertaken in areas where participants naturally gather, and thus they will not be asked to present themselves to a research center or other setting that could identify them as participating in an HIV-related research study. Individuals recruited online can access the screening assessment from a private space of their choosing. We will obtain a waiver of written documentation of informed consent for individuals completing the screening survey, consistent with our pilot work. Efforts will be made to ensure that the participant has an opportunity to complete the screening survey privately (e.g., if recruited in a community setting such as a club they will be asked to move to an empty table away from other customers). Screening will be completed anonymously but individuals who screen as eligible will be invited to attend a session to complete a qualitative interview (Aim 1), pilot of the intervention (Aim 2) or baseline assessment (Aim 3) and will be asked to provide contact information.

Participants in the research setting: Individuals participating in the Aim 1 qualitative interviews and aims 2 and 3 intervention groups will be asked to come to VCU or a participating NGO, but steps will be taken to insure that they can preserve their privacy when doing so (e.g., will be immediately escorted to the room where the interview or intervention will occur rather than being asked to wait in a waiting room).

Informed consent: At each stage of the study, study staff will provide a verbal and written description of the study using language comparable with our prior work and approved by the relevant IRBs. Participants will be given an opportunity to keep a blank copy of the informed consent forms which will contain contact information, including phone number and email, for the site PIs. Study personnel will answer any questions participants have. We will stress that participants can decline to answer any question and can withdraw from the study at any time. For the screening survey and Aim 1 qualitative interviews we will collect contact information (e.g., first name, phone #, email address) but will obtain a waiver of written documentation of informed consent, consistent with our pilot work. . We will also collect signed consent forms from participants in the Aim 2 and Aim 3. Signed consent forms will be stored in a locked filing cabinet in the site PI's research space.

Personally identifying information: Due to the longitudinal nature of the Aim 3 RCT, we will collect comprehensive tracking information, including name, address, phone number, email address, social media account information (e.g., Facebook, Instagram, Twitter, Tumblr) and contact information for individuals who would know how to reach the participants (e.g., friends, family, health care providers, emergency shelter staff). Participant identifying information will be stored on password-protected computers or in locked filing cabinets in the site PI's locked research space and will only be accessible by study personnel.

Handling of audio files: The aim 1 qualitative interviews will be digitally recorded audio files. Files will be downloaded from the portable digital recorder at the end of each day to a password-protected computer in the site PI's locked lab space. Files will be backed up and the original digital audio files will be erased from the portable digital recorders. The digital audio files of the Aim 1 qualitative interviews will be transcribed by VCU undergraduate research assistants (RAs). RAs will create transcripts but will insert placeholders for proper names (e.g., "and then [proper name] said she wasn't going to do that"). The transcripts will be verified for accuracy by the graduate RAs who conducted the interview by comparing to their notes and the audio files. Graduate RAs will also check to ensure that proper names and other identifying information have been removed from the transcripts. Comparable processes were used to create transcripts of the focus groups conducted during our pilot work. Digital audio files will also be recorded as an adherence check for the Aim 2 pilot intervention sessions and the Aim 3 RCT. Files will be downloaded from the portable digital recorder at the end of each day to a password-protected computer in the site PI's locked lab space. Files will be backed up and the original digital audio files will be erased from the portable digital recorders. The audio files will be reviewed by site PIs as described in the approach and feedback will be provided as needed.
All audio files will be deleted at the end of the study.

Handling of quantitative data: All participant data stored data collection or data analysis software will be identified by a 3 digit code. Only the PIs and study coordinators will have access to the master file linking participant names with data codes. Computers storing this information will be password protected.

Handling of objective indicators of economic and behavioral vulnerability. As part of the assessment strategy for Aim 3, we will ask participants to show us objective indicators of their economic circumstances and participation in biomedical prevention approaches. This will include verification of employment, income, housing stability, savings account balances, HIV testing, and of linkage to care. We will ask participants to show us a copy of a recent pay stub, their current lease, a bank statement, copies of recent physician visit statements/receipts, HIV test result, or medication labels. Information from these objective indicators will be entered on a data form that records the pertinent details as shown below:

Pay stub: Name of employer, dates worked, hours worked, income
Lease: Home address, beginning and end date of lease
Bank statement: Name of bank, type of account (checking or savings), date of statement, account balances
Physician visits: Name of physician, date of appointment
HIV test result: Date of test, test result
Medication labels: Name of medication, date prescription was filled

On the data form, participants will be identified by their study code. Once the information is recorded, these materials will be returned to the participants. Participants will be reminded in advance to bring objective indicators to the assessment sessions but it will also be possible for them to provide information afterwards (e.g., by taking a photo of a bank statement or prescription label and texting it to the project). If a participant sends us an image of a document, the information will be recorded and then the image will be deleted.

Emotional distress associated with topics discussed. The assessment procedures will involve sensitive and explicit topics related to sexual behavior, discrimination, substance use, and violence. This is required, given the nature of the behaviors that confer risk for HIV and other STD transmission and the lived experiences of TGW. We anticipate few negative reactions to the materials and procedures. However, it is possible that some participants will feel embarrassed, awkward or anxious when describing, reporting, or discussing private behaviors. The consent procedure informs participants that these topics will be explicitly covered and could cause some embarrassment or discomfort. We will also take steps to insure that conversations by study staff are appropriately and sensitively delivered to participants in order to minimize any potential distress these messages might cause. When completing automated assessments, participants will be able to ask questions of a staff person while completing the assessment, and will also be given contact information for the site P.I., including e-mail and phone number. Staff will be trained to respond to any participant indicator of distress or embarrassment. The investigators will also be available to consult with participants who experience distress as a result of their participation in the study. We anticipate few occurrences of such problems, but will have procedures in place to handle potential adverse reactions. We conducted both qualitative assessments (focus groups) and quantitative assessments comparable to those proposed in the present application during our pilot and did not have any adverse events.

Anxiety associated with vulnerability to HIV. As a result of study participation, some participants may experience increased anxiety concerning their vulnerability to HIV. Realistic sensitization and accurate appraisal of personal vulnerability to HIV are beneficial in motivating behavior change. The study staff will be experienced in presenting material in ways that link personal risk to avoidable behaviors and risk reduction to the adoption of safer behaviors. Staff will be trained to respond to any participant indicator of emotional distress. Study investigators will consult on the handling of any such problems, including talking individually with participants. Study staff will also be prepared to refer participants for additional HIV information, HIV testing and related services, and mental health services in their local area.

Monitoring and supervision of personnel: All interviews, assessments, and intervention procedures will be conducted by graduate students or professional staff familiar with the study population. Research and NGO recruitment staff will receive initial training and continuing education and supervision in areas related to the ethical conduct of research,

confidentiality protection, and other topics of human participant protection.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
We believe this to be unlikely. As noted in the significance section, TGW are disproportionately affected by HIV, substance use, mental health problems, and report high rates of engagement in transactional sex including commercial sex work. This is well documented. Our hypothesis is that these risk behaviors are frequently due to economic hardship caused by structural barriers such as discrimination in employment and housing. If changing the financial status of TGW results in reduced risk behaviors, the effect could be de-stigmatizing.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
As noted above, one aspect of the intervention is information/education on biomedical treatments for preventing HIV transmission. These include pre-exposure prophylaxis (PrEP) for HIV-negative participants and anti-retroviral (ARV) regimens for HIV-positive participants. We will encourage HIV testing and PrEP enrollment for our HIV-negative participants and ARV regimens for HIV-positive participants. For both groups, we will provide information and attempt to link them to care with LGBT-friendly service providers. We will also make referrals to LGBT-friendly medical or psychological providers as needed for other needs.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
If a participant is a danger to herself or others we will take appropriate action, including referral for mental health treatment if warranted. Such individuals may be withdrawn from the study.

   If a participant is not complying with the ground rules for the intervention (e.g., repeatedly disrespecting or violating the confidentiality of other participants) she could be administratively removed from the study. We consider these events unlikely . These determinations will occur on a case-by-case basis.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
We do not have pre-specified criterai for stopping or changing the study protocol. However, as this is an intervention development grant and the final intervention utilized will be informed by prior research (e.g., Aim 1 will inform Aims 2 and 3, Aim 2 will inform Aim 3), we may develop pre-specified criteria if we believe it is appropriate to do so. If we develop such criteria, we will inform the IRB and seek approval.

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

   The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
   - Participant safety (physical, psychological, etc.)
   - Data validity
   - Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**
   - ☐ DSMB
   - ☑ **DSMP**
   - ☐ No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

8. * **Describe your Data Safety Monitoring Plan for monitoring the study's data to ensure the safety of participants. This plan should include (but is not limited to) the following elements:**
   1. Who will monitor data
   2. What data and/or processes will be reviewed
   3. When and how frequently monitoring will occur
   4. What report/documentation will be submitted to the IRB at the time of continuing reviews

   See the help text for additional guidance.

   A Serious Adverse Event (SAE) occurs when any one of the following events happens to a participant enrolled in our research protocol and is brought to the attention of anyone involved with the project: (1) death, (2) life-threatening injury or illness, (3) serious but not life-threatening injury or illness, or (4) participant becomes an immediate risk to the safety of self or others. If project staff become aware than any of these situations have occurred, we will report the

event as described below.
Within 48 hours of becoming aware of an SAE, we will report the event to the Virginia Commonwealth University and University of Missouri-St. Louis Institutional Review Boards as well as the NIH project officer for the study. The report will include a description of the SAE, including date, full chronology of the event based on information available to us, a determination of whether the SAE is related to the study procedures, the steps taken by our staff and/or others to address the SAE, an estimate of the likelihood of the recurrence of the SAE both for the participant and for other study participants, and a discussion of whether the event resulted in new information that indicate that the study procedures should be changed.

In addition to the immediate report of SAEs as described above, we will report any other (i.e., non-serious) adverse events on an annual basis to the Virginia Commonwealth University and University of Missouri-St. Louis Institutional Review Boards as well as the NIH project officer for the study. These steps for reporting SAEs and other adverse events are consistent with our IRB requirements for reporting adverse events.

These data will be monitored by the PIs on an ongoing basis (at least monthly). We will monitor especially for adverse reactions to study materials or procedures and withdrawal from the study. We will report any adverse events and withdrawal from the study to the VCU IRB at continuing review.

ID: MS8_HM20011245 View: SF2 - Privacy

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

1. * **Describe how the research team will protect participants' privacy throughout the course of the study. Address privacy in the context of the following research activities as applicable:**

   - Identification of potential participants or secondary data/specimens of interest
   - Recruitment and screening activities
   - The informed consent process
   - Conduct of the study procedures
   - Data dissemination

   See the help text for additional guidance.
   In-person recruitment will be conducted in environments where it will be likely to find TGW, including transgender health clinics, community events (e.g., ball celebrations), meetings at our partner NGOs, and commercial sex work areas. This is consistent with our prior work approved by this IRB. Individuals present in those environments will be eligible to complete the screening, including individuals who are not TGW (those individuals will be ineligible). Individuals who screen eligible will be asked if they are interested in participating in the larger study (Aims 1, 2, and 3) and, if so, will be asked to provide their first name and contact information (phone # and email address). In addition, individuals may contact us after learning of the study from the flyer, or Facebook page, or after receiving an email with the flyer from one of our community partners.

   Individuals who screen eligible will be contacted by study staff via phone, email, or social media messaging service, who will explain the purpose of the study, and ask them to come in for the consent and study procedures which will be conducted in private settings. Individual interviews (Aim1) will be conducted in a private setting. Intervention sessions (Aims 2 and 3) will be conducted in group settings in a private space at one of our community partners. No identifying information will ever be included during data dissemination (e.g., publications). We will obtain informed consent for audiorecording and other study activities.

Individuals completing the screening process will be asked to move to a more private location (e.g., away from other individuals who might be present in that setting) to maximize privacy. All Aim 1 interviews will be conducted in a private room.

All Aim 2 and Aim 3 sessions will be conducted in a private room where only the facilitators, study personnel, and participants are present.

ID: MS8_HM20011245 View: SF2 - Data Confidentiality and Storage

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared.

1. * **Specify where this study's paper and electronic research data and/or physical specimens will be stored and how they will be secured from improper use and disclosure.**

   See the help text for additional guidance.

   Potential risks to participants in this study are negative consequences if confidentiality of information obtained in the study (including participant identity as a research participant) were violated.

   We believe that the steps described below will minimize these potential risks.

   All study personnel will complete training in the ethical conduct of research with human participants. In addition to insuring that all study personnel are well-versed in research ethics, we will protect against specific risks as follows.

   Confidentiality. A number of steps will be taken to protect the confidentiality of participant data and identity. The investigators have extensive experience in the safe collection, handling, and storage of sensitive and highly confidential data. All data and other project-related information will be stored in offices in locked file cabinets or password-protected computer files. Access to these files will be limited to project staff.

   Screening: Initial recruitment and screening will be undertaken in areas where participants naturally gather, and thus they will not be asked to present themselves to a research center or other setting that could identify them as participating in an HIV-related research study. We will obtain a waiver of written documentation of informed consent for individuals completing the screening survey, consistent with our pilot work. Efforts will be made to ensure that the participant has an opportunity to complete the screening survey privately (e.g., if recruited in a community setting such as a club they will be asked to move to an empty table away from other customers). Screening will be completed anonymously but individuals who screen as eligible will be invited to attend a session to complete a qualitative interview (Aim 1), pilot of the intervention (Aim 2) or baseline assessment (Aim 3) and will be asked to provide contact information.

   Participants in the research setting: Individuals participating in the Aim 1 qualitative interviews and aims 2 and 3 intervention groups will be asked to come to a participating NGO, but steps will be taken to insure that they can preserve their privacy when doing so (e.g., will be immediately escorted to the room where the interview or intervention will occur rather than being asked to wait in a waiting room).

   Informed consent: At each stage of the study, study staff will provide a verbal and written description of the study using language comparable with our prior work and approved by the relevant IRBs. Participants will be given an opportunity to keep a blank copy of the informed consent forms which will contain contact information, including phone number and email, for the site PIs. Study personnel will answer any questions participants have. We will stress that participants can decline to answer any question and can withdraw from the study at any time. For the screening survey we will collect contact information (first name, phone #) but will obtain a waiver of written documentation of informed consent, consistent with our pilot work.

   All eligibility criteria will be determined by participants' self-report via a computer-administered screening tool. When recruitment is conducted in person, the screening survey will be completed using a password protected tablet computer (e.g., iPad). We anticipate using only in-person recruitment for Aim 1. If we expand beyond in-person recruitment for Aims 2 and 3, we will seek IRB approval for additional recruitment methods.

Data collected during the screening survey will be downloaded each night after the end of participant recruitment. At that point, the screening survey data will be de-coupled from the participant identifiers. That is, a separate file will be created with contact information but will be separated out from the answers to the screening survey questions. Digital files will be stored on a password-protected computer.

We will also collect signed consent forms from participants in the Aim 2 and Aim 3. Signed consent forms will be stored in a locked filing cabinet in the site PI's research space.

A certificate of confidentiality has been issued for this award.

Personally identifying information: Due to the longitudinal nature of the Aim 3 RCT, we will collect comprehensive tracking information, including name, address, phone number, email address, social media account information (e.g., Facebook, Instagram, Twitter, Tumblr) and contact information for individuals who would know how to reach the participants (e.g., friends, family, health care providers, emergency shelter staff). Participant identifying information will be stored on password-protected computers or in locked filing cabinets in the site PI's locked research space and will only be accessible by study personnel.

NIH now automatically issues a certificate of confidentiality for all studies, including this one, that collect or use identifiable sensitive information as a term or condition of the grant award.

2. * **Who will have access to study data?**
   Study PI and co-investigators, graduate RAs. Undergraduate RAs will type transcripts of digital recordings.

3. * **If research data that contains any of the 18 HIPAA identifiers will be released to person(s) or group(s) outside of the VCU study team, identify the data recipient(s) along with their institutional or organizational affiliation(s).**
   We do not intend to release identifying information to persons or groups outside of the VCU Study team, except as required by the IRB and/or funder.

4. * **Select all identifiers that will be collected as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**

- [x] **Names**
- [x] **Geographic Locators Below State Level**
- [x] **Social Security Numbers**
- [ ] Dates (year alone is not an identifier)
- [ ] Ages >89
- [x] **Phone Numbers**
- [ ] Facsimile Numbers
- [x] **E-mail Addresses**
- [ ] Medical Record Numbers
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [x] **Other Unique Identifier**

- [ ] No Identifiers
- [ ] Employee V#

5. **If "Other Unique Identifier" was selected above, describe the identifiers:**
   Social Media Account information (e.g., Facebook, Twitter), contact information for individuals who would know how to reach the participant.

6. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names with assigned subject IDs, explain the following aspects of the coding process:**

   - The process for how subject IDs will be generated/assigned (e.g. random, sequential)
   - Whether there will be a key that links the subject ID with direct identifiers.

   If a key will be created, describe
   - The place where the key will be stored
   - The role(s) of all individuals who will have access to the key
   - When the key will be destroyed
   ?
   See the help text for additional guidance.

   For Aim 1 a code will be created for each participant. For the screening survey, we will start with a number (e.g., 101) and then number each participant with consecutive numbers (e.g., 101, 102, 103). A similar process will be used for the interviews.

   For Aim 2, a code will be created for each participant.

   For Aim 3, a code will be created for each participant.

   A key will be created with the tracking information and the participant code. This will be a separate file stored on encrypted computers and a hard copy will be kept in a locked cabinet in the PI's research space. Only the PI and co-investigators will have access to the codes. The key will be destroyed after the end of the study.

ID: MS8_HM20011245 View: SF2 - Data Retention

Data Retention

1. * **Select all of the ways information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - [ ] Immediately destroy the information
   - [ ] Store until the end of study & then destroy
   - [x] **Use as "screening failure" data by members of the study team**
   - [ ] Provide to others outside of the research team (with the participant's permission)
   - [ ] Request permission from participant to maintain the information
   - [ ] Other
   - [ ] N/A - study does not require screening procedures

2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No - see help text)**
   - (●) **Yes**
   - ( ) No

3. **If Yes , describe the process (oral, written, email, letter, etc.) that participants should use to request withdrawal of their data/specimens. Identify if there is a timepoint when withdrawal will no longer be an option**

and/or if the amount of data that can be withdrawn is reduced at different points in the study.
Participants will be able to withdraw their data by telling us they would like to withdraw their data -- in person, via phone, via email.

Participants will be able to withdraw their data at any point up until we have disseminated the study findings via public reporting of any type (conference presentation, article, or information posted to a research website such as clinicaltrials.gov).

4. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - (●) **Stored indefinitely with identifiers removed**
   - ( ) Stored indefinitely with identifiers attached
   - ( ) Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements
   - ( ) Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ( ) Other

5. * **Will audio/video the recordings and full face photographs be destroyed?**
   - (●) **Yes**
   - ( ) No

6. **If yes, describe at what point and how recordings will be destroyed:**
   All audio files will be deleted at the end of the study.

7. **If no, explain why the recordings need to be maintained:**

ID: MS8_HM20011245 View: SF2 - Sharing Plan

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.
   - ( ) Yes
   - (●) **No**

2. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   - ○ No - Will not obtain CoC for this study
   - ● **Yes - CoC has been obtained or issued automatically**
   - ○ Yes - CoC request is pending
   - ○ Yes - Plan to submit request for CoC and will amend study/ICF once status of request is known

3. * **Select the way(s) that individual-level information or biospecimens (including DNA) may be used by the VCU PI or VCU study team for other future research projects (i.e. analyses beyond/apart from the aims of this study)?**
   See help text for definitions.

   - ☐ Will use directly identifiable information or specimens.
     ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page)
   - ☐ Will use de-identified or indirectly identifiable information or specimens.
     ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page)
   - ☑ Will use anonymized information or specimens.
     ('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)
   - ☐ Will use aggregate results (summary-level results), not individual-level information or specimens.
     (The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)
   - ☐ Will contribute to an existing registry or repository
     (You will be asked more questions about this on a later page.)
   - ☐ Will not use information/specimens for purposes beyond this study.
   - ☐ Not sure and will submit an amendment when known
   - ☐ Other use(s) of individual-level information in a way not listed above

4. * **Select the way(s) the VCU PI/study team may share individual-level information or biospecimens (including DNA) with other researchers who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).**
   See help text for definitions.

   - ☐ Will share directly identifiable information or specimens with other researchers.
     ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. You will be asked more questions about this on a later page.)
   - ☐ Will share de-identified or indirectly identifiable information or specimens with other researchers.
     ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. You will be asked more questions about this on a later page.)
   - ☑ Will share anonymized information or specimens with other researchers.
     ('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject

research, but the recipient should check with their own IRB about review requirements.)

- ☐ Will only share aggregate results (summary-level results), not individual-level information or specimens. *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)*
- ☐ Will contribute to an existing registry or repository (You will be asked more questions about this on a later page.)
- ☐ Will submit data to an NIH genomic data repository (You will be asked more questions about this on a later page.)
- ☐ Will not share information/specimens with other researchers.
- ☐ Not sure and will submit an amendment when known
- ☐ Other sharing of individual-level information with other researchers

5. * **Since you responded in a question above that you may use or share anonymous, individual level data, indicate why the proposed use or sharing of anonymous data/specimens is not inconsistent with what participants would have reasonably understood from the consent document about the uses of their information. (Select all that apply.)**

   The consent form states that after identifiers are removed, information or specimens could be used for future research studies without additional informed consent from the subject (this is a new element of consent included in consent templates as of May 2018)

6. * **The Principal Investigator certifies that prior to releasing an anonymized dataset or anonymized specimens the following conditions will all be met:**

   - all 18 HIPAA identifiers (including all dates) will be removed;
   - all indirectly identifiable data elements (unusual, rare, uncommon data) will be removed, grouped, suppressed, or otherwise transformed to no longer be readily identifiable;
   - a different subject ID will be assigned than the one used for the main study and a linkage key will not be kept; and
   - the PI will review the dataset/specimens to confirm that the remaining information could not be used alone or in combination with any other information to re-identify the participants represented in the data.

   ***See help text for more information*.**
   Yes

7. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

   - The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
   - If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
   - The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
   - The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

   Yes

8. **If the Certificate of Confidentiality has been obtained by the PI, upload it here:**

ID: MS8_HM20011245 View: SF2 - Pertinent and Incidental Findings

Pertinent and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. disease, suicidal thoughts, wrong paternity, pregnancy, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**

- (●) **Yes**
- ( ) No

2. * **Describe any possible pertinent or incidental findings stemming from research-only procedures that may be of importance to a subject's health or well-being or which may relate to illegal or reportable activities.**
   No findings will stem from research-only procedures. Participants who have not been tested for HIV recently will be encouraged to do so. However, those tests will be administered by HIV testing personnel not formally affiliated with the research project (although it could include community partners in our research such as testing that occurs by staff at Health Brigade).

3. * **Explain what actions or procedures should research personnel take to handle such a discovery :**
   The study will assess some minor criminal behaviors, including illicit substance use and transactional sex which might include formal commercial sex work. Assessing this information is critical to the research as these are among the considerable risk factors the intervention is attempting to change. This information will be kept confidential.

4. * **Will findings be disclosed to participants and/or any other person/group outside of the study team?**
   - ( ) Yes
   - (●) **No**

5. **If pertinent and/or incidental findings will not be disclosed, explain why not:**
   I think the correct answer to this question might be N/A, since there will be no findings stemming from research-only procedures.

   Participants who choose to undergo HIV testing will have the option of finding out their test result (and will be encouraged to do so).

ID: MS8_HM20011245 View: SF2 - Risk Benefit Complete

Risk Benefit Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS8_HM20011245 View: SF2 - Populations with Special Considerations

Populations with Special Considerations

1. * **Check all participant groups that will be either**
   a) Specifically included in this study or
   b) Discernable in the research data/specimens.

   If the research is aimed at involving a broader subject population and may incidentally includes a listed population, only check the box if the participant group will be discernable in the research data/specimens. (Selections will branch)

   - [ ] Children
   - [ ] Emancipated minors

- [ ] Wards of the State
- [ ] Pregnant women or fetuses
- [ ] Neonates or Post-delivery Materials
- [ ] Prisoners
- [ ] Decisionally Impaired Adults
- [ ] VCU / VCUHS students or trainees
- [ ] VCU / VCU Health System employees
- [ ] Individuals with limited English proficiency
- [ ] Active military personnel
- [ ] Student populations in K-12 educational settings or other learning environments
- [ ] Members of a federally recognized American Indian and Alaska Native tribe
- [x] **None of the Above**

ID: MS8_HM20011245 View: SF2 - Populations with Special Considerations Section Complete

Populations with Special Considerations Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS8_HM20011245 View: SF2 - Study Funding

Study Funding

1. * **Have you applied for funding:**
   - (●) **Yes**
   - ( ) No
2. **Is this study already funded:**
   - (●) **Yes**
   - ( ) No
3. * **Select all funding sources for this study (pending or awarded):**
   - [ ] Industry

- [x] **Direct Federal**
- [ ] Indirect Federal
- [ ] State/Local Government
- [ ] Non-Profit - Sponsored Project
- [ ] Non-Profit - Gift
- [ ] Internal Grant
- [ ] Investigator/Departmental Funds
- [ ] None
- [ ] Other

4. **Select all related proposals:**

RAMS-SPOT ID# (FP/PT/PD#)	Sponsor	PI	Title	Status	Start	End
FP00006198	National Institute of Mental Health/NIH/DHHS	Eric Benotsch	Microeconomic Intervention to Reduce HIV Transmission in Economically Disadvantaged Transgender Women	Funded		

5. **If the following conditions are ALL met, provide the index code where ORSP will charge Single IRB (sIRB) fees associated with this review:**
   1. The study is externally funded (fees do not apply if the study is not funded), AND
   2. Multiple sites are executing the same research protocol (i.e. multicenter research), AND
   3. VCU IRB will provide IRB review on behalf of one or more non-VCU sites

6. * **Does the funder require the IRB to review this proposal for grant congruence?**
   - ○ Yes
   - ● **No**

ID: MS8_HM20011245 View: SF2 - Types of Sites

Types of Sites

VCU Site Information

1. * **Select all VCU sites that will be utilized in this study:**
   - [ ] Children's Hospital of Richmond at VCU
   - [ ] Clinical Research Services Unit (CRSU)
   - [ ] Massey Cancer Center
   - [ ] VCU Health Community Memorial Hospital
   - [ ] VCU Medical Center
   - [x] **VCU Monroe Park Campus**
   - [ ] VCU Qatar
   - [ ] Other VCU Site

2. * **Provide details regarding each VCU Site including:**
   - what clinics / facilities will be used
   - resources that are available for the conduct of this study
   Resources include personnel time, equipment, space, hospital beds, etc
   Data analysis will be conducted in the PI's office and lab. The office is located at 808 W. Franklin St. on the Monroe Park campus and the lab is located at 612 N. Lombardy St. on the Monroe Park campus. Data will be backed up on the VCU R drive.

Non-VCU Site Information

Non-VCU sites should be selected whenever any of the following situations apply::
a) Non-VCU sites that will be collaborating on a VCU-led study
b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
d) Non-VCU sites/locations where VCU investigators will conduct study activities

3. * **Select any of the following non-VCU sites utilized in this study:**

- ☐ McGuire VAMC
- ☐ Foreign Sites
- ☑ **Other Non-VCU Sites**
- ☐ No Non-VCU Sites

4. * **List all Non-VCU sites and locations:**

Provide information only for sites that have agreed to participate or given permission for study activities to occur.

Name	Role	Adequacy	IRB	FWA
University of Missouri-St. Louis	This is a two site study with equal research activities in community locations in Richmond and St. Louis, MO. Eric Benotsch at VCU is the lead PI. Investigators at UMSL include Sheila Grigsby, Ph.D., and Rick Zimmerman, Ph.D. All work in Aims 1, 2, and 3, will be conducted equally between both sites.	Performance Site: University of Missouri – St. Louis University: UMSL is a public metropolitan research university located in Missouri's most populous and economically diverse region. The largest University in the region, UMSL enrolls nearly 16,000 students and employs more than 1,400 full-time and part-time teaching and research faculty members. The campus has 70 academic and general purpose buildings covering over 350 acres. Research Infrastructure: Total external funding was $42.3 million as noted by the 2016 annual report, UMSL Office of Research Administration (ORA). In 2015, Academic Analytics ranked UMSL faculty scholarly productivity as 15th in the country in the category of high research activity. UMSL has in place the financial and asset management systems required to administer contracts such as the one described in this proposal. The ORA delivers services to investigators and sponsors and shares this responsibility with administrative units housed in each College or Department. It assists faculty in obtaining and administering externally funded research grants and contracts and administers internal grant programs throughout UMSL. Libraries: The University Library System provides support for graduate studies and research through collections in the five on-campus libraries including the Barnes Library and two science libraries. These libraries house over one million volumes, 300,000 photographs, one million government documents and more than one million microforms. About 15,000 full-text online periodicals are available currently. Numerous periodical indexes and full text databases may also be accessed electronically. Computer Infrastructure: Hardware and software packages are readily available and designed for faculty and students. Technical support is available at several places within UMSL including the CON which employs a full time Instructional Software expert along with three student assistants with expertise in computing hardware and software. A variety of statistical software including SPSS is available for statistical analysis to faculty, staff, and students. College of Nursing: The CON was established over 36 years ago at UMSL and is located in the Nursing Administration Building and Seton Hall on the South campus. The Research Office provides Research Assistant help, editing and review of manuscripts and proposals, assistance with preparation and managing	Site Engaged -- Has FWA and Will Obtain Own IRB Review	UMSL's FWA number is 00000011.

		of budgets, and assistance in preparation of reports required by funding agencies. Lab: The CON has a full simulation lab, procedures area, and an eight exam room suite for standardized patients. Office Facilities: The CON has sufficient space for each faculty member to have an individual office with appropriate office furniture, phone and wireless as well as networked computer. There is ample classroom space including full live webcasting capabilities. All classrooms are fully computerized with a variety of smartboards and other capabilities.	
Indiana University	Co-I Larissa Jennings, Ph.D. will provide data analysis of the qualitative data obtained in the study and will help with intervention development and problem solving during the Aim 3 test of the intervention.	No participants will be recruited in Indiana so the co-I and site will not directly interact with human participants. The Co-I will have access to deidentified data only (e.g., transcripts). We have entered in to an agreement stating that identifiers will not be released to this co-investigator. A copy of that agreement will be kept on file.	Site Not Engaged -- IRB Review Not Required

- * **How will communication occur between sites for discussion of study conduct, unexpected problems, project modifications, and interim results:**

Consider the following in your response:

- how frequently communication will occur between sites
- how are sites instructed to report unanticipated problems, adverse events, or noncompliance
- how sites can communicate needed revisions to study procedures
- who will dissimenate IRB decisions
- who will notify the IRB of potential problems and changes to the protocol

The investigators will communicate regularly via phone, email, and in person (the grant provides for 1 site visit per year for each PI/co-I). We have been working together for several years and communicate regularly.

- **For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**

- Completed Local Context Form for Relying on VCU's IRB
- Site specific informed consent form(s) and HIPAA authorization(s), if applicable

For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

ID: MS8_HM20011245 View: SF2 - Personnel

Personnel

1. * **Indicate in the space below, list all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as: Conflict of Interest investigators, including the PI and student investigator, medically/psychologically responsible investigator, and other personnel whose roles are essential to the conduct of the research.

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

View	Eric Benotsch	Principal Investigator	Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Regulatory Management Data Management Participant Identification Study Design Participant Recruitment Intervention Services Data Collection - Interviews/Surveys	Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation	yes
View	Lauretta Cathers	Co/Sub-Investigator	Data Analysis Data Collection - Direct Observation Participant Consent Data Management Participant Identification Study Design Data Coding Participant Recruitment Intervention Services Data Collection - Interviews/Surveys	Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation	yes
View	Ashlee Sawyer	Research Assistant	Data Analysis Project Coordination Participant Consent Data Management Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys	Experience - Research Education and/or Professional Preparation Student	no
View	Ariella Tabaac	Research Assistant	Data Analysis Participant Consent Data Management Participant Identification	Experience - Research Education and/or Professional Preparation	no

			Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys	Student	
View	Cheuk Tam	Research Assistant	Data Analysis Participant Consent Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys	Experience - Research Education and/or Professional Preparation Student	no
View	Shelby Smout	Research Assistant	Data Analysis Participant Consent Data Management Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys	Experience - Research Education and/or Professional Preparation Student	no
View	Juliet Fueglein	Research Assistant Trainee/Student (i.e. not Student-Investigator)	Participant Identification Data Entry Participant Recruitment Data Collection - Interviews/Surveys	Student Trainee	no
View	Kathleen Lash	Research Assistant Trainee/Student (i.e. not Student-Investigator)	Participant Consent Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys	Student Trainee	no
View	Kyle Mason	Research Assistant Trainee/Student (i.e. not Student-Investigator)	Data Analysis Data Collection - Direct Observation Participant Consent Data Management	Experience - Research Education and/or Professional Preparation Student	no

Participant Identification	Trainee
Data Entry	
Data Coding	
Participant Recruitment	
Intervention Services	
Data Collection - Interviews/Surveys	

2. **Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.**

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

There are no items to display

3. * **Describe the process that will be used to ensure that all persons at all involved sites assisting with the research are adequately informed about the protocol and their research related duties and functions:**
The PI and co-Is have worked together for several years. We will have conference calls with the full investigative team at least twice per quarter for the remainder of year 3 of the grant. In addition, the St. Louis site PI and I have a call every two weeks. We have regular contact by email (typically weekly, but sometimes more often as needed). I meet individually with the research assistants on the grant at least weekly and also have a monthly meeting with all of students in my lab.

4. **CV/Biosketch: (required for PI, Medically/Psychologically Responsible Investigators and Student/Trainee Investigators)**

ID: MS8_HM20011245 View: SF2 - Conflict of Interest

Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**

   Financial interests include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project.

   ○ Yes
   ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**

   Non-financial interests could include such things as:
   - utilizing your unlicensed intellectual property in the study,
   - serving as an unpaid advisory board member or officer/director with a related entity, and
   - equity or business ownership in a company that has yet to make a profit and is related to this project
   - conflicts of time/effort,
   -personal and professional relationships/affiliations,
   - intellectual passions or personal beliefs
   - other factors that could create bias in the study

◯ Yes

● **No**

3. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.

None

ID: MS8_HM20011245 View: SF2 - Other VCU Requirementsv2

Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. **Cost Coverage Analysis**
Information on coverage analysis requirements and processes can be found through VCU's Clinical Research Compliance Program at https://research.vcu.edu/compliance_program/research_coverage.htm

1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**

◯ Yes

◯ No

● **Not Applicable**

2. **ClinicalTrials.gov Program & OnCore**
For guidance, see https://cctr.vcu.edu/support/clinical-trials/clinicaltrialsgov.html or email CCTRCTGOV@vcu.edu

1. * **Is this a Clinical Trial?**

● **Yes** ◯ No

2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

- Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
- When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
- When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless the federal department or agency will post it).

● **Yes** ◯ No

3. **Community Engagement**
For more information, see https://community.vcu.edu/

1. * **Is there a community partner in this research study?**

- (●) **Yes**
- ( ) No

2. * **Provide details about each community partner. If there are more than 5 community partners, add the 5 most significant partners.**

Organization	Zip Code / Country	Role
Nationz Foundation	23227	Provides guidance to the researcher about the study design, subject recruitment, data collection, or data analysis. Partner does NOT make decisions about study design.
Health Brigade	23230	Provides access to study subjects or project sites only. Partner is not involved with study design, subject recruitment, data collection, or data analysis
Minority Health Consortium	23219	Provides guidance to the researcher about the study design, subject recruitment, data collection, or data analysis. Partner does NOT make decisions about study design.

4. **Family Educational Rights and Privacy Act (FERPA) Requirements**
For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**
- ( ) Yes
- (●) **No**

5. **General Data Protection Regulation (GDPR) Requirements**
Contact the VCU Research Data Privacy Office with questions about GDPR requirements: https://research.vcu.edu/data_privacy

1. * **Does this study involve the VCU site, or any sites under the VCU IRB's oversight, obtaining data in, or from, the European Economic Area? (see Help Text for list of countries included in the EEA)**
- ( ) Yes
- (●) **No**

6. **Information Security**
For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan.
- (●) **Category 1: all data that require breach notifications in the event of improper release, including all non-publicly available personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
- ( ) Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.
- ( ) Category 3: all non-proprietary data that is considered publicly available for unrestricted use and disclosure. Such information is available to all members of the University community and to all individuals and entities external to the University.

2. * **I confirm use of the VCU Data Classification Tool in determining the data classification category selected in Question 1:**
   - (●) **Yes**
   - ( ) No

.

7. **Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)**
   For guidance, see https://www.massey.vcu.edu/research/protocol-review/

   1. * **Does this study target any of the following populations?**
      - cancer patients,
      - family members of cancer patients,
      - cancer healthcare providers, or
      - cancer prevention where cancer is integral to the research question
      - ( ) Yes
      - (●) **No**

8. **VCU Health Department of Patient Centered Services**

   1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**
      - ( ) Yes
      - (●) **No**
      - ( ) Not Applicable

9. **VCU Faculty-Held IND or IDE**
   For guidance, see **http://go.vcu.edu/indide**

10. **VCU Health System locations**

    1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, VCU Medical Center and Massey Cancer Center)?**
       - ( ) Yes
       - (●) **No**

11. **VCUHS Department of Pathology**
    Learn more about requesting and establishing an account with Pathology here: See
    https://pathology.vcu.edu/research-services/

12. **VCU Institutional Biosafety Committee (IBC)**
    To contact the Biosafety Office, call 804 828-6347 or extension 400-4984, or view their website at:
    https://research.vcu.edu/ibc

    1. * **Does this project involve the use of Bio-Hazardous Substances such as gene transfer, use of organisms or their products, biological toxins, and/or viruses?**
       - ( ) Yes
       - (●) **No**

    2. * **Does this project involve recombinant DNA (rDNA) and/or synthetic nucleic acids?**
       - ( ) Yes
       - (●) **No**

13. **VCU Radiation Safety Committee (RSC)**
To contact the Radiation Safety Section, call 804 828-9131, or view their website at: https://research.vcu.edu/rsc

    1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**
        - ○ Yes
        - ● **No**

14. **Virginia-Stem Cell Research Oversight (SCRO)**
For guidance, contact the Office of Research Integrity and Ethics (ORIE) at: ORIE@vcu.edu

    1. * **Does this study involve stem cells?**
        - ○ Yes
        - ● **No**

15. **VCU Scientific Review Committee (SRC)**
For guidance, see https://cctr.vcu.edu/support/study-participation-recruitment/scientific-review

    1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**
        - ● **Yes**
        - ○ No

16. **Upload any documents requested in the questions above:**

ID: MS8_HM20011245 View: SF2 - Institutional Requirements Complete

Institutional Requirements Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS8_HM20011245 View: SF2 - Documents

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission:**
A list of potential documents is given in the help text.

    NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

    Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of

the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:
- Click the Update button located to the left of the document to be updated.
- In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.
- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
- A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent - Aim 3 RCT	HM20011245 Aim 3 consent form final.03.17.2020.pdf	0.07	3/23/2020 10:07 AM	Eric Benotsch	Consent/Assent/Information Sheet	Yes
View	Consent - Qualitative interview assessing religious discrimination	HM20011245 Consent form for qualitative interview regarding religious discrimination.pdf	0.02	3/23/2020 10:07 AM	Eric Benotsch	Consent/Assent/Information Sheet	Yes
View	E-mail reruitment script - Aim 3	Aim 3 email script.03.17.2020.docx	0.02	3/17/2020 3:39 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Phone recruitment script - Aim 3	Aim 3 Telephone script.03.17.2020.docx	0.02	3/17/2020 3:39 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Qualitative interview guide (Aim 3)	Interview Guide for Measuring Participants Experiences of Religious Discrimination - Aim 3.docx	0.01	3/17/2020 3:13 PM	Eric Benotsch	Research Measure	Yes
View	Screening Survey - Aim 3	Screening Survey - HM20011245.Aim 3 final.docx	0.02	3/4/2020 3:13 PM	Eric Benotsch	Research Measure	Yes
View	Intervention Manual (Intro, Modules 1, 2,3, 5)	Integrated Intro.Modules.1.2.3.5.Aim3 March 2020.docx	0.03	3/4/2020 1:34 PM	Eric Benotsch	Research Protocol	Yes
View	Quantitative Measure for Baseline and follow-up	Baseline Measure.final.docx	0.02	3/2/2020 3:42 PM	Eric Benotsch	Research Measure	Yes
View	Budget Worksheet for use with module 3	pdf-1020-make-budget-worksheet(1).pdf	0.01	12/20/2019 12:11 PM	Eric Benotsch	Research Protocol	Yes
View	Intervention Manual - Module 4	FINAL_Module 4_Aim 3.docx	0.02	12/20/2019 12:06 PM	Eric Benotsch	Research Protocol	Yes
View	Aim 2 and 3 process measure	Process Measure.docx	0.03	12/19/2019 3:04 PM	Eric Benotsch	Research Measure	Yes
View	Consent -	HM20011245 Aim 2 consent form version 2	0.06	8/8/2019	Eric	Consent/Assent/Information	Yes

	Aim 2 pilot test	clean copy 8.7.2019.pdf		11:32 AM	Benotsch	Sheet	
View	Session reminder scripts	Session Reminder Scripts.docx	0.01	8/1/2019 3:31 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Sample Cover Letter	Sample Cover Letter.docx	0.01	8/1/2019 3:13 PM	Eric Benotsch	Other	Yes
View	Sample Resume #3	Functional Resume Example.docx	0.01	8/1/2019 3:13 PM	Eric Benotsch	Other	Yes
View	Sample Resume #2	Combination Resume Example.docx	0.01	8/1/2019 3:13 PM	Eric Benotsch	Other	Yes
View	Sample Resume #1	Chronological Resume Example .docx	0.01	8/1/2019 3:12 PM	Eric Benotsch	Other	Yes
View	CDC Needle Cleaning Procedures	cdc-hiv-clean-your-syringes.pdf	0.01	8/1/2019 3:10 PM	Eric Benotsch	Other	Yes
View	E-mail recruitment script - Aim 2	E-mail script Aim 2.docx	0.01	6/26/2019 2:15 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Phone Recruitment Script - Aim 2	Telephone script Aim 2.docx	0.01	6/26/2019 2:15 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Screening Survey for Aim 2	Screening Survey - HM20011245.v4.docx	0.01	6/26/2019 2:13 PM	Eric Benotsch	Research Measure	Yes
View	Consent - Aim 2 Screening Survey	HM20011245 ConsentForm_Screening Survey_Aim 2.docx	0.01	6/26/2019 1:34 PM	Eric Benotsch	Consent/Assent/Information Sheet	No
View	Consent - Aim 1 Screening Survey	HM20011245 ConsentForm_Screening clean copy.pdf	0.11	8/14/2018 9:44 AM	Eric Benotsch	Consent/Assent/Information Sheet	No
View	Consent - Aim 1 Qualitative Interview-TGW	Consent - Qualitative Interview for transgender women - HM20011245.v6.pdf	0.09	8/14/2018 9:44 AM	Eric Benotsch	Consent/Assent/Information Sheet	No
View	E-mail Script Screening Assessment	E-mail script screening assessment.docx	0.01	8/13/2018 1:42 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Facebook Page appareance	TWHealth Facebook page appearance.docx	0.01	8/13/2018 1:04 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Phone recruitment script	Telephone script.v2.docx	0.02	8/13/2018 1:04 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	E-mail recruitment script	E-mail script.v3.docx	0.03	8/13/2018 1:03 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Aim 1 Screening	Screening Survey - HM20011245.v3.docx	0.03	7/24/2018 1:51 PM	Eric Benotsch	Research Measure	Yes

	Survey						
View	Flyer	TWHealth Flyer_07192018.docx	0.01	7/24/2018 1:51 PM	Eric Benotsch	Recruitment/Advertising	Yes
View	Consent - Aim 1 Qualitative Interview - Key Informants	Consent - Qualitative Interview for key informants - HM20011245.v3 clean version.pdf	0.06	5/7/2018 2:24 PM	Eric Benotsch	Consent/Assent/Information Sheet	No
View	Aim 1 Interview Guide - Community Financial Partners	Interview Guide for Community Financial Partners Staff - HM20011245.docx	0.01	4/2/2018 2:02 PM	Eric Benotsch	Research Measure	Yes
View	Aim 1 Qualitative Interview Guide - NGO.GO personnel	Interview Guide - NGO.GO personnel - HM20011245.docx	0.01	4/2/2018 2:02 PM	Eric Benotsch	Research Measure	Yes
View	Aim 1 Qualitative Interview Guide - Previously vulnerable trans women	Interview Guide - Previously vulnerable TGW - HM20011245.docx	0.01	4/2/2018 2:01 PM	Eric Benotsch	Research Measure	Yes
View	Aim 1 Qualitative Interview Guide - Currently vulnerable trans women	Interview Guide Currently Vulnerable TGW - HM20011245.v2.docx	0.02	4/2/2018 2:00 PM	Eric Benotsch	Research Measure	Yes
View	Benotsch - Biosketch	Benotsch_Benotsch_BiographicalSketch.docx	0.01	7/28/2017 4:51 PM	Eric Benotsch	CV/Biosketch	Yes
View	Main Quantitative Survey	Main Quantitative Survey - HM20011245.docx	0.01	7/28/2017 4:49 PM	Eric Benotsch	Research Measure	No
View	R34 Grant Application - entire application	4047242_Egrant.pdf	0.01	7/26/2017 12:50 PM	Eric Benotsch	Funding Proposal	Yes
View	R34 Grant Application - Science and References	Science and ref.docx	0.01	7/25/2017 5:21 PM	Eric Benotsch	Research Protocol	Yes

ID: MS8_HM20011245 View: SF2 - Documents Complete

Documents Complete

Protocol Progress:
? INITIAL SETUP

? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

End of Application

Click Continue below to exit and submit this project

ID: MS8_HM20011245 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Aim 2 pilot test
2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Written/Signed Consent by Participant**
☐	Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult)
☐	Written/Signed Consent for Genetic Testing
☐	Written/signed assent by Child or Decisionally Impaired Adult
☐	Verbal Assent by Child
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of Some or All Elements of Consent
☐	Waiver of Assent by Child or Decisionally Impaired Adult
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of Documentation of Consent/Assent (not signed)
☐	Exception from Informed Consent (for emergency research only)

4. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student (i.e. not Student-Investigator)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

5. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
   Immediately prior to the first intervention session. The basics of the process will be provided over the phone prior to participants being scheduled for the first session.
6. * **Describe the process for minimizing coercion to participate:**
   Participants will have decided based on a phone conversation to participate and will be free to change their minds once they arrive for the session.
7. * **How much time will participants be given to make a decision:**
   We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.
8. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS8_HM20011245 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Screening survey - Aim 2
2. * **Select all that apply to this consent / assent group:**

Name
☐ Written/Signed Consent by Participant
☐ Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult)
☐ Written/Signed Consent for Genetic Testing
☐ Written/signed assent by Child or Decisionally Impaired Adult
☐ Verbal Assent by Child
☐ Short Form Consent (limited applicability)
☑ **None of the Above (select waiver below)**

3. * **Select any waivers that apply to this consent / assent group:**

☐ No Waivers Requested
☐ Waiver of Some or All Elements of Consent
☐ Waiver of Assent by Child or Decisionally Impaired Adult
☐ Waiver of Parental Permission or Legally Authorized Representative Consent
☑ **Waiver of Documentation of Consent/Assent (not signed)**
☐ Exception from Informed Consent (for emergency research only)

4. * **Select all study team role(s) that will obtain consent / assent from this group:**

☑ **Principal Investigator**
☑ **Co/Sub-Investigator**
☐ Medical or Psychological Responsible Investigator
☐ Student Investigator
☑ **Research Coordinator**
☐ Research Nurse
☐ Consultant
☑ **Research Assistant**

- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student (i.e. not Student-Investigator)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

5. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
In community settings where TGW are recruited (e.g., clinics) or online.

6. * **Describe the process for minimizing coercion to participate:**
The incentive is quite modest $5. We will be friendly rather than coercive in our approach.

7. * **How much time will participants be given to make a decision:**
As much time as is practical which will depend on the setting, the time of day (e.g., if approached right as the clinic opens could be several hours, if approached shortly before the clinic closes could be a shorter period), and how long we will be recruiting in the setting. We will ensure each participant has at least 15 minutes to make a decision.

8. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
N/A

ID: MS8_HM20011245 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
Aim 1 Qualitative Interview - Key Informants

2. * **Select all that apply to this consent / assent group:**

Name

- [ ] Written/Signed Consent by Participant
- [ ] Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult)
- [ ] Written/Signed Consent for Genetic Testing
- [ ] Written/signed assent by Child or Decisionally Impaired Adult
- [ ] Verbal Assent by Child
- [ ] Short Form Consent (limited applicability)
- [x] **None of the Above (select waiver below)**

3. * **Select any waivers that apply to this consent / assent group:**

- [ ] No Waivers Requested
- [ ] Waiver of Some or All Elements of Consent
- [ ] Waiver of Assent by Child or Decisionally Impaired Adult
- [ ] Waiver of Parental Permission or Legally Authorized Representative Consent
- [x] **Waiver of Documentation of Consent/Assent (not signed)**
- [ ] Exception from Informed Consent (for emergency research only)

4. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student (i.e. not Student-Investigator)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

5. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
In person, prior to the interview.

6. * **Describe the process for minimizing coercion to participate:**
These will be professionals either (a) working with the TGW community or (b) providing economic services to individuals in the area. Interviews will be arranged by phone ahead of time. It's unlikely that such an individual would

feel coerced to participate. They will be free to change their minds once they arrive for the session.

7. * **How much time will participants be given to make a decision:**
They will be contacted by phone prior to the interview and will given as much time as they need to make a decision--for example, the in-person interview will be scheduled in the future. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.

8. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS8_HM20011245 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
Aim 3 intervention

2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Written/Signed Consent by Participant**
☐	Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult)
☐	Written/Signed Consent for Genetic Testing
☐	Written/signed assent by Child or Decisionally Impaired Adult
☐	Verbal Assent by Child
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of Some or All Elements of Consent
☐	Waiver of Assent by Child or Decisionally Impaired Adult
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of Documentation of Consent/Assent (not signed)
☐	Exception from Informed Consent (for emergency research only)

4. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student (i.e. not Student-Investigator)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

5. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
   Immediately prior to the first intervention session. The basics of the process will be provided over the phone prior to participants being scheduled for the first session.
6. * **Describe the process for minimizing coercion to participate:**
   Participants will have decided based on a phone conversation to participate and will be free to change their minds once they arrive for the session.
7. * **How much time will participants be given to make a decision:**
   We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.
8. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS8_HM20011245 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Aim 1 Qualitative Interview - transgender participants (consent form is for both previously vulnerable and currently vulnerable)
2. * **Select all that apply to this consent / assent group:**

Name
☐ Written/Signed Consent by Participant
☐ Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult)
☐ Written/Signed Consent for Genetic Testing
☐ Written/signed assent by Child or Decisionally Impaired Adult
☐ Verbal Assent by Child
☐ Short Form Consent (limited applicability)
☑ **None of the Above (select waiver below)**

3. * **Select any waivers that apply to this consent / assent group:**

☐ No Waivers Requested
☐ Waiver of Some or All Elements of Consent
☐ Waiver of Assent by Child or Decisionally Impaired Adult
☐ Waiver of Parental Permission or Legally Authorized Representative Consent
☑ **Waiver of Documentation of Consent/Assent (not signed)**
☐ Exception from Informed Consent (for emergency research only)

4. * **Select all study team role(s) that will obtain consent / assent from this group:**

☑ **Principal Investigator**
☑ **Co/Sub-Investigator**
☐ Medical or Psychological Responsible Investigator
☐ Student Investigator
☑ **Research Coordinator**
☐ Research Nurse
☐ Consultant
☑ **Research Assistant**

- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student (i.e. not Student-Investigator)
- ☐ Other
- ☐ N/A: Requesting Waiver of Consent

5. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
In person, for individuals who screened as eligible. Discussion of the research activities will occur over the phone prior to setting an appointment to meet with the person. Informed consent will occur at the in-person session, generally immediately prior to conducting the interview.
6. * **Describe the process for minimizing coercion to participate:**
Participants will have decided based on a phone conversation to participate and will be free to change their minds once they arrive for the session.
7. * **How much time will participants be given to make a decision:**
We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.
8. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS8_HM20011245 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
Qualitative interview assessing religious discrimination (conducted during Aim 3)
2. * **Select all that apply to this consent / assent group:**

	Name
☐	Written/Signed Consent by Participant
☐	Written/Signed Consent by Parent/Guardian (for child) or Legally Authorized Representative (for adult)
☐	Written/Signed Consent for Genetic Testing
☐	Written/signed assent by Child or Decisionally Impaired Adult
☐	Verbal Assent by Child
☐	Short Form Consent (limited applicability)
☑	**None of the Above (select waiver below)**

3. * **Select any waivers that apply to this consent / assent group:**

- [ ] No Waivers Requested
- [ ] Waiver of Some or All Elements of Consent
- [ ] Waiver of Assent by Child or Decisionally Impaired Adult
- [ ] Waiver of Parental Permission or Legally Authorized Representative Consent
- [x] **Waiver of Documentation of Consent/Assent (not signed)**
- [ ] Exception from Informed Consent (for emergency research only)

4. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student (i.e. not Student-Investigator)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

5. * **Describe the consent procedures used for this group. Include when, where, and how consent / assent will be obtained both initially and, if applicable, during ongoing participation in the study:**
In person, for individuals who screened as eligible and indicated interest in participating. Discussion of the research activities will occur over the phone prior to setting an appointment to meet with the person. Informed consent will occur at the in-person session, generally immediately prior to conducting the interview.

6. * **Describe the process for minimizing coercion to participate:**
   Participants will have decided based on a phone conversation to participate and will be free to change their minds once they arrive for the session.

7. * **How much time will participants be given to make a decision:**
   We will contact them within a day or two of them screening eligible and the appointment could be several days after that. Once at the in-person meeting, we will ensure they have at least 15 minutes to decide if they need it.

8. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
   N/A

ID: MS8_HM20011245 View: SF_IRB_StudyLocation_NonVCUSitesDetails

Non-VCU Site Details

1. * **Name of institution or site:**
   University of Missouri-St. Louis

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing:**
   This is a two site study with equal research activities in community locations in Richmond and St. Louis, MO. Eric Benotsch at VCU is the lead PI. Investigators at UMSL include Sheila Grigsby, Ph.D., and Rick Zimmerman, Ph.D.

   All work in Aims 1, 2, and 3, will be conducted equally between both sites.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   Performance Site: University of Missouri [illegible] St. Louis

   University: UMSL is a public metropolitan research university located in Missouri[illegible]s most populous and economically diverse region. The largest University in the region, UMSL enrolls nearly 16,000 students and employs more than 1,400 full-time and part-time teaching and research faculty members. The campus has 70 academic and general purpose buildings covering over 350 acres.

   Research Infrastructure: Total external funding was $42.3 million as noted by the 2016 annual report, UMSL Office of Research Administration (ORA). In 2015, Academic Analytics ranked UMSL faculty scholarly productivity as 15th in the country in the category of high research activity. UMSL has in place the financial and asset management systems required to administer contracts such as the one described in this proposal. The ORA delivers services to investigators and sponsors and shares this responsibility with administrative units housed in each College or Department. It assists faculty in obtaining and administering externally funded research grants and contracts and administers internal grant programs throughout UMSL.
   Libraries: The University Library System provides support for graduate studies and research through collections in the five on-campus libraries including the Barnes Library and two science libraries. These libraries house over one million volumes, 300,000 photographs, one million government documents and more than one million microforms. About 15,000 full-text online periodicals are available currently.
   Numerous periodical indexes and full text databases may also be accessed electronically.
   Computer Infrastructure: Hardware and software packages are readily available and designed for faculty and students. Technical support is available at several places within UMSL including the CON which employs a full time Instructional Software expert along with three student assistants with expertise in computing hardware and software. A variety of statistical software including SPSS is available for statistical analysis to faculty, staff, and students.
   College of Nursing: The CON was established over 36 years ago at UMSL and is located in the Nursing Administration Building and Seton Hall on the South campus. The Research Office provides Research Assistant help, editing and review of manuscripts and proposals, assistance with preparation and managing of budgets, and assistance in preparation of reports required by funding agencies.
   Lab: The CON has a full simulation lab, procedures area, and an eight exam room suite for standardized patients.
   Office Facilities: The CON has sufficient space for each faculty member to have an individual office with appropriate office furniture, phone and wireless as well as networked computer. There is ample classroom space including full live webcasting capabilities. All classrooms are fully computerized with a variety of smartboards and other capabilities.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

- ○ Exempt study submission
- ● **Site Engaged -- Has FWA and Will Obtain Own IRB Review**
- ○ Site Engaged -- Requests to Rely on VCU IRB Review
- ○ Site Not Engaged -- IRB Review Not Required
- ○ Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**
   UMSL's FWA number is 00000011.

ID: MS8_HM20011245 View: SF_IRB_StudyLocation_NonVCUSitesDetails

Non-VCU Site Details

1. * **Name of institution or site:**
   Indiana University
2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing:**
   Co-I Larissa Jennings, Ph.D. will provide data analysis of the qualitative data obtained in the study and will help with intervention development and problem solving during the Aim 3 test of the intervention.
3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   No participants will be recruited in Indiana so the co-I and site will not directly interact with human participants. The Co-I will have access to deidentified data only (e.g., transcripts).

   We have entered in to an agreement stating that identifiers will not be released to this co-investigator. A copy of that agreement will be kept on file.
4. * **Select the IRB review path the Non-VCU institution or site will follow:**

- ○ Exempt study submission
- ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
- ○ Site Engaged -- Requests to Rely on VCU IRB Review
- ● **Site Not Engaged -- IRB Review Not Required**
- ○ Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Eric Benotsch

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [x] **Principal Investigator**
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Student Investigator
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical
   - [x] **Data Collection - Interviews/Surveys**
   - [x] **Data Collection - Direct Observation**
   - [ ] Clinical Services
   - [x] **Intervention Services**
   - [ ] Data Entry
   - [ ] Data Coding

- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes
6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Lauretta Cathers
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

- (●) **Yes**
- ( ) No

3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [x] **Intervention Services**
- [ ] Data Entry
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [ ] **Participant Consent**

- [x]
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes
6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Ashlee Sawyer
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

- [ ] Principal Investigator

- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Assistant**
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Ariella Tabaac
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Assistant**
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical

Experience - Related Skills

- [ ]
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Cheuk Tam
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - ○ Yes
   - ● **No**
3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Assistant**
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical

- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [ ] Data Management
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes
6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Shelby Smout
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

   - ☐ Principal Investigator
   - ☐ Co/Sub-Investigator
   - ☐ Medical or Psychological Responsible Investigator
   - ☐ Student Investigator
   - ☑ **Research Assistant**
   - ☐ Other
4. * **Study related responsibilities:**

   - ☐ Study Design
   - ☐ Data Collection - Lab
   - ☐ Data Collection - Clinical
   - ☑ **Data Collection - Interviews/Surveys**
   - ☐ Data Collection - Direct Observation
   - ☐ Clinical Services
   - ☐ Intervention Services

   Data Entry

- [x]
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes
6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Juliet Fueglein

2. * **Is this individual a 'COI Investigator'?**

Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

- ○ Yes
- ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Student Investigator
- ☑ **Research Assistant**
- ☑ **Trainee/Student (i.e. not Student-Investigator)**
- ☐ Other

4. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☐ Data Collection - Clinical
- ☑ **Data Collection - Interviews/Surveys**
- ☐ Data Collection - Direct Observation
- ☐ Clinical Services
- ☐ Intervention Services
- ☑ **Data Entry**
- ☐ Data Coding
- ☐ Data Management
- ☐ Data Analysis

- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes
6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [ ] Experience - Research
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [x] **Trainee**
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Kathleen Lash
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

○ Yes

● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Student Investigator
- ☑ **Research Assistant**
- ☑ **Trainee/Student (i.e. not Student-Investigator)**
- ☐ Other

4. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☐ Data Collection - Clinical
- ☑ **Data Collection - Interviews/Surveys**
- ☐ Data Collection - Direct Observation
- ☐ Clinical Services
- ☐ Intervention Services
- ☑ **Data Entry**
- ☑ **Data Coding**
- ☐ Data Management
- ☐ Data Analysis
- ☐ Project Coordination
- ☑ **Participant Identification**
- ☑ **Participant Recruitment**

- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities
6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [ ] Experience - Research
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [x] **Trainee**
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: Personnel

Personnel

1. * **Name:**
   Kyle Mason
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

- Principal Investigator

- [ ]
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] **Research Assistant**
- [x] **Trainee/Student (i.e. not Student-Investigator)**
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [x] **Intervention Services**
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities
6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [x] **Trainee**
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

ID: MS8_HM20011245 View: SF - Community Engaged Research

Community Engaged Research

1. * **Name of the organization:**
   Nationz Foundation
2. * **Zip code or country of the organization:**
   23227
3. * **Select the role that best describes this community partner:**

- ○ Provides access to study subjects or project sites only. Partner is not involved with study design, subject recruitment, data collection, or data analysis
- ● **Provides guidance to the researcher about the study design, subject recruitment, data collection, or data analysis. Partner does NOT make decisions about study design.**
- ○ Makes decisions WITH the researcher about the study's research activities and/or helps conduct those activities (i.e., study design, subject recruitment, data collection, and/or data analysis)

ID: MS8_HM20011245 View: SF - Community Engaged Research

Community Engaged Research

1. * **Name of the organization:**

Health Brigade

2. * **Zip code or country of the organization:**
   23230
3. * **Select the role that best describes this community partner:**

- (●) **Provides access to study subjects or project sites only. Partner is not involved with study design, subject recruitment, data collection, or data analysis**
- ( ) Provides guidance to the researcher about the study design, subject recruitment, data collection, or data analysis. Partner does NOT make decisions about study design.
- ( ) Makes decisions WITH the researcher about the study's research activities and/or helps conduct those activities (i.e., study design, subject recruitment, data collection, and/or data analysis)

ID: MS8_HM20011245 View: SF - Community Engaged Research

Community Engaged Research

1. * **Name of the organization:**
   Minority Health Consortium
2. * **Zip code or country of the organization:**
   23219
3. * **Select the role that best describes this community partner:**

- ( ) Provides access to study subjects or project sites only. Partner is not involved with study design, subject recruitment, data collection, or data analysis
- (●) **Provides guidance to the researcher about the study design, subject recruitment, data collection, or data analysis. Partner does NOT make decisions about study design.**
- ( ) Makes decisions WITH the researcher about the study's research activities and/or helps conduct those activities (i.e., study design, subject recruitment, data collection, and/or data analysis)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent - Aim 3 RCT
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   HM20011245 Aim 3 consent form final.03.17.2020.pdf(0.07)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent - Qualitative interview assessing religious discrimination
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   HM20011245 Consent form for qualitative interview regarding religious discrimination.pdf(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   E-mail reruitment script - Aim 3
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Aim 3 email script.03.17.2020.docx(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Phone recruitment script - Aim 3
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Aim 3 Telephone script.03.17.2020.docx(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Qualitative interview guide (Aim 3)
2. * **Type:**
   Research Measure
3. * **File:**
   Interview Guide for Measuring Participants Experiences of Religious Discrimination - Aim 3.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Screening Survey - Aim 3

2. * **Type:**
   Research Measure
3. * **File:**
   Screening Survey - HM20011245.Aim 3 final.docx(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Intervention Manual (Intro, Modules 1, 2,3, 5)
2. * **Type:**
   Research Protocol
3. * **File:**
   Integrated Intro.Modules.1.2.3.5.Aim3 March 2020.docx(0.03)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Quantitative Measure for Baseline and follow-up
2. * **Type:**
   Research Measure
3. * **File:**
   Baseline Measure.final.docx(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Budget Worksheet for use with module 3
2. * **Type:**
   Research Protocol
3. * **File:**
   pdf-1020-make-budget-worksheet(1).pdf(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Intervention Manual - Module 4
2. * **Type:**
   Research Protocol
3. * **File:**
   FINAL_Module 4_Aim 3.docx(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Aim 2 and 3 process measure
2. * **Type:**
   Research Measure
3. * **File:**
   Process Measure.docx(0.03)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent - Aim 2 pilot test
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   HM20011245 Aim 2 consent form version 2 clean copy 8.7.2019.pdf(0.06)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Session reminder scripts
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Session Reminder Scripts.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Sample Cover Letter
2. * **Type:**
   Other
3. * **File:**
   Sample Cover Letter.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Sample Resume #3
2. * **Type:**
   Other
3. * **File:**
   Functional Resume Example.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Sample Resume #2
2. * **Type:**
   Other
3. * **File:**
   Combination Resume Example.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Sample Resume #1
2. * **Type:**
   Other
3. * **File:**
   Chronological Resume Example .docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   CDC Needle Cleaning Procedures
2. * **Type:**
   Other
3. * **File:**
   cdc-hiv-clean-your-syringes.pdf(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   E-mail recruitment script - Aim 2

2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   E-mail script Aim 2.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Phone Recruitment Script - Aim 2
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Telephone script Aim 2.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Screening Survey for Aim 2
2. * **Type:**
   Research Measure
3. * **File:**
   Screening Survey - HM20011245.v4.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent - Aim 2 Screening Survey
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   HM20011245 ConsentForm_Screening Survey_Aim 2.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent - Aim 1 Screening Survey
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   HM20011245 ConsentForm_Screening clean copy.pdf(0.11)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent - Aim 1 Qualitative Interview-TGW
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent - Qualitative Interview for transgender women - HM20011245.v6.pdf(0.09)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   E-mail Script Screening Assessment
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   E-mail script screening assessment.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Facebook Page appearance
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   TWHealth Facebook page appearance.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Phone recruitment script
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Telephone script.v2.docx(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   E-mail recruitment script
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   E-mail script.v3.docx(0.03)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Aim 1 Screening Survey
2. * **Type:**
   Research Measure
3. * **File:**
   Screening Survey - HM20011245.v3.docx(0.03)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Flyer
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   TWHealth Flyer_07192018.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent - Aim 1 Qualitative Interview - Key Informants
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent - Qualitative Interview for key informants - HM20011245.v3 clean version.pdf(0.06)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Aim 1 Interview Guide - Community Financial Partners

2. * **Type:**
   Research Measure
3. * **File:**
   Interview Guide for Community Financial Partners Staff - HM20011245.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Aim 1 Qualitative Interview Guide - NGO.GO personnel
2. * **Type:**
   Research Measure
3. * **File:**
   Interview Guide - NGO.GO personnel - HM20011245.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Aim 1 Qualitative Interview Guide - Previously vulnerable trans women
2. * **Type:**
   Research Measure
3. * **File:**
   Interview Guide - Previously vulnerable TGW - HM20011245.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Aim 1 Qualitative Interview Guide - Currently vulnerable trans women
2. * **Type:**
   Research Measure
3. * **File:**
   Interview Guide Currently Vulnerable TGW - HM20011245.v2.docx(0.02)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Benotsch - Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Benotsch_Benotsch_BiographicalSketch.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Main Quantitative Survey
2. * **Type:**
   Research Measure
3. * **File:**
   Main Quantitative Survey - HM20011245.docx(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   R34 Grant Application - entire application
2. * **Type:**
   Funding Proposal
3. * **File:**
   4047242_Egrant.pdf(0.01)

ID: MS8_HM20011245 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   R34 Grant Application - Science and References
2. * **Type:**
   Research Protocol
3. * **File:**
   Science and ref.docx(0.01)