# JHSPH IRB Research Plan for New Data Collection

*Use this template for new data collection and if you also will analyze secondary data. Answer the questions below and for numbered sections that do not pertain to your study, retain the section numbers and bolded questions, and write "N/A". Please start typing in the gray boxes provided.*

**PI Name: Susan Sherman, PhD**
**Study Title:** Exploring barriers and facilitators to women who use drugs (WWUD) awareness, acceptance and uptake of COVID-19 testing, the CARE study
**IRB No.: 00014847**
**PI Version No. / Date: Version 14, March 14, 2023**

**I. Aims of the Study:** Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

Through community-informed research, we aim to examine barriers and facilitators of COVID-19 testing and retesting as well as vaccination interest among WWUD. The ultimate goal is to inform community-based testing and vaccination targeting this high-risk and underserved population. The CARE (COVID Action Research Engagement) study leverages a decade of community-based research with WWUD (R21 DA033855, R01DA038499), including our ongoing evaluation (EMERALD study) of the SPARC drop-in center for high-risk women conducted in extensive collaboration with the community and service providers (R01DA041243). Specifically, the study has the following aims.

1. To explore predisposing social factors (e.g., housing, food security), individual-level factors (e.g., drug use, mental health), and beliefs (e.g., medical mistrust) that are facilitators and barriers of COVID-19 testing and vaccination, and perceived risks (e.g., income generation, violence) resulting from a diagnosis through in-depth interviews among WWUD (N=15) and a cultural domain analysis (N=45).
2. To gain an understanding of the enabling community-level environment (e.g., medical and social service agencies that currently serve WWUD, existing city-wide COVID-19 testing sites) that could facilitate or hinder WWUDs' COVID testing and vaccination uptake through observations (N=4) and key informant interviews (N=10).
3. To examine predisposing social factors, individual-level factors, and beliefs that are associated with COVID-19 testing and retesting among a cohort (N=250) of WWUD at baseline,3-month, and 6-month follow-ups.
4. To collaborate with the SPARC Center to implement at-home COVID testing as part of routine outreach services for WWUD in Baltimore City, Maryland.

5. To examine the feasibility (e.g., testing uptake) and acceptability (e.g., participant burden, testing self-efficacy) of at-home COVID testing among WWUD who are clients of SPARC outreach.

Qualitative sub-study

S1. explore the nature of women sex workers' occupational risk environment, its connection to mental health and changes to both due to the COVID-19 pandemic through in-depth interviews with street-based women who sell sex (N=20-25) in Baltimore, MD

**II. Background and Rationale:** Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

**Women who use drugs are at heightened risk for COVID-19.** WWUD experience high rates of structural vulnerabilities (e.g., homelessness, unemployment, poverty, criminalization) that, coupled with a heightened susceptibility to COVID-19, render them critical for being targeted in COVID prevention efforts. High rates of sexual and physical violence potentiate these vulnerabilities in a unique gendered way that is distinct from their male drug-using counterparts.[3-5] Similar to other vulnerable populations, WWUD face a higher burden of infectious and chronic diseases (e.g., diabetes, hypertension, respiratory diseases, HIV, HCV) that elevate their susceptibility to more severe COVID symptoms or fatality[4] compared to similarly-aged women who do not use illicit drugs.[7,8] Elevated COVID-19 susceptibility is heightened by drug inhalation which depresses breathing[9,10] causing such respiratory diseases as chronic obstructive pulmonary disease and asthma, with prevalence estimates of 20% and 18%, respectively.[7] Due to these high burdens of comorbidities, WWUD are a priority population for testing and vaccination. However, testing remains out of reach for many WWUD due to historic and entrenched barriers to healthcare utilization. Further, a positive COVID-19 test result may be potentially perceived as a threat to more immediate needs such as income generation (e.g., engagement in sex work), drug use (e.g., ability to obtain drugs) and safety from violence (e.g., confinement with an abusive partner).

**Access to trusted health services for people at the margins, including WWUD, is diminished.** The COVID-19 epidemic has presented challenges to healthcare and public health systems, requiring adaptability of treatment and prevention strategies within systems that are not easily responsive to real-time change.[8] Surging need for COVID-related healthcare has diverted providers and resources away from trusted low-barrier services.[9] Harm reduction services such as syringe services programs (SSPs) and drop-in centers are often the only point of contact for WWUD to access necessary medical and social services.[12-14] Yet a recent rapid mixed-methods assessment found that 43% of SSPs in the U.S. reported a decrease in availability of services as resources are being diverted to address the current pandemic, thereby also reducing opportunities for PWUD to engage with social services.[13,15] The prolonged impact of this service reduction, along with city-wide lockdowns, may leave WWUD without trusted providers to help them understand COVID testing and medical care at a time when messaging from trusted medical providers is critical.

**There are numerous barriers to healthcare engagement.** For many people who use drugs, structural factors such as unstable housing and poverty are persistent barriers to healthcare utilization.[14] When healthcare is accessed, it is often in emergency departments. In our recent EMERALD study (IRB#00007664) of female sex workers (FSW) who use drugs (N=385), 52% of study participants had received healthcare only in the emergency department in the past six months. Reduced access to healthcare and accompanying health information is particularly detrimental to COVID prevention in WWUD given the complex, multi-level barriers to healthcare engagement. Understanding these dynamic complexities as they relate to COVID testing are vitally important. Individual-level barriers to healthcare utilization for WWUD span demographic factors such as education, age, ethnicity, mental illness and trauma, as well as health literacy.[19,21-24] Younger (compared to older) and Black (compared to white) WWUD access healthcare less frequently than their nondrug-using counterparts.[21] Experiencing a mental health crisis can be debilitating and render an individual unable to engage with preventive healthcare,

such as in the case of major depressive episode or a manic episode of bipolar disorder. For WWUD, embedded structural factors such as poverty and its associated social insecurities (e.g., need for shelter, food, safety) take precedence, thereby creating consistent barriers to healthcare.[21,25,26] Like many other health crises, the novel COVID-19 magnifies existing social and economic inequities, resulting in a disproportionate burden of disease experienced by those already most structurally vulnerable like WWUD.[22] A recent study about healthcare access among people who inject drugs found that 53% of participants said that judgement from providers was a reason for not accessing care, and 22% said that it was their "biggest barrier" to care.[23] These barriers can create or exacerbate logistical difficulties in accessing healthcare such as limited office hours or appointment availability, long wait times, prohibitive out-of-pocket costs, and lack of transportation.[19,21-23,29-33]

A general distrust of medical providers is rooted in personal experiences as well as historic mistreatment at the hands of healthcare providers and medical researchers.[24,40,41] Medical mistrust has been found to be negatively associated with clinical trial participation, cancer screenings, organ donation, and the utilization of healthcare.[42-44] Each of these factors, as well as the intersections between them, reduces utilization of necessary services.

The CARE (COVID Action Research Engagement) study builds on an extant literature of elevated health risks among WWUD, which are driven in part by seemingly intransigent barriers to healthcare utilization. These risks and barriers are difficult to undo in the best of circumstances, let alone in a global pandemic that disproportionately impacts WWUDs' ability to seek drugs or treatment, to earn money, and to access services. We are building on the EMERALD study which is shortly ending data collection and has the requisite infrastructure to conduct the proposed research activities. The CARE study will provide a nuanced and holistic understanding of how to meaningfully engage this highly marginalized population in COVID-19 testing, with the target population directly involved via the CAB in shaping that engagement. The study fills a timely gap in the literature, given continued shortcomings in reaching WWUD in service engagement without the additional urgency of COVID-19's impact. The study will directly inform the scale up of community-informed COVID-19 testing that is accessible, low barrier, and potentially serve as a bridge to utilization of other services.

A range of individual and structural barriers impede COVID-19 testing among WWUD, although their risk of COVID-19 morbidities and mortality is high. A nuanced understanding of enabling and predisposing factors of COVID testing among this high-risk population is urgently needed to inform tailored interventions. Low-barrier harm reduction services, such as SPARC's mobile outreach, which attend to a number of women's specific needs, are ideal enabling environments for at-home COVID-19 testing and vaccinations.[10,26,30] Integrating testing into existing SPARC outreach services can effectively reduce major structural impediments to COVID testing access and uptake, and could be replicated in other settings with WWUD and similar populations. Lastly, partnerships with community organizations from the onset of research can enhance its relevance, community responsiveness, and eventual sustainability.

Qualitative sub-study:

The International Labor Organization has recognized sex work as an occupation since 1996.[1] Yet, sex work remains illegal throughout the world, including in the U.S. Sex work is defined as trading sex for goods, money, or drugs. The illegality of sex work in essence erodes the occupational safety and human rights that this recognition often affords industries.[2] Street-based sex work, where clients are recruited on the street, is associated with significantly high rates of HIV risk behaviors, violence, and police abuse.[3-5] Illegal sex work environments reduce

women's ability to engage in preventative health behaviors that leave them at risk for morbidities such as HIV and drug overdose.[6-8] We have identified salient features of sex work "risk environments," including indoor (e.g., exotic dance clubs) and outdoor (e.g., street-based) venues, that are associated with STIs, HIV risk behaviors, and problematic illicit drug use.[6,9-12] Elevated levels of structural vulnerability (e.g., poverty, housing instability, hunger, violence) and mental health morbidities (e.g., depression, PTSD, anxiety) intensify the impact of these occupational risk environments.[13-15] Further, street-based FSW often work in isolation in environments that are characterized by violence and police harassment.[3-5] COVID-19 amplifies existing social inequities and morbidities (i.e. poor mental health) among this and similar marginalized populations. The proposed exploratory study will deepen our understanding of the relationship between the unique occupational risk environment of street-based sex work and poor mental health outcomes as well as provide an in-depth understanding of the mental health risk environment. The study is informed by Rhodes' risk environment framework, which we and others have used to document the significant association of environmental features (e.g., social, economic, physical, policy) and health outcomes including HIV and overdose.[7,16]

## III. Study Design:

A. Provide a BRIEF overview of your study design and methods. The study design must relate to your stated aims/objectives. DETAILS WILL BE REQUESTED LATER. *If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens)*

The CARE study is a two-year multi-method longitudinal study funded through the NIH RADx-UP program. The National Institutes of Health (NIH)-supported Rapid Acceleration of Diagnostics-Underserved Populations (RADx-UP) aims to ensure that all Americans have access to COVID-19 testing, with a focus on communities most affected by the pandemic. RADx-UP is part of a $1.4 billion NIH-supported initiative to help speed innovation in the development and implementation of COVID-19 testing. The RADx-UP Coordination and Data Collection Center (CDCC) is led by the Duke Clinical Research Institute (DCRI) and the Center for Health Equity Research at UNC-Chapel Hill (UNC-CHER), in partnership with Community Campus Partnership for Health (CCPH). The CDCC will coordinate administrative, testing, and data transfer and harmonization across all RADx-UP projects, including the CARE study.

Through Aims 1 and 2, we will employ a rapid ethnographic assessment using a diversity of qualitative methods, i.e., in-depth interviews, cultural domain analysis (CDA), and observations with: 1) WWUD; 2) medical and social service providers who currently work with WWUD; and 3) providers of city-wide COVID-19 testing/vaccination staff and management. Qualitative data collection will allow for a more nuanced elucidation of both the experiences of WWUD as well as the nature and readiness of the testing environment to develop COVID-19 testing and vaccination strategies. A longitudinal cohort of WWUD (Aim 3) will examine behavioral, social, and structural correlates of testing, repeat testing, and COVID-19 infection. The cohort will be recruited through targeted sampling, a method that we have enhanced in our previous research with similar populations. Next, we will collaborate with SPARC to develop and implement an at-home COVID testing program within their existing mobile outreach services, informed by Aim 3 findings as well as key informant interviews with SPARC mobile outreach

staff. The interview guide is informed by PRISM, a framework that emphasizes the assessment of individual- and organizational-level contextual factors that contribute to implementation outcomes. Aim 5 will be a brief evaluation of implementation-related outcomes (e.g., acceptability, feasibility) related to the at-home COVID testing provided to SPARC outreach guests. We will survey SPARC outreach guests over the phone about their use of and attitudes toward at-home COVID testing, and general experiences with COVID and with SPARC outreach services. The study will be guided by a CAB comprised of the study population, who will help lead a community forum to engage community in interpreting the results and make recommendations for the nature and locations of COVID-19 testing and vaccination.

Qualitative sub-study:
We will conduct in-depth interviews (N=20-25) with women who sell sex that are enrolled in the CARE cohort. Interviews will cover topics related to features of the sex work occupational risk environment such as police presence, violent experiences, and sex work in the context of drug use. Interviews will also cover mental health broadly and in particular as it relates to risk environment features. Finally, we will cover changes to mental health and occupational sex work features due to COVID-19.

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

To address Aim 1, we will recruit WWUD for in-depth interviews (n=15) and for the cultural domain analysis using two activities: free listing (n=30) and pile sorting (n=15).

To address Aim 2, we will conduct ethnographic observations of COVID testing sites (n=2 visits across 2 sites, 4 total observations) and conduct key informant interviews (n=10) with providers serving WWUD and conducting COVID testing and (future) vaccination in Baltimore.

There is no sample size calculation for these qualitative methods; sample size is informed by representation and saturation. An ideal sample allows us to collect sufficient information to reach saturation while maintaining a diversity of reported experiences. Based on our previous research experiences with this population, we expect n=15 in-depth interviews with WWUD to be sufficient. For free listing (n=30) and pile sorting (n=15) we expect, based on the literature, to reach general reliability for each part of these Aim 1 activities. For Aim 2, based on our previous experience we expect n=10 key informant interviews to be sufficient to reach saturation.

To address Aim 3, we will examine predisposing social factors, individual-level factors, and beliefs that are associated with COVID-19 testing and retesting among a cohort (N=250) of WWUD at baseline, 3-month, and 6-month follow-ups.

We conducted power calculations for comparing the average rate of POCT uptake between two groups defined by a binary factor over 6-months of follow-up. We assume that on average N=200 or N=180 contribute to three data points to account for possible losses to follow-up. We further assume that the proportion of POCT in the reference category is 0.3 to 0.5, with an intra-person correlation of Rho=0.4 and two-sided alpha=0.05. Thus, for example, for a binary covariate with 40% in the high-risk category (e.g., injection drug use) and N=200 we have >80% power to detect an OR=0.5 with average of 40-50% POCT uptake in the reference

category. If the total sample size is 180, with the same scenarios, power is >80% to detect OR=0.47. For a binary factor with 70% at high risk (e.g., homeless), N=200 and reference rate of 40%, we have 83% power to detect an OR=0.24. For equal group sizes (i.e., a scale cut at the median) the power is >85% to detect an OR=1.99 and a reference testing rate of 30%.

To address Aim 4, we will conduct key informant interviews with SPARC mobile outreach staff. There is no sample size calculation. We will invite all SPARC mobile outreach staff who are currently employed at SPARC and have worked on at least two outreach shifts in the past 3 months. There are currently 8 SPARC staff that meet these criteria.

To address Aim 5, we will conduct brief phone surveys with SPARC guests to understand their use of and attitudes toward at-home COVID testing. This is a cross-sectional survey of all guests that receive SPARC outreach services.

Qualitative sub-study:

From the CARE cohort, we will recruit 20-25 women who sell sex for in-depth interviews. We will purposively sample participants to enhance diversity of participants' age, race, and time in sex work. There is no sample size calculation for these qualitative methods; sample size is informed by representation and saturation. An ideal sample allows us to collect sufficient information to reach saturation while maintaining a diversity of reported experiences. Based on our previous research experiences with this population, we expect 20-25 in-depth interviews to be sufficient.

## IV. Participants:

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

A. **Inclusion Criteria:**

### Aim 1 activities: In-depth Interviews, free listing, pile sorting

Inclusion criteria:
(1) age ≥18 years;
(2) self-identified woman;
(3) self-reports having used heroin, crack cocaine, cocaine or opioids at least 3 times in the past week;
(4) willing to be audio-recorded;
(5) able to complete the interview in English; and
(6) able to provide informed consent

### Aim 2 key informant interviews

Inclusion criteria:
(1) age ≥18 years;
(2) employed by organization for at least 6 months;
(3) willing to be audio-recorded;
(4) able to complete the interview in English; and

(5) able to provide informed consent

**Aim 3 activities**

Inclusion criteria:

(1) age ≥18 years;
(2) self-identified woman;
(3) self-reports having used heroin, crack cocaine, cocaine or opioids at least 3 times in the past month;
(4) self-reported covid-19 vaccinated and 2 weeks have passed from last dose *or* passes health check screening
(5) able to complete the interview in English; and
(6) able to provide informed consent

**Aim 4 key informant interviews**

Inclusion criteria:

(1) age ≥18 years;
(2) currently employed by SPARC;
(3) worked on at least two mobile outreach shifts in the past 3 months;
(4) willing to be audio-recorded;
(5) able to complete the interview in English; and
(6) able to provide informed consent

**Aim 5 activities**

Inclusion criteria:

(1) has received at least one delivery from SPARC outreach within the past month;
(2) able to complete the interview in English; and
(3) able to provide informed consent

**Qualitative sub-study:**

Inclusion criteria:

(1) currently enrolled in the CARE cohort or recently completed final CARE follow-up;
(2) sold or traded sex for money, drugs, or other resources at least 3 times within the past 3 months;
(3) willing to be audio-recorded;
(4) able to complete the interview in English; and
(5) able to provide informed consent

## V. Study Procedures:

*In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section. If your study will develop in phases, address each item below by phase.*

### A. Recruitment Process:

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

Aim 1

The following recruitment process will take place for each of the three qualitative activities in Aim 1 including IDIs, free listing, and pile sorting.

Participants will be recruited from community organizations and drop-in centers (e.g., SPARC, Charm City Care Connection) that serve people who use drugs in Baltimore. The study coordinator will contact the director of each organization/clinic by email or phone to introduce the goals of the study and describe the study procedures. Respective organizational staff will ascertain study interest among WWUD who use their services and provide those who are interested (i.e., based on willingness to talk) with a phone number to call.

Women will be purposively sampled to ensure diversity of age, race, healthcare utilization, and substance use history. We will update organizational staff periodically throughout the recruitment process to describe participants that we are seeking to recruit based on our purposive sampling (e.g., looking for participants under 30, Hispanic participants, etc.). A seasoned study member (qualitative interviewer) will receive all calls, assess interest in participating and conduct the screening by phone, separately for each individual. The screener is located in Appendix A.

We will also conduct street-based recruitment in areas known to be hot spots for WWUD, primarily in the Highlandtown area, Brooklyn, and Wilkens Circle. The study team will go out 1-2 days/week, depending on interview volume, with each shift lasting approximately 3 hours and staffed by 2 interviewers. Upon arrival, interviewers will assess the recruitment area for immediate safety concerns. The interviewers will stay together at all times when recruiting participants and carry a JHU ID and charged cell phone. Potential participants who are in the recruitment area will be discreetly approached and provided a brief study description. In order to protect the privacy of the women we approach we will not mention drug use during recruitment.

The study PI will make the determination to halt recruitment when we reach saturation and additional interviews would be superfluous.

Aim 2

Observations: We will identify two COVID testing sites run by Johns Hopkins and the Baltimore City Health Department. Observations will be conducted by a trained study member with experience in qualitative data collection. The study member will arrive at the testing site and introduce themselves to staff as a researcher and observer. Staff will not have direct interaction with any community members who are visiting the testing center and will not document any individual participant activities.

Key informant interviews: Key informants will be purposively sampled based on their expertise and identified through existing relationships with staff at community organizations and healthcare centers in Baltimore City that serve WWUD. The study coordinator will contact the potential participants by email or phone to introduce the goals of the study and describe the procedures. If interested, study staff will set up a time for an interview via Zoom or over the phone.

Aim 3
We will employ targeted sampling recruitment on a mobile study van as we have done in the recent studies of WWUD and FSW. Briefly, targeted sampling involves using a combination of geospatial analyses of secondary data sources (e.g., drug arrest data) and primary data collection (e.g., key informant interviews with service providers and WWUD) in order to identify areas where and when the target population congregate to inform the development of the sampling frame. Using geocoded secondary data sources and Getis-Ord GI* for hotspot cluster analyses and heat maps of secondary data, we will identify locations of drug use and times of peak activity. After identifying the totality of times and locations of potential WWUD activity, we will construct a list of venue-day-time (VDT) units for the sampling frame.

The study team will conduct street-based recruitment in areas identified as hot spots for WWUD, primarily in the Highlandtown area, Brooklyn, and Wilkens Circle. The study team will go out 3-5 days/week, depending on interview volume, with each shift lasting approximately 4 hours and staffed by 2-3 staff. Upon arrival, study staff will assess the recruitment area for immediate safety concerns. Staff will stay together at all times when recruiting participants on the street and carry a JHU ID and charged cell phone. Potential participants who are in the recruitment area will be discreetly approached and provided a brief study description. We will not mention drug use when we approach women for recruitment. Those who are interested in the study will be asked to complete a health check questionnaire (Appendix I) and then a study screener (Appendix J) The screener will mask the study's inclusion criteria by using unrelated questions (e.g., arrest history).

As of June 2022 we will also be distributing flyers to both existing participants and willing local businesses with our phone number on them. The goal is that recruitment rates will increase due to increased knowledge of the study amongst Women Who Use Drugs. The women will be able to contact our team at the study phone number provided to see when our mobile RV will be out in their community so they can be screened/participate in the study if eligible. We are hoping that in employing these two recruitment methods we will increase our overall enrollment into Aim 3 of the study.

These recruitment and safety strategies have evolved over time and will continue to do so. Our SPARC outreach experiences for the last 15 months providing drop-off bags and socially distant services, totaling ~600 intercepts/month, provides extremely useful information. SPARC outreach staff are in close contact with study staff to share their "lessons learned."

Aim 4: The managing director of SPARC will provide the names of all employees meeting our inclusion criteria. The study coordinator will contact the potential participants by work email to introduce the goals of the study and describe the procedures (Appendix L). If interested, study staff will schedule in-person interviews at a private location in SPARC.

Aim 5: The study team will provide SPARC with FDA approved at-home rapid COVID-19 tests. These tests will be included in the delivery bags for women who receive supplies from SPARC. One week before the rapid COVID-19 tests are included in the delivery bags that week's delivery bags will contain a flyer to let SPARC participants know that the following week they will be receiving an at-home COVID test from the CARE study team. The following week, the at-home COVID tests will have a flyer included with them in the delivery bags that lets the SPARC patrons know we will be reaching out to them soon to see if they would be interested in completing a paid survey with the CARE study about their experiences with COVID-19 testing. The SPARC outreach coordinator will provide first names and phone numbers for all SPARC outreach guests who received a service delivery in the past week to the study team. We will delay calling participants until one week after their delivery to ensure that they have time to potentially use the at-home COVID test. A casual staff member (e.g., part time student, volunteer) at SPARC will call each name on the list, introduce themselves as calling from SPARC about their experiences with outreach, and ask if they are interested in participating in a brief survey about COVID testing and SPARC outreach services.

If interested, the interviewer will consent the participant (Appendix M) and complete the survey (Appendix N). After the survey is completed, the interviewer will mail out a prepaid Visa gift card worth $15 for remuneration. If they are not interested, the interviewer will thank them for their time and note that they declined the survey. If the interviewer calls and the person who answers the phone is not the name provided by SPARC, the interviewer will only explain the purpose of the call as a "women's health survey" and will not mention SPARC, COVID, or any other outreach services.

<u>Qualitative sub-study:</u>
Participants will be recruited from the ongoing CARE cohort recruited in Aim 3 of the parent study. Interviewers will join the CARE mobile study van in the field during regularly scheduled data collection shifts. CARE study staff will be informed of the qualitative sub-study prior to any data collection. When a CARE participant completes their CARE study visit, staff will tell the participant about the qualitative study and refer them to the interviewer for screening. The interviewer will then administer a brief screener (see Appendix K) to assess sex work-related eligibility, but will also include unrelated questions to mask inclusion criteria.

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

   Privacy will be protected in several ways. We will have several long-term staff conducting recruitment who have a deep understanding of human subjects research and confidentiality. In advance of recruitment, all staff will attend a refresher training on a range of issues related to human subjects research, including understanding the importance of maintaining confidentiality of data and respecting participant privacy.
   During the course of recruitment, the interviewer will respect participant privacy by not disclosing sensitive information to other staff or anyone outside of the study. All recruitment

and screening procedures in which staff engage will occur confidentially from a private location. KIIs will be recruited via private email and/or over the phone from a private location. When speaking to potential IDI, free listing and pile sorting participants on the phone, we will ask them to check to see that they are in a private area where their conversation cannot be overheard. When recruiting in-person for Aims 1, 3, and the qualitative sub-study we will only speak to potential participants one-on-one, out of earshot of anyone else who might be in the area. Anyone who approaches the team will be told that this is a health study to mask the inclusion criteria and nature of the research. Women who respond to the CARE flyer are asked to leave a message on our study phone number. Once received we will call the potential participant back to let them know what day and time we will be back in their respective zone to complete the screening process in person, and if eligible enroll into the study.

Aim 5: SPARC is a community-based organization, it is important to protect the privacy of its guests, particularly for recruitment. SPARC will not share guests' personal contact information with the study team. Rather, casual staff members that work at SPARC (but do not work on outreach) will call current SPARC outreach guests so that names and personal contact information stay within SPARC. Guests will be assigned a unique ID that conforms to the convention described in V.A.1. Aim 3.

B. **Consent Process**:

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

   a. Who will obtain informed consent, and their qualifications:

   Aims 1 & 2: Study staff will obtain oral consent from potential participants, as the research presents no more than minimal risk to the participants and involves no procedures for which written consent is normally required outside of the research context. All interviewers will have completed training in human subjects research and will be instructed in particular aspects of obtaining consent of study participants.

   Aim 3: Interviewers and/or field supervisors will obtain written informed consent from the participants prior to enrollment. All interviewers will have completed training in human subjects research and will be instructed in particular aspects of obtaining consent from study participants.

   Aim 4: Interviewers will obtain oral consent from key informants and they will only be speaking about their professional experiences.

   Aim 5: Interviewers will obtain oral consent from potential participants, as the research presents no more than minimal risk to the participants and involves no procedures for which written consent is normally required outside of the research context. All interviewers will have completed training in human subjects research and will be instructed in particular aspects of obtaining consent of study participants.

Qualitative sub-study: Study staff will obtain oral consent from potential participants, as the research presents no more than minimal risk to the participants and involves no procedures for which written consent is normally required outside of the research context. All interviewers will have completed training in human subjects research and will be instructed in particular aspects of obtaining consent of study participants.

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

Aim 1: Consent forms will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations and will take place immediately before the applicable study activity. If the participant agrees to participate in the study, study staff will record their consent to participate. Participants who complete free listing will also be offered the opportunity to participate in an in-depth interview (until we reach n=15 interviews). In those cases, we will re-consent participants using the oral IDI consent to ensure comprehension of study risks and activities. Participants may choose to have a paper copy of the consent form given or mailed to them if they complete free listing and/or an in-depth interview over the phone.

Aim 2 observations: Prior to observations, the PI will reach out to staff overseeing COVID testing efforts at Hopkins and BCHD to describe the study, answer questions, and seek permission for observations. The PI will also ask that testing site coordinators are made aware of the study and the observer's presence. When arriving at the testing site, the observer will introduce themselves to the site coordinator to make their presence known to staff. Given the volume of testing and other activity at COVID testing sites, and the public nature of the site, individuals approaching the site for testing will be made aware of the observer but will not be consented.

Aim 2 key informant interviews: Consent forms will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations. Informed consent for KIIs will be conducted over Zoom or over the phone. If the participant agrees to participate in the study, study staff will record their consent to participate prior to the start of the interview. Participants may choose to have a paper copy of the consent form mailed to them.

Aim 3 cohort: Consent forms will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations and will take place immediately before the applicable study activity. If the participant agrees to participate in the study, both the participant and interviewer will record their names, and sign and date the consent form. Participants will be offered a paper copy of their consent form. If a participant agrees to participate in the 6-month follow-up visit, both the participant and interviewer will record their names, and sign and date the consent form before beginning the 6-month follow-up survey. Participants will be offered a paper copy of the 6-month consent form.

Aim 4: Interviewers will obtain oral consent from key informants and they will only be speaking about their professional experiences.

Aim 5: Consent will be received orally over the phone prior to the start of the interview. Consent forms will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations. Participants may choose to have a paper copy of the consent form emailed, mailed, or dropped off to them.

Qualitative sub-study: Participants will be consented in a private location where the interview will take place. This may be a private area of the mobile study van, a private outdoor space immediately near the van, or the study tracking car parked immediately adjacent to the study van, depending on space availability. Consent forms will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation, in accordance with all applicable regulations and will take place immediately before the applicable study activity. If the participant agrees to participate in the study, they will provide oral consent.. Participants may choose to have a paper copy of the consent form given and interviewers will keep one copy for study records.

c. The process you will use to determine whether a potential participant meets eligibility criteria:

Aim 1: Potential participants will be screened over the phone or in-person by study staff; this will take place immediately before the interview or prior to scheduling the participant for in-person activity. The screener will mask the study's inclusion criteria by asking a series of questions about alcohol use, zip code, and other questions unrelated to inclusion criteria. These screening procedures are informed by the research team's extensive experience recruiting and screening women for both the Sapphire (IRB#5934) and EMERALD study (IRB#7664).

Aim 2: Key informants will be screened over Zoom prior to the start of the interview. The screener will include questions to ascertain the KII inclusion criteria (Section IV, question A).

Aim 3: Potential participants will be screened in-person by study staff; this will take place immediately before Aim 3 activities. The screener will mask the study's inclusion criteria by asking a series of questions about alcohol use, zip code, and other questions unrelated to inclusion criteria. These screening procedures are informed by the research team's extensive experience recruiting and screening women for both the Sapphire (IRB#5934) and EMERALD study (IRB#7664). Enrolled study participants that are due for their 6-month follow-up visit will be consented immediately before the 6-month Aim 3 activity.

Aim 4: SPARC will provide the researchers with names of mobile outreach staff and interviewers will obtain oral consent from those mobile outreach staff participants.

Aim 5: Interviewers will have names and phone number for all guests receiving SPARC outreach services and the date of their last outreach visit, therefore no eligibility screening will need to be performed.

Qualitative sub-study: Potential participants will be screened in person immediately prior to the interview but after they have completed all CARE study activities for that visit. As CARE participants already must be 18 years or older and identify as a woman, we will only screen for engagement in sex work. However, the screener will include items unrelated to inclusion criteria such as arrest history to mask inclusion criteria.

d. Whether you will obtain a signature from the participant or will use an oral consent process:
   Aims 1 & 2, Aim 5, qualitative sub-study: An oral consent process will be used to obtain consent from participants for all study activities.
   Aim 3: A written informed consent process will be used to obtain consent from participants for all Aim 3 study activities.
e. Whether you will obtain a legally authorized representative's signature for adults lacking capacity:
   N/A
f. If children are included in the study, if and how you will obtain assent from them:
   N/A
g. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision):
   N/A
h. If you are seeking a waiver of informed consent or assent, the justification for this request:
   N/A
i. Whether you will include a witness to the consent process and why:
   We will not include a witness to consent. The study staff member who obtains consent from the participant will confirm by signing the consent document.
j. If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials:
   N/A

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

| Country | Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.) | Languages |
|---|---|---|
| USA | Adult consent (6) | English |

| | | |
|---|---|---|
| | | |

C. **Study Implementation**:

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

Aim 1

Individuals will be offered socially distant in person (e.g., SPARC Center, study van, outdoor space) or phone-based engagement in free listing and in-depth interviewing. The nature of pile sorting makes it very difficult to do over the phone so we will conduct this activity safely in person. If individuals engage in study activities over the phone, we will encourage them to participate in the interview from a safe and private space where they have privacy and can control who enters the room.

We will offer in-person activities for all WWUD who are participating in Aim 1 activities (in-depth interviews, free listing and pile sorting). They will be given the option to meet study staff at the SPARC Women's Center, or outdoors in a safe, private space such as a local park or community garden. (see Safe HSR Protocol for safety precautions) We also know that many of our past participants have preferred in-person activities as they don't always have access to a safe space or a phone from which they can engage in study activities.

*In-depth interviews:* In-depth interviews will be conducted by a trained interviewer experienced in qualitative interviewing techniques and already an IRB-approved member of the study team. After providing consent, participants will engage in a 60-minute in-depth interview. Interviews will follow a semi-structured format, with both open- and closed-ended questions. The key domains of the guide (Appendix B) were derived from a review of the literature and the team's past experience working with WWUD. Participants will be offered in-person or phone-based options for IDIs when initially recruited and screened (see safe HSR protocol).

All interviewers will begin by telling participants that we are most interested in hearing about factors that influence decisions to seek health care, in particular care related to COVID (i.e., testing, treatment for symptoms). Interviews will begin with some global opening questions designed to elicit discussion of WWUD community health and structural barriers to health seeking, before exploring individual level health priorities, health seeking, and beliefs around COVID (Appendix A, in-depth guide). Subsequent probe questions will explore the influence of WWUDs' social environment (e.g., scarcity of income, stigma, restrictions to health care access during COVID crisis), as well as factors that would help WWUD to more readily seek care and engage with COVID-19 testing and vaccination (e.g., access to trusted health providers, transportation) and factors that may deter testing and vaccination (e.g., loss of income, interference with drug use). Interviews will also explore potential (or actual if previously tested) impact of COVID testing on such factors as income (e.g., sex work) and experiences of violence resulting from confinement with an abusive partner. We will also explore salient features of COVID testing sites that would be

convenient, desirable, and enable testing. The wording of questions will be modified, as appropriate, to reflect whether the WWUD has received a COVID-19 test or treatment for COVID-19. All participants will complete a brief demographic survey (Appendix C).

Cultural Domain Analysis: The cultural domain analysis is made up of two steps: free listing and pile sorting. Activities will be conducted by a trained interviewer experienced in qualitative interviewing techniques and already an IRB-approved member of the study team. All participants will provide oral consent before engaging in study procedures and will complete a short demographic survey (Appendix C).

*Step 1:* Free listing helps define items in a cognitive domain, and is an unstructured, open-ended task used to elicit the words and brief phrases that inductively characterize a domain. During data collection, each participant will be asked to list items that would influence their decision to get COVID-19 testing/vaccination. Participants will list as many items as they can in response, initially unprompted. To elicit additional items, interviewers will use common free list probing techniques, including non-specific prompts, such as *"What other kinds of things might make it hard for women to get a COVID test?".* The interviewer will then read back free lists to check for accuracy, followed by non-specific prompts and semantic cues, such as, *"Can you think of anything else that is similar to this item?* Free list items may be single words or short phrases (e.g., racism, stigma, fatalism mentality, cost of transport, lack of knowledge and understanding of COVID 19) (see Appendix D for free listing exercise instructions and format). Participants who complete the free listing exercise will then be offered the opportunity to participate in an in-depth interview; participants may complete both free-listing and the in-depth interview, but the free listing exercise must always be completed first (so as not to bias free list responses, as interview questions bring up potential free list topics). Participants may complete the in-depth interview immediately after free listing, or schedule for another time. This will continue until all in-depth interviews (n=15) are recruited, or saturation has been reached.

*Step 2:* Pile sorting will be conducted after compiling the free lists from step 1. In pile sorting, the researchers create cards labeled with items generated through the free listing. By way of example the free list exercise may generate 40-50 items, these will be placed on index cards and assigned a unique number. The interviewer will then ask a participant to "place all the items you think are similar into piles," using as many or as few piles as necessary. After completing this stage of the exercise participants will be asked to review and label each pile with a descriptive title. Given that items cannot be generated in advance of data collection there is presently no guides or index cards.

<u>Aim 2</u>

*Observations:*

A trained qualitative research assistant will conduct a total of 4 observations each lasting between 2-4 hours at 2 different COVID testing/vaccine sites (one Hopkins, one BCHD) that have been identified as places to observe a typical location where WWUD as part of the broader Baltimore population would presently be directed. Identified sites will have been contacted in advance of data collection to secure permission for the observation. The procedure for all observations will follow the same format. The research assistant will attend the observation venue at a pre-agreed day/time to conduct a 2-to-4-hour

observations. A point person staff member from the testing site who will be present during the observation will be informed in advance and the research assistant will be expected to meet with them directly prior to commencing the observation. The research assistant will take detailed field notes during the observation, assisted by an observational guide located in Appendix E. No observational notes will identify people observed. No compensation will be provided to the organization for any observation.

*Key informant interviews:*
Key informant interviews (N=10) will be conducted with providers serving WWUD and conducting COVID testing in Baltimore. Interviews will provide insight into providers' experiences of providing COVID- and non-COVID-related services and information to WWUD; perceptions about barriers and facilitators of COVID testing and vaccination for WWUD; and perceptions about WWUDs' health priorities. The interview guide for key informants working with WWUD is in Appendix F and the guide for key informants working with non-WWUD is in Appendix G. The activities described will be performed on Zoom or over the phone by trained qualitative interviewers with experience in conducting in-depth interviews.

Aim 3
Individuals will be offered socially distant in-person (e.g., study van, outdoor space) engagement. They will be given the option to meet study staff at the study van, at SPARC, at our Hopkins offices (in Hampton House), or outdoors in a safe, private space such as a local park or community garden located immediately next to the mobile van (see Safe HSR Protocol for safety precautions). As of January 2022 participants will also complete their 3-month follow-up surveys over the phone. Participants due for their 6-month follow-up visit will also be offered socially distant in-person engagement, with the option to meet study staff at the study van, at SPARC, at our Hopkins offices, or outdoors in a safe private space at areas indicated above. Participants due for their 6-month follow-ups may also complete surveys over the phone in addition to in-person.

Baseline visit: After providing written consent, all participants will: 1) complete a 45-60 minute interviewer-administered survey; 2) receive pre-test COVID counseling from trained staff; 3) be offered COVID-19 testing using the Lumira Dx rapid antigen test; 4) receive COVID-19 test result and any necessary referrals (see Appendix H for referral sheet for participants); and 5) provide locator information for follow-up.
The baseline survey will ascertain the following: demographics; past and current structural vulnerability indicators such as hunger, housing status, employment and insurance; possession of PPE and social distancing practices; sex work and intimate partner history; medical history and health; drug- and sexual-risk behaviors; drug tobacco, and alcohol history; access to healthcare; experiences of violence; COVID knowledge and risk perception; vaccine hesitancy and history; and attitudes (e.g., medical mistrust) about medical systems and providers. These items will build on surveys previously conducted with sex workers by Dr. Sherman in Baltimore and elsewhere.

POC COVID Testing (POCT): All study participants will be offered self-collected or staff-administered COVID-19 testing at the onset of their study visits, with results given in about 15 minutes. In order to examine correlates of COVID-19 testing, being tested is not

required for study participation. POCT will be comprised of self-collection of anterior nasal swabs, followed by rapid antigen testing. We will use the Lumira Dx SARS-CoV-2 antigen test, a 12-minute, microfluidic immunofluorescence assay for the detection of nucleocapsid protein antigen. This test has been authorized by FDA under an emergency use authorization only for the detection of SARS-CoV-2 nucleocapsid protein. When present, SARS-CoV-2 antigens bind to antibodies conjugated to particles on the test strip. These antigen-conjugate particle complexes migrate to the reaction area, where they are captured by a second set of antibodies and detected. Study staff will be trained in collecting or coaching participants in swab collection, visibly demonstrating how to self-collect a specimen, and taking the swab from the participant for on-site analysis. Training for safe and precise specimen collection will be provided to all study staff by a representative from Lumira DX before the start of data collection.

If a participant receives a positive Covid-19 result we will immediately stop the study procedures. We will offer the participant a $15 Visa gift card for their time and provide the participant with guidance for how to proceed, including guidance for self-isolation, testing referrals for others they may have been in contact with, resources for isolated housing, food delivery, and other social service programs, and health care (Appendix H). COVID-19 positive participants will be eligible to rescreen into the study after 10 days. COVID-19 test results will be reported to the Baltimore City Health Department at the end of each shift via email using secure end-to-end encryption.

3-month follow-up visit: At the 3-month follow-up visit participants will: 1) complete an hour long interviewer-administered survey 2) receive pre-test COVID counseling from trained staff; 3) be offered COVID-19 using the Lumira Dx rapid antigen test; 4) receive COVID-19 test result and any necessary referrals. Participants will be eligible for their follow-up visits 14 days before their actual follow up date (3 months from previous visit). We will attempt to follow-up with all participants within one month of their follow-up eligibility date. If the follow-up window is missed, participants are still eligible to complete any remaining visits.

6-month follow-up visit: At the 6-month follow-up visit participants will: 1) complete an hour long interviewer-administered survey 2) receive pre-test COVID counseling from trained staff; 3) be offered COVID-19 using the Lumira Dx rapid antigen test; 4) receive COVID-19 test result and any necessary referrals. Participants will be eligible for their follow-up visits 14 days before their actual follow up date (3 months from previous visit). We will attempt to follow-up with all participants within one month of their follow-up eligibility date.

We will employ methods based on our previous observational studies of mobile populations which resulted in 70%-80% follow up rates. We will monitor the Maryland Inmate Locator and send retention letters to participants who may be incarcerated to enhance their study participation upon release. We have found that our study van’s continued presence in the community has enhanced follow-up rates, as many study participants approach the van when they think that they are due for follow-up. Given the short time period between the two study visits, we are confident that we will achieve sufficiently high follow-up to power the proposed analyses.

All participants will be offered naloxone, condoms, fentanyl test strips, and refreshments (e.g., water, granola bars) as well as CARE swag labeled with the study logo and phone number (e.g., branded hand sanitizer) at all visits. Participants will also be informed of COVID-19 vaccination availability in Baltimore City (see Appendix H). Staff will offer to help schedule vaccine appointments and no-cost transportation for participants through our partnerships with local organizations such as the BCHD, Charm City Care Connection, and SPARC.

If a participant has a positive antigen test they will be advised by staff members to quarantine for 10 days and to seek emergency medical care if their symptoms are severe (according to current CDC guidelines). Participants with a positive test will also be given a resource sheet with information about COVID-19 and how to isolate according to CDC/Baltimore City guidelines. (Appendix H).

Given the recent surge in COVID-19 cases in Baltimore city as of January 2022, we will be suspending in-person data collection. We will instead reach out to enrolled participants to complete their 3-month follow-up surveys over the phone using the contact information provided at baseline. We expect enrolled participants to complete their 6-month follow-up surveys in person, however if another surge in COVID-19 cases in Baltimore city occurs we may also implement phone surveys at this follow-up visit as well, using contact information provided at the 3-month follow-up visit.

Personal Identifiers

To ensure protection of data and participants' confidentiality and privacy, we will use limited identifiers. All biologic specimens will be collected and tested on the study van, avoiding the need to go to other clinics to request testing results.

For linkages between test results and survey data, the study will use unique identifier (UID) codes. The UID will be constructed using information known only to the participant and will be used to link all surveys, specimens, and laboratory results. The UID will be developed as part of the registration process, after the participant has given written informed consent to participate. Participants will be asked to recreate the UID at the start of each follow-up visit.

The UID will also provide a mechanism through which we can measure participant interaction with the intervention components of the study. As part of the registration process participants will be asked for information that will be used to create their UID. Thereafter, they will reproduce their UID (with staff assistance) at the beginning of each study visit.

The code will be formulated from questions that are easily answered, reproducible, culturally appropriate, individually unique, and that WWUD will be comfortable answering. The unique identifier will be an 8-digit reproducible alphanumerical number developed using the first two letters of the participant's last name, the first two letters of the participant's first name, the digits of the day of the month they were born (01-31), and the last two digits of the participant's birth year.

During the process of creating the unique ID code with the participant, the study team member will indicate that they only need to respond with the appropriate number(s) or letter(s) to the question and do not need to give the full response (e.g. participant will only need to provide the first letters of their name, rather than state their full name). Doing so offers an additional sense of privacy for the participants. This unique identifier code can be recreated throughout the study and will facilitate linking study participants with study data while maintaining anonymity. This process has been successfully used in past research studies (IRB#s 2895, 6652) conducted by members of this study team.

Unique Identifier: __ __ __ __ __ __ __ __
L L F F D D Yr Yr

To facilitate coordination of follow-up study visits, participants of the prospective study will be asked to leave their first name or nickname and telephone contact information. A hard copy of the contact list will be stored in a locked cabinet and an electronic version will be saved on a password-protected computer. Only researchers tasked with scheduling and following-up with participants will have access to the list, by permission of the PI.

The list will not be linked to study data, and names and phone numbers will be removed after the participants complete the last follow-up visit. In all communications with participants outside of the study site, the investigators will not mention drug use, COVID-19 testing or results, or participation in a research study. During phone calls, texts, or when leaving voicemails with participants or their stable contacts staff will only refer to the study as a women's health study.

As of July 2022 when visiting the addresses provided by participants in their locator forms for 3 and 6 month follow up visits we will be leaving a contact card at the addresses visited if no one answers the door. Contact cards will also be left at addresses found in the Maryland Judiciary Case Search system, as this information is publicly accessible and can potentially provide a more up to date address for a participant than what we may have in their most recent locator form. The contact card will contain the study logo and phone number, and will not include any information as to the nature of what is being researched in the study.

All study data will be entered into a secure, encrypted database and, once entered, will be non-retrievable without permission from the PI or study Director.

Aim 4: Key informants will be offered in-person engagement at a private room in SPARC for in-depth interviews. The interview guide is informed by our implementation framework, PRISM. The guide is semi-structured and focused on key characteristics of the existing SPARC mobile outreach program and clients, current program operations, and staff/organizational perspective on the integration of at-home COVID testing into SPARC outreach activities. Interviews will be audio-recorded and strive to maintain a balance between structured responses and conversational discussion. Interview recordings will be transcribed verbatim for data analysis.

Aim 5: SPARC outreach guests will complete their interviews over the phone. At the beginning of the call, an interviewer will ascertain interest in participation and, if interested, will consent the participant. The interviewer will conduct the survey and record answers in Qualtrics. The survey will take between 10-15 minutes. The survey is cross-sectional and no other engagement is expected.

Qualitative sub-study:
Individuals will be offered in-person (e.g., study van, outdoor space near van) engagement for in-depth interviews.
Following a structured guide, interviews will open with global questions about day-to-day routines to accustom them to the interview style and to build rapport. Next, we will explore a range of sex work environmental features including: their relationship with other street-based FSW; client-perpetrated violence; police interactions; criminalization of sex work; and the built environment's role in sex work safety (e.g., safe spaces to take clients, abandoned houses). Next, we will ask if/how the street-based workplace impacts mental health (i.e., increase stress, anxiety, depression, isolation). We will also explore COVID-19's impact on the street sex work market, mental health, income, and safety threats from clients and police. Interviews will follow a semi-structured format with both open- and closed-ended questions. The interview guide will be informed by the study's conceptual model. Participants will be compensated with a $50 Visa gift card. Interviews will be audio-recorded and strive to maintain a balance between structured responses and conversational discussion. Interview recordings will be transcribed verbatim for data analysis. We will use the same personal identifier used in the CARE study.

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

   Aim 1
   Women who are eligible and provide oral consent will complete a brief demographic survey (Appendix C). Potential participants will complete at least one of the following study activities: individual in-depth interview; free listing activity; or pile sorting activity. Any participant who completes free listing will be offered participation in the in-depth interviews (until n=15 interviews are completed or interviews cease recruitment due to saturation), but free listing must always be conducted first. All activities are anticipated to last no more than 60 minutes. If free listing participants decide to also do an in-depth interview, they do not have to complete the interview immediately and can return at another scheduled time. In these cases, participants will engage in two study visits for a total of 120 minutes of study activity.

   Interviews and free listing activities will be offered over the phone or in-person; pile sorting must take place in-person. In-person activities will take place at SPARC or in a private outdoor space. Interviews will be digitally recorded and transcribed verbatim using a transcription service. Transcripts will be proofread and corrected based on the original recording.

   Aim 2

*Key informant interviews:* All interviews will be conducted over the phone or in a private Zoom room. Key informants who are eligible and provide oral consent will complete a 60-minute individual key informant interview. Interviews will be digitally recorded and transcribed verbatim using a transcription service. Transcripts will be proofread and corrected based on the original recording.

Aim 3
Women who are eligible and provide consent will complete three study visits at baseline, 3-month, and 6-month follow-up visits which involve a 60 minute survey and COVID-19 testing. The baseline visit is anticipated to last no more than 75 minutes; the 3-month and 6-month follow-ups will last about 60 minutes. Participants will engage in three study visits for a total of no more than 195 minutes of study activity. Study staff will reach out to participants via methods they provide in their locator form to schedule their follow-up visits. Study visits will take place over the phone and in-person (e.g., study van, outdoor space).

Qualitative sub-study: Women who are eligible and provide written consent will complete an individual in-depth interview. All activities are anticipated to last no more than 60 minutes. In-person activities will take place at on the CARE study van, a private outdoor space immediately adjacent to the study van, or in the study tracking car. Interviews will be digitally recorded and transcribed verbatim using a transcription service.

Aim 4: All interviews will be conducted in person at SPARC. Key informants who provide oral consent will complete a 60-minute individual key informant interview. Interviews will be digitally recorded and transcribed verbatim using a transcription service. Transcripts will be proofread and corrected based on the original recording.

Aim 5: All SPARC patron interviews will be conducted over the phone. SPARC guests who provide oral consent will complete a 10-15 minute survey. Survey responses will be recorded by an interviewer in Qualtrics, provided by JHSPH IT, for participant data collection.

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

   Aim 1: Women will be asked to engage in research activities for approximately 1 hour. Participants who complete both the free listing and in-depth interview will engage in research activities for approximately 2 hours.
   Aim 2: Key informants will be asked to engage in research activities for approximately 1 hour.
   Aim 3: Women will be asked to engage in research activities for approximately 1 hour per visit. Participants who attend the baseline 3-month, and 6-month follow-up visits will engage in research activities for approximately 3 hours. The total amount of time a participant could be engaged in this Aim is 6 months between baseline and their follow-up visits.

Participants who complete free listing first may complete an in-depth interview for a total of two study activities (until we recruit n=15 in-depth interview participants or reach saturation). Other than in this case, participants will only complete one study activity and are not eligible to participate in additional activities described in Aims 1 and 2. Participants who complete Aims 1 or 2 are eligible to participate in Aim 3.

Aim 4: Key informants will be asked to engage in research activities for approximately 1 hour.

Aim 5: Eligible SPARC patrons will be asked to engage in research activities for approximately 10-15 minutes.

Qualitative sub-study: Women will be asked to engage in research activities for approximately 1 hour.

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

*Analysis for in-depth interviews (Aim 1) and Aim 2 activities:* IDI, observation, and key-informant interview analysis will follow the thematic analysis method. The analysis will use two independent coders. First, the coders will select 2 interviews to code and discuss. The coders will read transcripts thoroughly several times and check them against recordings for accuracy. Initial codes will be developed based on the aim and the interview guide. Each coder will independently code; then they will meet to discuss codes and themes that emerged from the data. Based on this, a preliminary codebook will be created. Then the coders will select 2 interviews to both code based on the revised codebook and will again meet to discuss emerging codes and discrepant coding. Coders will begin restrictive coding based on the codebook for the remaining interviews once consensus on codes and themes is reached. The coders will meet after every 5 transcripts are coded to discuss modifications to the codebook based on themes and codes that have emerged.

*Analysis for free listing and pile sorting (Aim 1):* We will use cultural domain analysis (CDA) after each of the data collection activities. After the free listing exercise, our analytical team will: review the items, eliminate duplicates, and combine similar items to reduce the list; calculate the frequency of items; and selected items with a frequency ≥ 5 and items with lower frequency but high importance based on qualitative analyses of interview data[34] will be used in the pile sorting exercise. Pile sort data will be analyzed using the Anthropac multidimensional scaling (MDS) tool to identify each statement as a separate point on a two-dimensional map, which provides a visual representation of participants sorting data. MDS graphs prioritize meaning through spatial proximity (i.e., items that appear closer together are more conceptually similar; items appearing farther apart are more conceptually distinct).[35] MDS calculates a stress value (i.e., goodness-of-fit indicator) where lower stress values more accurately reflect congruence between the raw data and the computed distance matrix. We will conduct a cluster analysis of the MDS to identify meaningful groupings of items across participants.[36] The CDA procedures are expected to result in between 4-6 dimensions of WWUD-centric barriers/facilitators to COVID testing/vaccination and offer insight alongside the interview and observational data analysis on how to decrease barriers to WWUD COVID-19 testing/vaccination uptake.

*Analysis for Aim 3 activities:* To assess the association of risk factors with POCT (the outcome) over the 6-month follow-up period, we will apply logistic regression models adjusting for repeated measurements per person with a generalized estimating equations approach for longitudinal data. Initial models will include baseline demographic and structural factors and later models will look at time-dependent covariates such as COVID-19 testing in the prior 3-months period or vaccine uptake as well as measures of vaccine hesitancy and medical mistrust. This approach allows for maximal use of all available data. Sensitivity analyses will be performed to explore the impact of potentially differential loss to follow-up using propensity score weighting as well as evaluating longitudinal models for women that have completed all three study visits.

Finally, an exploratory analysis will be conducted to examine the behavioral consequences of COVID testing and the association of these behaviors with participants' characteristics and other drug and risk behaviors for negative health outcomes (e.g., HIV, overdose) using logistic regression models.

Aim 4: Interviews will be reviewed for completeness and accuracy, and transcripts entered into qualitative software programs that facilitate management, coding, and analysis of narrative data. We will utilize Rapid Assessment Process[49] and matrix analysis[50] to quickly analyze and synthesize KII data. Coders will create templated summaries of each interview using neutral domains defined *a priori* and transfer summary points into a matrix to allow for ease of identifying patterns within each domain. Results will immediately inform intervention development and implementation of at-home COVID testing delivered by SPARC outreach.

Aim 5: Descriptive statistics (e.g., means, median, frequencies) will be produced for each survey question. We will then stratify COVID testing uptake by key demographics (e.g., age, race, education), COVID history, and history of SPARC outreach use using Pearson chi-square tests to understand bivariate differences in testing uptake. Informed by these results, we will construct a multivariable model with use of the at-home COVID test as uptake. Additionally, we will analyze the COVID testing acceptability questions that will be asked of a subset of participants who report using the at-home COVID test. We will also produce descriptive statistics for these questions. We expect few (<15%) of the sample to engage in at-home COVID testing based on early COVID testing uptake during Aim 3 activities. Depending on the sample size of guests who used the at-home COVID test, we will use Pearson chi-square tests (or Fisher's exact tests for small cell sizes) to understand bivariate differences in at-home COVID test acceptability.

Qualitative sub-study: Interviews will be reviewed for completeness and accuracy, and transcripts entered into qualitative software programs that facilitate management, coding, and analysis of narrative data (e.g., NVivo). The following analysis steps will be then be followed: 1) members of the analytic team, including the interviewers, will independently read the interview transcripts from the first two interviews and generate inductive, in vivo codes driven by the text and deductive codes driven by the research question. Through discussions among the qualitative analysis team, consensus will be reached on code names and jointly-developed definitions for each code word to form an inclusive codebook.

Using the codebook, the team will jointly code an initial set of transcripts, discussing disagreements until consensus is reached, following which the remaining transcripts will be coded using the codebook. Following the independent coding, team members will meet to compare and contrast coding decisions. Minor differences will be discussed until consensus is reached. We will use thematic analysis to identify the most important factors that emerge from the data and use the technique of constant comparison to analyze the combined data to identify commonalities and differences before aggregating related factors into more global themes.

5. Answer the following **if they are relevant to your study design**:

A. If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.
N/A

B. If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the "Biospecimen Repository" section below.

Aim 3: All study participants will be offered POC COVID-19 (POCT) testing and results at the onset of both of their study visits. No identifying information will attached to biospecimens, unique identifiers will be used to identify specimens during the testing process. All collected biospecimens and testing strips will be destroyed at the end of the study visit.

C. If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.
N/A

D. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.

BC0502280117

E. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.

The LumiraDx SARS-CoV-2 Ag test has been authorized by FDA under an EUA only for the detection of SARS-CoV-2 nucleocapsid protein. The COVID antigen tests have been validated for CLIA use, and will be performed under CLIA oversight at the point-of-care. We have not seen any significant failure in the test strips or device during the time this has been in clinical use at JHH. We will report test results to participants as soon as they are available, within 20 minutes of sample collection. Deidentified results will also be reported to the RADx-UP CDCC, as required by the NIH. We do not expect to have any incidental findings as these tests are only authorized to detect SARS-CoV2 antigens.

F. If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information: N/A

a. Will the study staff be blind to participant intervention status?

b. Will participants receive standard care or have current therapy stopped?

c. Will you use a placebo or non-treatment group, and is that justifiable?

d. Explain when you may remove a participant from the study.

e. What happens to participants on study intervention when the study ends?

f. Describe the process for referring participants to care outside the study, if needed.

## VI. Data Custody, Management, Security, and Confidentiality Protections:

*Note: Principal Investigators are responsible for Data Protection and Use throughout the life of the study. You will need all of the following:*

- *a data security plan that addresses each stage: data collection, transfer/analysis, storage, and sharing;*
- *a data management plan overseeing data access, storage, etc.;*
- *a data sharing plan that is consistent with obligations under the funding agreements associated with the study, and with the language in the consent documents.*

### A. <u>Personally Identifiable Information (PII)</u>:

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

| | Recruitment/Consent | Data Collection |
|---|---|---|
| **Name, signature, initials, or other identifiable code** | ☒ | ☐ |
| **Geographic identifier: address, GPS location, etc.** | ☒ | ☐ |
| **Dates: birth, death, clinical service, discharge, etc.** | ☒ | ☐ |
| **Contact information: phone numbers, email address, etc.** | ☒ | ☐ |
| **ID: Social Security Number, driver's license number, etc.** | ☐ | ☐ |
| **Health record identifiers: medical record, insurance plan number, etc.** | ☐ | ☐ |
| **Account numbers** | ☐ | ☐ |
| **Device identifiers: e.g., implants** | ☐ | ☐ |
| **Internet identifiers: IP address, social media accounts** | ☒ | ☐ |
| **Biometric identifiers, including finger and voice prints** | ☐ | ☐ |
| **Audio recordings** | ☐ | ☒ |
| **Video or full face photographic images** | ☒ | ☒ |
| **Genomic/genetic data** | ☐ | ☐ |
| **Any other unique identifying number, characteristic, or code (note: this does not mean the unique code assigned by the investigator to code the data)** | ☐ | ☐ |
| **Other:** Click here to enter text. | ☐ | ☐ |

**Recruitment:**

Will you collect identifiers for the purpose of contacting potential participants? Yes ☒ No ☐

If **yes**, will you retain the identifiers after the recruitment contact has been made? Yes ☐ No ☒

**B. Data Collection:**

*Collection of data for a research study can take on many forms. It can be as simple as gathering the data with pen and paper or developing an on-line adaptive survey that changes based on the participant's answers. Regardless of the method, PII collection for the purposes of identifying the participants will most likely be collected. Once collected, the raw data should go through a de-identification process to further protect PII.*

In what form(s) will you collect and store PII? When you respond, refer back to the table above; think of PII collected during recruitment, consent, data collection, and other study purposes.

1. **Hard Copy/Paper:** Yes ☐ No ☒

   If yes, please answer the following:

   a. How will the data be kept secure during transfer from study collection site to storage site?

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

   c. If study IDs/Codes are used, will they be stored separately from the study data? Yes ☐ No ☐

   d. Will the hard copy/paper be destroyed after data abstraction and cleaning are complete? Yes ☐ No ☐

      If No, when do you plan to destroy the hard copies?

2. **Electronic:** Yes ☒ No ☐

   If yes, please answer the following:

   a. Will the data be collected or stored on a portable device (laptop, mobile phone, tablet, PDA) Yes ☒ No ☐

      If Yes, will the device be protected by encryption? Yes ☒ No ☐

   b. Will the device(s) be study-owned or privately-owned (e.g., personally owned by data collectors or study participants?)
      Personally owned ☐ Study provided ☒
      *Note: If personally owned, please address the privacy and data security risks under VII. Risks below.*

c. Is the app (application)/website used for data collection being developed in-house (Hopkins) or by a 3rd party vendor? In-house ☒ 3rd party ☐

If 3rd party, provide the name of vendor and URL:

Identify Mobile Ecosystem (check all that apply): Apple ☐ Google ☐ Website ☐

d. Will the data be stored on a secure server (@JHSPH/on-site)? Yes ☒ No ☐

e. Will the data be stored in the Cloud/Web? Yes ☒ No ☐

f. Will it be encrypted? Yes ☒ No ☐

g. Will you be backing up your data? Yes ☒ No ☐

**3. Mobile Apps** Yes ☐ No ☒

**FOR STUDIES USING MOBILE APPS**: When the use of a mobile app is approved solely for a research use, the IRB either requires that it be restricted to people who consented to the research, or when a screen/script is used, for participants to understand that this is not a medical tool or a public app, but is for use only in a research study only. Please check the appropriate box(es) below that describe your study:

☐ Use of the app is restricted to people in the research, with access limited to those who have consented to the study.

☐ The consent information for participants clarifies that the app is not for clinical or public use but is restricted to this research study

4. **<u>Audio Recording</u>:** Yes ☒ No ☐

If yes, please answer the following:

a. Will you store the audio recording securely in a locked cabinet/room until transcription is complete? Yes ☒ No ☐

b. Will you use a transcription service? Yes ☒* No ☐

**If yes, if the PII comes from JHH/JHHS, you must use an approved vendor; otherwise, be aware of the data security protections that the transcription service provides.*

c. Will the audio recording be destroyed immediately after transcription? Yes ☐ No ☒

If no, why not? How long will it be retained?

Audio recordings will be destroyed upon completion of analysis.

4. **Photograph/Video:** Yes ☒ No ☐

   If yes, please answer the following:

   a. Will the photographs/videos be stored securely in a locked cabinet or room? Yes ☒ No ☐
      The KII videos will be stored on a password protected computer.
   b. Will the photograph/video be destroyed? Yes ☒ No ☐

      If yes, when?
      KII participants (Aim 2) will be offered the opportunity to conduct their interview over Zoom. Participants may opt to keep their video off and only the audio of the interview will be recorded. Video recording will be destroyed upon completion of analysis.

**C. PII De-Identification of Data Used for this Study:**

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

   A password protected spreadsheet containing a name and selected address for mailing participant payment will be stored on OneDrive to facilitate and track participant payment. The study coordinator, interviewers, and the PI will have access to this spreadsheet. This document will be destroyed when data collection is complete.

   All other participant information will be destroyed within 12 months from the end of data collection.

2. What is the method you will use to de-identify the data?

   N/A

3. Is your research data governed by HIPAA (U.S. clinical data remaining within the covered entity)?

   a. Yes ☐ No ☒

   b. If yes, who is doing the de-identification?

   c. If yes, what level of de-identification will you achieve (Limited data set? De-identified?)

**D. Data Storage and Analysis:**

*One of the keys to protecting PII is the proper use of tools to share and conduct your analysis. JH and JHSPH offers several options for you to consider. Please select the systems that you plan to use to protect your study data by clicking the box. Consult JHSPH IT for assistance if needed*.
*Check all systems used for data collection, storage and analysis*.

☐ **JH Virtual Desktop**: The Hopkins Institute for Clinical and Translational Research (ICTR) provides a virtual Windows desktop (SAFE Desktop). It includes productivity software such as Microsoft Word and Excel, as well as statistical software, including SAS, Stata, R, R Studio, and Python. 100 GB of storage space is provided.

☒ **OneDrive-JHSPH**: Managed by JHSPH IT and available only to people with a JHSPH ID, a file storage and file sharing solution in the Microsoft cloud for faculty, staff, and students. With OneDrive, you can store files and access them anywhere with internet access.

(https://my.jhsph.edu/Offices/InformationTechnology/ComputerSupport/SharedFolders/OneDrive-JHSPH/Pages/default.aspx)

☐ **JHU OneDrive**: Managed by IT@JH, personal cloud storage component of the Office 365 produce suite that allows users to store and share documents and files from any device with an internet connection. Share documents with colleagues, inside and outside of JHU (no JHED ID required). (https://it.johnshopkins.edu/services/collaboration_tools/OneDrive/)

☐ **JHSPH RedCAP**: These are departmentally managed applications. RedCAP is an application designed for collaborative research projects.

☐ **JHSPH HPCC:** High Performance Computing Cluster (HPCC: https://jhpce.jhu.edu/) can provide the high capacity computing required for very large data sets.

☐ **JHSPH Sharepoint:** For user-controlled private web sites, secure document storage, navigable directories, contacts and people searches, increased collaboration and sharing opportunities.
(https://my.jhsph.edu/Offices/InformationTechnology/CommunicationServices/MyJHSPH/Pages/default.aspx)

☐ **Independent Departmental Servers and Systems**: These servers are typically managed by departmental or research team IT staff. Because these servers are not centrally managed by JHSPH IT, all documentation regarding data security protections will need to be provided by the owner/administrator of the server. This responsibility may fall to the data owners (PI).

☒☐ **Other**: Please provide details regarding any other systems being utilized, for example Qualtrics, ODK, etc. Examples may include servers and applications located at another university participating in your study or a 3rd party web-based application.
We will use Qualtrics, provided by JHSPH IT, for participant data collection.

**E. Other Data Security Measures:**

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

1. During the analysis phase, do you plan to use computer systems that are not managed by JHSPH or JH? Yes ☐ No ☒

   If yes, please explain:

2. Do you have a designated person on your research team other than the PI who is the technical contact for a Data Security plan? Yes ☐ No ☒

   If yes, please provide a contact name:

3. Does your sponsor have other specific data security requirements for the study data?
   Yes ☐ No ☒

If possible, please explain:

4. Please add any other information that you believe is relevant to data security.
   We will use Zoom to conduct interviews with key informants. Access to Zoom rooms will be password protected. Zoom uses Advanced Encryption Standard for audio, video, and recordings with a one-time key for each session so that only session participants with the key can access the data.

**F. Certificate of Confidentiality:**

*All NIH studies include Certificate of Confidentiality protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (https://humansubjects.nih.gov/coc/index)*

Does the study have Certificate of Confidentiality protections? Yes ☒ No ☐

**G. Data Sharing and Disclosure:**

a. Please describe your data sharing plan, including whether you plan to share your data with your sponsors or with other investigators. Explain whether the shared or disclosed data will be individually identifiable. **Your data sharing plan should be consistent with Sponsor requirements, and the consent document should include a description of your data sharing plan.**

Transcripts will be made available to the analysis team for coding and qualitative data analysis. All files will be stored and password protected in one-drive. None of the data will be identifiable, all transcripts will be numbered and any identifying information will be removed from transcripts prior to being saved in one drive for analysis.

Per the terms of the grant mechanism, we will be sharing deidentified data collected for Aim 3 with the CDCC and RADx-UP via a secure portal. Data will be harmonized with other RADx-UP/CDCC projects to create a publicly available dataset on national COVID-19 testing availability in underserved populations. We have been granted exceptions to the RADx/CDCC policy of uploading identified data; we therefore will only be sharing fully deidentified data with RADx/CDCC. Additionally, we will only be sharing data from survey questions that are common to all projects; any other survey questions not in these common data elements will not be shared publicly.

We will use the following procedure to share data with the CDCC: At the time of data transfer, the project team will download the CSV file with the data from their database in REDCap. This file will then be uploaded by a designated project team member into the secure RADx-UP CDCC data portal. The CDCC will be using a PowerApps/PowerBI portal connected to Microsoft Azure. The portal and the database will be housed on the Microsoft

Cloud. The secure, cloud-based portal will require individual credentials and sign-in to access the data upload feature. Credentials will be assigned by the CDCC, or if the institution has federated credentials through In Common, their access will be granted via that method.

b. Are there laws limiting data sharing in the country where the research site(s) is located? If yes, please address those limitations and how you will comply with them.
No

c. Will you make your data publicly available? If yes, what is your plan for de-identification?

Yes. Partial data will be publicly available to other researchers via the harmonized RADx-UP/CDCC dataset. We have an agreement with the RADx-UP/CDCC group that we will only share de-identified data. We will achieve this by only recording identifiable data (e.g. name, date of birth, address, etc.) in a secure database that is kept separate from survey data. Only the survey data file will be uploaded to the RADx/CDCC portal.

d. Will you deposit it into a repository for broader use? If yes, identify the repository and provide information about the data protections.

No

**H. JHM Clinical Records:**

Will you use clinical data of 500 records or more from Johns Hopkins Hospital and its affiliates?
Yes ☐* No ☒

**If yes, please complete the JHM Data Security Checklist available on the JHSPH IRB website: www.jhsph.edu/irb and upload a copy of the checklist to the "Miscellaneous" section.*

## VII. Risks of the Study:

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

There is potential for participants to experience discomfort and/or psychological or emotional distress from being asked sensitive questions or being observed during interviews, cultural domain analysis activities, observations, key informant interviews, or survey data collection. There is also risk of loss of confidentiality. If a breach of confidentiality were to occur participants risk disclosure of personal information. KII participants risk disclosure of information about their organization and activities.
Aim 3 participants are subject to all the risks listed above and the additional risk of people not involved in the study finding out their COVID-19 status as well as risk of COVID-19 infection. (see Safe HSR document for a description of COVID-19 safety procedures and infection risk mitigation)

B. Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.

The interviewer will provide a list of local professional health and social services for women who experience distress or discomfort during study activities. Direct referrals will be made for women who would like additional support or services. Case management, clinical, and mental health services are available through the SPARC Center and participants can be connected to providers immediately. Warm referrals can also be made to other providers, including Paul's Place, IBR Reach, Voices of Hope, Safe Haven, and Charm City Care Connection. The qualitative sub-study will use the same referral system as CARE interviews. Additionally, if a participant expresses suicidal intent with a plan for action (i.e., not passive thoughts of death), we will stop the interview and immediately call the Baltimore Crisis Response Inc. (BCRI) which runs a 24 hour crisis hotline for individuals needing immediate assistance. Interviewers will wait with the participant until BCRI arrives on the scene or BCRI resolves the situation over the phone. The consent form will include this information and detail when this procedure will be triggered. Interviewers will be trained in recognizing and clarifying suicidal intent in participants prior to data collection.

For Aim 3, all survey data is collected in private spaces away from other participants or staff. Study staff will maintain participant privacy by only disclosing COVID-19 status privately. As of January 2022 3-month follow-up data collection will also take place over the phone and 6-month follow-up data collection may also take place over the phone and in private spaces.

For Aim 4, interviews will be conducted in a private space at SPARC, ideally on an administrative working day where guests are not present. Researchers will not share who has participated in the interviews with the other SPARC staff who are not eligible for interviews.

Aim 5: SPARC guest interviews will be conducted over the phone privately with one staff member. SPARC outreach staff will not see the participants answers and researchers will not share who has participated in the interviews with SPARC staff. Any survey results shared with participants or SPARC staff as part of dissemination will be presented in aggregate.

Research staff will be trained in human subjects protection to minimize the risk of loss of confidentiality. Audio files, video files, and notes will only be accessible by the interviewer and the PI and all transcripts will be de-identified (if they contain any identifying information) prior to data analysis by a second coder. All data will only be accessible to the interviewer or observer and PI.

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

Based on similar work with this population, we do not expect participants to experience any harms.

D. Describe the research burden for participants, including time, inconvenience, out of pocket costs, etc.

Aim 1

Women who participate in Aim 1 activities will be asked to engage in approximately 1 hour of research participation. Women will be given a $50 Visa gift card for remuneration. If participants complete free listing and then an in-depth interview, they will be asked to engage in approximately 2 hours of research and will receive 2 $50 Visa gift cards, for a total of $100.

Aim 2

There is no burden for individuals during observations. Key informant interview participants will be asked to engage in approximately 1 hour of research. We will offer them a $50 Visa gift card for their time.

Aim 3
Women who participate in Aim 3 activities will be asked to engage in approximately 3.25 hours of research participation at three different times (baseline, 3-month and 6-month follow-ups). Women will be given a $50 Visa gift card for remuneration at baseline, a $50 gift card at 3-month follow-up and a $50 Visa gift card at 6-month follow-up. For participants completing their 3-month follow-up surveys and 6-month follow-up surveys over the phone, a $50 gift card will be either mailed to them or dropped off to them directly by study staff.

Aim 4: Key informant interview participants will be asked to engage in approximately 1 hour of research. There will be no remuneration.

Aim 5: SPARC patron participants will be asked to engage in approximately 10-15 minutes of research. Participants will be given a $15Visa gift card for their renumeration. Participants who complete the study activities will be mailed the $15 Visa gift card or it will be dropped off to the participant, depending on the participant's preference.

Qualitative sub-study: Women who participate in Aim 1 activities will be asked to engage in approximately 1 hour of research participation.

E. Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.

During data collection, participant privacy will be protected by conducting interviews over the phone, in a private, password-protected Zoom room, in a private location outdoors, in a private room at the SPARC Center, in our Hopkins offices, in a private space on the mobile study van, in the study tracking car, or in an outdoor location immediately adjacent to the van. Study staff will let participants know there may be sensitive questions and will encourage phone and Zoom participants to call from a private location of their own choosing. Participants will be informed that they may choose not to answer any questions.

## VIII. Direct Personal and Social Benefits:

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

Women may receive referrals to local programs, medical programs, support groups, vaccination sites, and health projects. Otherwise, there are no personal benefits for participation.

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

The results will contribute to a better understanding of the factors that influence decisions of WWUD to seek health care, in particular care related to COVID-19 (i.e., testing, treatment for symptoms). The work of Aim 4 will result in implementing at-home testing for COVID as part of routine SPARC mobile

outreach deliveries, offering SPARC guests an additional health promoting service. Aim 5 results will show utilization of at-home testing in this population, as well as important implementation outcomes related to at-home COVID testing including acceptability and feasibility of this service being integrated with existing SPARC outreach services. The qualitative sub-study will contribute to a better understanding of the occupational features of sex work and their differential effects on mental health of sex workers.

## IX. Payment or Token of Appreciation:

A. Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If yes, please describe below.

Aim 3 participants will be offered naloxone, condoms, fentanyl test strips, and refreshments (e.g., water, granola bars) as well as CARE swag labeled with the study logo and phone number (e.g., branded hand sanitizer).

B. If you plan to provide a monetary payment, describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

Upon completion of the Aim 1 study activity, in-depth interview, free listing, pile sorting, and KII participants will receive a one-time $50 gift card to compensate them for their time.

For participants who participate over the phone, a prepaid VISA card will be mailed to a location of their choice, along with a letter that includes instructions for use.

Upon completion of the Aim 3 study activity, participants will be given a $50 Visa gift card for compensation at baseline, a $50 Visa gift card at 3-month follow-up, and a $50 Visa gift card at 6-month follow-up.

Aim 4: Key informant interview participants will be asked to engage in approximately 1 hour of research. There will be no remuneration.

Aim 5: SPARC patron participants will be asked to engage in approximately 10-15 minutes of research. Participants will be given a $15 Visa gift card for their renumeration. Participants who complete the study activities will be mailed the $15 Visa gift card or it will be hand-delivered to the participant, depending on the participant's preference.

Upon completion of the qualitative sub-study, participants will be given a $50 Visa gift card for compensation.

A password protected spreadsheet will be stored in OneDrive that documents payment to ensure that all payments are completed in a timely manner and to prevent duplicate payment.

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

The maximum amount of remuneration a participant can receive is $300 in the case of a participant who completes free listing, an in-depth interview, all three Aim 3 surveys, and the qualitative sub-study (six $50 Visa gift cards, one for each activity). There is no consequence for not completing all phases of research.

## X. Study Management:

### A. Oversight Plan:

1. Describe how the study will be managed.

Overall oversight for the study will be the responsibility of the PI, Professor Susan Sherman. The Project Director, Emily Clouse, will provide oversight of all data collection and analysis activities. The Field Coordinator, Katherine Haney, will be responsible for recruitment and data collection. Her responsibilities will include developing a manual of procedures, leading data collection trainings, supervising all study staff, and serving as point of contact in the event of any issues. The Data Manager, Catherine Tomko, will be in charge of housing all data collected from the study. She will ensure that qualitative data is properly managed and stored and will perform QA/QC checks to confirm data that is collected is valid and of the highest quality.

Weekly management meetings will be held and will provide an opportunity for key staff to update the Principal Investigator on the status of data collection, discuss any QA/QC issues, and develop solutions for moving forward.

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

All personnel involved in data collection will have completed CITI human subjects training and Good Clinical Practices training.

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

The PI will oversee the development of all data collection materials, trainings, and analyses. She will attend weekly study management meetings and oversee the data collection process through regular updates from staff.

B. **Recordkeeping:**
Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact: housecall@jhu.edu

Adherence to the protocol, proper recording and storage of study data collection forms, IRB regulatory correspondence, and other study documentation will be managed on a daily basis by the Study Coordinator and overseen by the PI. A QA/QC system will be developed to ensure data integrity. All study data will be stripped of identifiers and will be housed on JHU OneDrive.

C. **Safety Monitoring:**

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

All study staff will receive a safety training session as well as training in the conduct of this type of research. Protocols will be developed to ensure staff and participant safety (e.g. check in with Program Coordinator at the start and end of recruitment and IDIs). As all study contacts will be virtual, there will not be a medical monitor on site. Developed protocols are based on our previous work, including the Principal Investigator's experience with these procedures for the SAPPHIRE study (IRB#00005939) and the EMERALD Study (IRB # 00007664).

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:

   a. The DSMB membership, affiliation and expertise.

   N/A

   b. The charge or charter to the DSMB.

   N/A

   c. Plans for providing DSMB reports to the IRB.

N/A

3. Describe plans for interim analysis and stopping rules, if any.

We do not anticipate conducting an interim analysis.

D. **Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)**:

Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.

Adverse events are unlikely to occur in respect to this study population and the study, however should any problem or unforeseen event occur, it will be immediately reported in real time (i.e., same day) by study staff to the Director and PI, Dr. Sherman, who in turn will report it to the JHSPH IRB

.

In the event that a disclosure is made by a participant, and in line with Maryland Statutes, Family Law Article 5- 704, 5-705 (Maryland FLA) if we believe that abuse/neglect of a child or vulnerable adult has taken place the PI will make an oral report to the local Department of Social Services. If the PI believes the adult or child to be in imminent danger a report will be made to the police, as well as the local DSS. In line with Maryland FLA, within 48 hours of the oral report the PI will send a written Form 180 to the LDSS and a copy to the local State's Attorney Office. When in doubt the PI will always report and/or consult with the LDSS. In cases where mandatory reporting is invoked, the PI will always write up an anticipated event report and submit to IRB within 48 hours.

NOTE: The IRB does not require PROMPT reporting of all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**. Anticipated AEs may be reported with the Progress Report.

E. **Other IRBs/Ethics Review Boards:**

If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances). **For federally funded studies, subrecipient AND subrecipient's IRB MUST have a Federal Wide Assurance (FWA) number.**

| Non-JHSPH IRB/REC | FWA Number |
|---|---|
| | |
| | |
| | |

F. **"Engaged" in Human Subjects Research:**

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the

JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

**Insert collaborator names and FWA numbers, if available. Note who will be "engaged" in human subjects research by filling in the following table:**

| | JHSPH | | |
|---|---|---|---|
| For federally funded studies, collaborators' FWA | 00000287 | | |
| Primary Grant/Contract Recipient | | | |
| Grant/Contract Subrecipient | | | |
| Hiring Data Collectors | | | |
| Training Data Collectors | | | |
| Obtaining Informed Consent and/or Identifiable Data | | | |
| Accessing/Analyzing Identifiable Data | | | |
| Overseeing storage, access and use of biospecimens | | | |

**COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:**

## XI. Secondary Data Analysis of Existing Data:

A. **Study Design:**

1. Describe your study design and methods. The study design must relate to your stated aims/objectives.

2. Provide an estimated sample size and an explanation for that number.

3. Provide a brief data analysis plan and a description of variables to be derived.

B. **Participants:**

1. Describe the subjects who provided the original data and the population from which they were drawn.

Note: If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application.

2. If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.

3. Explain whether (and how) you plan to return results to the participants either individually or as a group.

## XII. Oversight Plan for Student-Initiated Studies:

A. For student-initiated studies, explain how the PI will monitor the student's adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements, and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, and their qualifications.

B. What is the data custody plan for student-initiated research? *(Note: Students may not take identifiable information with them when they leave the institution.)*

## XIII. Creation of a Biospecimen Repository:

Explain the source of the biospecimens, if not described above, what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

A. Describe where the biospecimens will be stored and who will be responsible for them.

B. Describe how long the biospecimens will be stored, and what will happen at the end of that period.

C. Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens.

D. Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.

E. If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.

F. Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form.

G. Explain whether the repository will have Certificate of Confidentiality protections.

H. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.

I. Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.

## XIV. <u>Data Coordinating Center</u>:

Complete if JHSPH serves as the Data Coordinating Center.

A. How will the study procedures be developed?

B. How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?

C. Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.

D. How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?

E. What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?

F. What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.

G. Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?

H. Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?

## XV. Drug Products, Vitamins, Food and Dietary Supplements:

Complete this section if your study involves a drug, botanical, food, dietary supplement or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.

A. List the name(s) of the study product(s), and the manufacturer/source of each product.

| Name of Study Product | Manufacturer/Source |
|---|---|
| | |
| | |
| | |

B. List each study product by name and indicate its approved/not approved status.

| Approved by the FDA and Commercially Available | Approved by Another Gov't Entity (provide name) | Cleared for Use at Local Study Site |
|---|---|---|
| | | |
| | | |
| | | |

C. If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.

D. If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off-label use of the study product.

E. If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.

F. Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping. Complete and upload into PHIRST the Drug Data Sheet available on the JHSPH IRB website at www.jhsph.edu/irb.

G. What drug monitoring and/or regulatory oversight will be provided as part of the study?

## XVI. Medical Devices:

Complete this section if your study will involve an approved or investigational medical device (**diagnostic**, non-significant risk, significant risk).

A. List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval or its equivalent from a local authority, to ensure that the device is in good working order.

| Name of Study Product | Manufacturer/Source | Powered? |
|---|---|---|
| | | |
| | | |
| | | |

B. List each study product by name and indicate its status as approved by a government authority or not approved.

| Approved by the FDA and Commercially Available | Approved by Another Gov't Entity (provide name and approval information) | Not Approved |
|---|---|---|
| | | |
| | | |
| | | |

C. If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a **diagnostic device**, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so, and explain how those results will validated (or not) against the current "gold standard".

D. If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.

E. If you are using an investigational device that is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study. Provide a description of the device, and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.

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