Study Title: Increasing HIV/STI Home Testing, Linkage to Care, and Linkage to PrEP via a Digital Intervention among Black Women in a Geographic Hotspot

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BSPH IRB Research Plan for New Data Collection

IRB Version: 01Sep2023

For new data collection, new data collection plus secondary data analysis, biospecimen repositories, and data coordinating center protocols.

DO NOT DELETE ANY QUESTIONS FROM THIS TEMPLATE

PI Name: Liesl Nydegger, PhD, MPH, Johns Hopkins University

Study Title: **Increasing HIV/STI Home Testing, Linkage to Care, and Linkage to PrEP via a Digital Intervention among Black Women in a Geographic Hotspot**

IRB No.: **IRB00030508**

PI Version No. / Date: **Version 2** **10/4/2024**

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

We aim to field test (n=6; Phase 2) and pilot (n=60; Phase 3) the intervention with Black women in counties in and surrounding Austin, Dallas, Houston and San Antonio. We are developing the intervention based on formative research from focus groups conducted in Phase 1 of the study (JHSPH IRB no: 00023755).

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.*

In 2018, Black women account for 13% of US women yet account for 58% of HIV diagnoses among women [1]. Black women in Travis County are 18.4 times more likely to contract HIV compared to women of other races/ethnicities [2]. In addition, Black women have higher rates of STIs than other women [3–5]; many are asymptomatic, undiagnosed, and untreated [6]. STIs increase the risk of contracting HIV, thus it is important to conduct HIV and STI testing in tandem. Alarmingly, studies show no racial/ethnic disparities in sexual risk behaviors, yet the HIV/STI incidence for Black women is much higher than other racial/ethnic groups [7–9]. In Travis County, over 20% of women learned one year after contracting HIV that they were HIV-positive [10] highlighting the need for increased and efficient testing. Previous studies among Black women reported barriers to HIV testing including HIV stigma, medical mistrust, low perceived risk, fear of results, and discrimination [11–13].

Home testing has the potential to address many of these barriers to HIV/STI testing among Black women. Additionally, home testing can link Black women to earlier treatment to prevent transmission, provide linkage to PrEP, reduce HIV disparities, and increase viral suppression among those who test positive for HIV. Previous studies conducted among racially/ethnically diverse participants determined that women, particularly Black women, found home testing to be safe, easy, and preferred over clinic testing [14, 15]. Home testing is reliable with nearly identical results to clinic testing [16], and costs less to test and treat per STI infection compared to clinic testing and treatment [17]. Thus, home testing can increase testing among Black women at risk for HIV and provide a unique opportunity to link them to care and PrEP avoiding structural barriers to early diagnosis, treatment, and linkage to PrEP. Previous home testing studies have been problematic, consisting largely of non-experimental designs and few implemented interventions (e.g. [18]), only tested for 1 or 2 STIs (e.g., [14]), included small samples of Black women [19], particularly in the South, or did not link participants to care (e.g. [20]). A home testing intervention has yet to link participants to PrEP. The proposed study will conduct formative research to develop and test a web-based, tailored, theory-driven intervention for Black women at high risk for HIV to increase home testing, and linkage to care and PrEP.

Previous formative research conducted by PI Nydegger demonstrated that the majority of participants are interested in PrEP and nearly all participants experience individual, interpersonal, and structural level barriers to accessing clinical appointments.

Structural-level barriers included poverty, substandard/unstable housing, community violence, lack of insurance, and limited access to social services, transportation, and childcare [21, 22]. Individual-level barriers reported included substance use and intimate partner violence [21, 22].

In Phase 1 (JHSPH IRB no: 00023755), we conducted focus groups to elicit additional information that were guided by the sIMB, Critical Race Theory (CRT), and access to care frameworks, along with mental contrasting, and implementation intentions. In **Phase 2—Field Test w/ 6 participants (present application)**, we will develop the web-based intervention and educational control and field test both conditions. We will make any necessary adjustments before conducting the RCT in **Phase 3—RCT w/ 60 participants (present application)**.

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10. Texas Department of State and Health Services TB/HIV/STD Section. Black women and HIV in Travis County [Internet]. Austin, Texas; 2018. Available from: https://www.dshs.texas.gov/hivstd/txbwi/
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13. Wright PB, Stewart KE, Curran GM, Booth BM. A qualitative study of barriers to the utilization of HIV testing services among rural African American cocaine users. J Drug Issues. 2013;43:314–34.
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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 (BSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).

Phase 2—Field Test w/ 6 participants: After developing the intervention, we will conduct a field test of the web-based intervention with 6 Black women in counties in and surrounding Austin, Dallas, Houston and San Antonio. Participants will be randomly assigned to either the control (n = 3) or intervention (n = 3). Participants should complete the intervention in 27 days but will be given up to 35 days. The follow-up questionnaire will be sent two weeks after completing the final intervention session.

Phase 3—RCT w/ 60 participants: After making any necessary adjustments based on Phase 2, we will conduct an RCT with 60 Black women in counties in and surrounding Austin, Dallas, Houston and San Antonio. Participants will be randomly assigned to either the intervention or the educational control. After the intervention is complete the participant will be sent follow-up assessments at 1- and 3-months.

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, distinguish the screening sample size from the enrolled sample size; a table may be helpful. For electronic survey studies involving online recruitment and survey completion: consider how you will set controls on how many people will join your study.

Phase 2—Field Test w/ 6 participants: N=6
Participants will be screened via a Qualtrics questionnaire. Based on Phase 1 (JHSPH IRB no: 00023755), we anticipate screening 37 individuals for 6 eligible participants. Participants will be randomly assigned to the intervention (n=3) or educational control (n=3) in Excel by the project manager. Participants who complete the

screener and appear to be eligible will be assigned a participant code (starting at 401). After Cami reviews participants' screeners and follows up with them to ensure they're eligible, if need be, Cami will use a random number generator in excel to randomly assign each participant to the control (1) or intervention (2). The purpose of Phase 2 is to ascertain feasibility, acceptability, and feedback from participants on both the intervention and educational control conditions. Thus, we anticipate enrolling 3 participants in each condition to provide feedback for us to incorporate before conducting the RCT in Phase 3.

Phase 3—RCT w/ 60 participants: N=60
The primary objective will be to determine a reasonable effect size for the intervention rather than to demonstrate statistically significant group differences. We are aware of the limitations of small-scale pilots (e.g., large standard errors) to determine the promise of novel treatment approaches [23]. These effect size estimates that we will obtain will be primarily used to establish a pattern of results that are supportive of the intervention. With 30 participants per group and effect size range of d = .40 to .60, power to detect the difference ranges from .54 to .75. With N = 60 we will have .80 power to detect effect sizes in the medium-large range above d = .65. Effect size estimates will include odds ratios for completion of home testing and Cohen's d equivalents [24] for continuous measures of putative mechanisms. A sample size of 60 allows adequate examination of effect sizes while staying within the scope of a developmental project. We recognize that only medium-large effect sizes will be likely to attain statistical significance with this sample size.

Similar to Phase 2—Field Test, participants will be screened via a Qualtrics questionnaire. We anticipate screening 370 individuals to enroll 60 eligible participants. Participants will be randomly assigned in Excel by the project manager to the intervention (n=30) or educational control (n=30) using the same method outlined in Phase 2—Field Test. Once 60 participants are randomly assigned to a group, we will stop recruitment. Only participants randomly assigned to a condition will receive a link to the intervention or educational control.

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24. Kraemer H.C., Mintz J., Noda A., Tinklenberg J., & Yesavage J. (2006). Caution regarding the use of pilot studies to guide power calculations for study proposals. Arch. Gen. Psychiatry 64(5), 484–489. doi:10.1001/archpsyc.63.5.484.

*C. Does your study meet the NIH definition of "clinical trial": "***"A research study in which one or more human subjects are prospectively assigned to one or more interventions** (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes"? *If yes, the study must be listed on clinicaltrials.gov, study personnel must complete GCP training, and federally funded studies must post consent forms on approved sites, like clinicaltrials.gov.*

Yes.

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 or who are wards of the State. 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:

Phases 2 & 3: Cisgender Black women will be recruited for both **Phase 2—Field Test** and **Phase 3—RCT**. Eligible participants will a) be 18-59 years of age (ages most likely to contract HIV), b) identify as a cis-gender woman, c)

identify as Black/African-American (Black/African-American mixed race/ethnicity is included), d) read/speak/type in English, e) have not tested for HIV/STIs in the past 12 months, f) live in a county in or surrounding Austin, Dallas, Houston or San Antonio, g) will report having vaginal or anal sex with a cisgender man in the past 6 months, h) report either 2 or more sex partners in the past 12 months or a high HIV-risk sexual partner in the past 12 months (i.e., used injection or noninjection drugs, had sex with men, been to prison, had concurrent sex partner, had an STI, was living with HIV, or was unaware of any of these characteristics), and i) have access to a device (i.e., computer, laptop, tablet) and internet or smartphone.

B. Exclusion Criteria:

Phases 2 & 3: Exclusion criteria include individuals who a) are younger than 18 years or over the age of 59, b) identify as any gender other than a cis-gender woman, c) identify as any race/ethnicity other than Black/African-American, d) are unable to fluently speak, read, or type in English, e) took a HIV/STI test within the past 12 months, f) live outside of a county in or surrounding Austin, Dallas, Houston or San Antonio, g) did not have vaginal or anal sex with a cisgender man in the past 6 months, h) had only 1 sex partner in the past 12 months who was not a high HIV-risk sexual partner, or i) does not have a device (i.e., computer, laptop, tablet) and internet access or a smartphone.

***NOTE**: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. 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. Check "yes" to the HIPAA question in the PHIRST application.*

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 BSPH clear. If you will collaborate with other institutions or organizations, or plan to subcontract BSPH responsibilities to others, make clear their responsibilities in the Study Oversight section of this document. Be aware that all recipients of federal funding for non-exempt human subjects research must have a Federal Wide Assurance (FWA), which is a promise to comply with human subjects research regulations.

*If the BSPH will serve as a **data coordinating center**, indicate in the sections below which procedures BSPH 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 their qualifications*.

Phases 2 & 3: Participants for the proposed study will be recruited from social media and Google advertisements and distributing flyers to organizations in counties in and surrounding Austin, Dallas, Houston or San Antonio. The project manager, Cami Gaudin Gonzalez, will reach out to different types of organizations like community health centers, domestic violence shelters, women focused organizations, libraries, Black-led organizations and organizations that work with Black women and email, drop off, or mail the flyers. We will use targeted ads for specific populations on social media and Google. Keywords can be used for both inclusion and exclusion criteria to narrow down the targeted priority population.

Interested individual will be directed to a Qualtrics questionnaire to complete a brief online screener assessment to determine eligiblity for both **Phase 2—Field Test** and **Phase 3—RCT**. The Qualtrics questionnaire collects IP addresses to allow us to verify that participants are in an eligible location. Screening data will be used as study data. Eligible participants will be directed to the Baseline Assessment. All participants who complete the Baseline Assessment will be assigned a unique ID number by the project manager in the order of completion, starting with 401. Next, eligible participants who completed the Baseline Assessment will be invited to participate in the study, and sent the informed consent via DocuSign.

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*.

Phases 2 & 3: Flyers will include a link to the Qualtrics eligibility screener and/or a QR code. The main privacy concerns is with people commenting on social media advertisements. We will turn off commenting to prevent these issues. Additionally, all flyers will include the team's Google Voice number, which is monitored by Cami Gaudin Gonzalez, so individuals can call or text Cami if they have questions or privacy concerns. Flyers will also include the team's secure email address monitored by Johns Hopkins University and will go directly to Cami.

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*:

   Phases 2 & 3: To complete the screening questionnaire to determine eligibility, participants first will be provided with the electronic informed consent via Qualtrics and will use the "I accept" button to consent to the screener. Eligible participants will then use docusign for the consent form for the study for both **Phase 2—Field Test** and **Phase 3—RCT**. Cami Gaudin Gonzalez will walk participants through the full consent (docusign) over the phone to ensure participants understand what they are consenting to and answer any questions. Participants will not be sent the link for the baseline assessment until Cami Gaudin Gonzalez ensures each participant understands the study and is randomly assigned to the intervention or control. The PI and program manager, Cami Gaudin Gonzalez, both have advanced graduate training in methods and ethics.

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

   Phases 2 & 3: First, participants will be asked their age. Participants ages 18 to 59 will receive the informed consent for the eligibility assessment in the online assessment (See Compact Informed Consent—Screener). The study team's phone number and email will be in the consent form to reach out if they have any questions. Participants who select "I agree" will continue with the screening (See Eligibility Screener). Next, eligible participants will be sent to a separate Qualtrics page to enter their first name, email address, and phone number. The project manager will email each participant with a DocuSign of the informed consent (See Full Consent) and set up a time to discuss the informed consent prior to signing. If participants have no questions, they can sign the informed consent using DocuSign, however, the project manager will discuss the informed consent with all participants prior to enrolling to ensure they fully understand the informed consent and study. After discussing the informed consent and signing the DocuSign, Cami will randomly assign participants to the intervention or control, and then email participants the baseline assessment.

   c. *The process for determining whether a potential participant meets eligibility criteria. If you will collect personally identifiable information for screening purposes, collect only data needed for this purpose and explain what will happen to the data for individuals who are not eligible*:

Phases 2 & 3: The Qualtrics questionnaire includes skip logic to determine eligibility. Eligible participants will enter their first name, email address, and cell phone number to be contacted to participate in both **Phase 2—Field Test** and **Phase 3—RCT**. The Qualtrics questionnaire collects IP addresses to allow us to verify that participants are in an eligible location. Qualtrics does not collect IP addresses for participants who do not complete the screener. Once the baseline questionnaire is complete, participants will be sent to a different Qualtrics questionnaire to obtain name, email address, and phone number for sending the Full Consent to eligible participants and to contact to set up a time to go over the consent, and for compensation.

d. *Whether you will obtain a signature from the participant or will use an oral consent process*:

Phases 2 & 3: Participants will consent twice. First, to complete the eligibility screening. Second, to complete the baseline assessment and participate in the intervention/educational control.

e. *Whether you will obtain a legally authorized representative's signature for adults lacking capacity*:

Phases 2 & 3: Adults lacking capacity will be ineligible for the study.

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). If any of the children are "wards of the state", additional regulatory requirements will apply:*

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*:

No, because participants will consent using DocuSign. The project manager will communicate with participants prior to completing the DocuSign to ensure they do not have any questions.

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
United States		English

C. **Study Implementation**:

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

Phase 2—Field Test w/ 6 participants: We will conduct a field test among a small sample of 6 participants to finalize the intervention. This will include finalizing recruitment strategies, measurements, intervention and control programming, and any participant feedback. Eligible participants will complete the baseline assessment (See Baseline Assessment). After consenting and completing the HIPAA waiver via DocuSign (See Full Consent and HIPAA Waiver), participants will provide their name, email, and phone number to be shared with the Kind Clinic Virtual Services team at Texas Health Action and will be randomly assigned to complete the intervention (n=3) or educational control (n=3).

Kind Clinic Virtual Services is a program of Texas Health Action. As the Kind Clinic Virtual Services team members are who we will be working with, we will refer to Kind Clinic Virtual Services when laying out the details of the partnership.

All participants will be sent a link to complete their assigned condition. Kind Clinic Virtual Services will email all participants a link to complete clinic paperwork.

Intervention: Participants in the intervention condition will complete 5 web-based sessions that coincide with HIV/STI self-testing procedures by Kind Clinic Virtual Services. Each session will have different content but will follow a similar format. Intervention session topics are: 1) Completing and submitting clinic forms, 2) Using the HIV/STI self-testing kit, 3) Mailing in the HIV/STI self-testing kit, 4) Obtaining HIV/STI test results, and 5) Attend virtual follow-up appointment with Kind Clinic Virtual Services to discuss test results and PrEP. The general format for each session is that participants will be introduced to that session's topic with a combination of videos and infographics, followed by examples or testimonials. Next will be mental contrasting and implementation intentions. For mental contrasting, participants will visualize achieving that session's behavioral goal (e.g., using the HIV/STI self-testing kit) and identify positive feelings or outcomes that may occur once they complete the behavior. Then participants will identify potential barriers to completing that session's behavioral goal. Based on the barriers identified, participants will select a situational cue and action plan in the form of an "if-then" sentence (implementation intentions). The remainder of the intervention will have the participant engage in activities to memorize the "if-then" plan. The day after each session is completed, participants will receive an assessment (see Phase 2: Session Assessments) to provide feedback on the session they just completed. Kind Clinic Virtual Services will provide information regarding if participants completed each session's task. Participants will not be sent the link to the next session until the study team confirms with Kind Clinic Virtual Services that the participant completed the task. Participants who have completed the session task will move onto the next session (see Table 1). If the participant did not complete the behavior, they will be given a 2-day grace period to complete the behavior. If Kind Clinic Virtual Services indicates after the grace period that the participant still has not completed the session's behavior, the participant will be deemed ineligible and will not complete the remaining intervention sessions.

Table 1. Intervention sessions and days between sessions

Session	# of Days Between Sessions*
1. Completing and submitting clinic forms	4
2. Using the HIV/STI self-testing kit	2
3. Mailing in the HIV/STI self-testing kit	8
4. Obtaining HIV/STI test results	7

5. Attend virtual follow-up appointment with Kind Clinic Virtual Services to discuss test results and PrEP	7
**Note*: Days between sessions are based on Kind Clinic Virtual Services's self-testing procedures.	

Based on the 2-day grace period for each session, participants will have 25 – 35 days to complete all behaviors. Once all behaviors are completed or 35 days has been reached, whichever comes first, participants will take the final session assessment 2 weeks later.

Educational Control: The educational control will consist of 5 sessions. Each session will consist of videos and infographics and will be approximately the same length of time of each corresponding intervention session. The educational control session topics include: 1) Basic information about STIs, 2) Basic information about HIV and HIV stigma, 3) Stories from people who are living with HIV and/or STIs, 4) Disclosure to sexual partner(s) about living with HIV or an STI, and 5) Basic information about PrEP. Participants will receive the next session on the same schedule as the Intervention group (see Table 2). Similar to the Intervention group, Kind Clinic Virtual Services will inform the study team if participants completed each session's tasks. The Session Assessments will be send the day after completing each session.

Table 2. Educational control sessions and days between sessions

Session	# of Days Between Sessions
1. Basic information about STIs	4
2. Basic information about HIV and HIV stigma	2
3. Stories from people who are living with HIV and/or STIs	8
4. Disclosure to sexual partner(s) about living with HIV or an STI	7
5. Basic information about PrEP	7

Two weeks after participants complete the final session assessment, they will be e-mailed/texted a follow-up assessment (See Phase 2 Follow-Up Assessment—2 weeks).

Phase 3—RCT w/ 60 participants: We will pilot the intervention using a randomized controlled trial. First, we will incorporate adjustments to recruitment, assessments, intervention, and educational control based on participant and study team feedback based on the implementation in Phase 2. Similar to **Phase 2—Field Test w/ 6 participants**, eligible participants in Phase 3—RCT will complete the baseline assessment (See Baseline Assessment). After consenting via DocuSign (See Full Consent), participants will be randomly assigned to complete the intervention (n=30) or educational control (n=30). Implementation of sessions and assessments will be identical to **Phase 2—Field Test w/ 6 participants** except for the follow-up assessments. Participants in **Phase 3—RCT** will receive follow-up assessments after the final session assessment at 1 month (See Phase 3 Follow-Up Assessment—1 Month), 3 months (See Phase 3 Follow-Up Assessment—3 Months).

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*.

Phase 2—Field Test w/ 6 participants: Eligible participants who complete the screening assessment will be sent a DocuSign of the informed consent via email and the project manager will set up a day and time to speak with each participant to go over the informed consent and have them ask any questions. We expect each of these phone calls will take approximately 5 – 15 minutes. Aside from the study team sending compensation and links to sessions and assessments via email or text, for the remainder of the study, participants will only interact with the study team if they have questions or need assistance.
Informed consent: 1 contact via phone for 5 – 15 minutes
Assessments: 7 times via email
Compensation: 3 times via email
Questions or assistance: as needed via phone, email, text, or zoom

Participants who completed the session but not the session assessment will be reminded via email and text, once each day for 2 days after session completion.

Phase 3—RCT w/ 60 participants: Eligible participants who complete the screener assessment will be sent a DocuSign of the informed consent via email and the project manager will set up a day and time to speak with each participant to go over the informed consent and have them ask any questions. We expect each of these phone calls will take approximately 5 – 15 minutes. Aside from the study team sending compensation and links to sessions and assessments via email or text, for the remainder of the study, participants will only interact with the study team if they have questions or need assistance.
Informed consent: 1 contact via phone for 5 – 15 minutes
Assessments: 8 times via email
Compensation: 4 times via email
Questions or assistance: as needed via phone, email, text, or zoom

Participants who completed the session but not the session assessment will be reminded via email and text, once each day for 2 days after session completion.

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

Phase 2—Field Test w/ 6 participants: Participants will be engaged in the study for approximately 40 days from completion of the eligibility screening to the follow-up assessment.

Phase 3—RCT w/ 60 participants: Participants will be engaged in the study for approximately 115 days from completion of the eligibility screening to the last follow-up assessment.

Both Phases 2 and 3 are expected to take 1 year to complete.

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

Phase 2—Field Test w/ 6 participants: Given the small sample size of 6 participants, we will perform primarily descriptive statistics and qualitatively analyze open-ended responses. The focus will be on feasibility of intervention/educational control, acceptability of intervention/educational control, acceptability of recruitment materials, acceptability of assessment measures, and acceptability of instructions.

Phase 3—RCT w/ 60 participants: A statistician will conduct all analyses with de-identified data. Initial analysis will evaluate the data for unusual distributions and outliers that have the potential to unduly impact model parameters and if necessary, appropriate ameliorative strategies will be used (e.g., natural log transformation). Generalized linear mixed models (GLMM) will be the primary analytic method to evaluate Phase 3 data. GLM models combine fixed effects (e.g., treatment) random effects (e.g., person) in a framework that accommodates these data features in the proposed design. Models will be fit using a distribution and link function appropriate to the outcome; primarily we anticipate fitting models with continuous distributions using an identity link function and binomial distributions using a logit link function. Longitudinal models will be fit following model-building strategies in which change across time is assessed prior to adding other fixed effects. To evaluate change between baseline and 5 months, an unconditional model (i.e., no independent variables) and an unconditional growth model (i.e., only independent variables for time) will be fit to test for change between baseline and 5 months. The models will be compared using the Akaike Information Criterion (AIC) to determine the optimal model. Next, a priori specified time-invariant and time-varying predictors will be added to the models. Finally, in the event of a significant time effect, interactions between time and other covariates will be added to the model, which would include

treatment, the baseline measure of the outcome, and demographic and clinical covariates. All models will treat intercepts as random on subject, and random slope parameters will be included if they significantly improve model fit. GLMM models fit using maximum likelihood (ML) estimation include all observations that are complete within a time-point and thus represent a viable missing data treatment. We will also include a variety of covariates which mitigates parameter bias for missing at random data. The intervention dosage will be evaluated for each of the outcomes in Phase 3. The models described above will be fit in an identical manner with the following exceptions: they will only include the intervention participants and rather than using intervention condition as the independent variable, they will use the quantity of the intervention sessions received. The primary objective will be to determine a reasonable effect size for the intervention rather than to demonstrate statistically significant group differences. We are aware of the limitations of small-scale pilots (e.g., large standard errors) to determine the promise of novel treatment approaches. These effect size estimates that we will obtain will be primarily used to establish a pattern of results that are supportive of the intervention. With approximately 30 participants per group and effect size range of d = .40 to .60, power to detect the difference ranges from .54 to .75. With N = 60 we will have .80 power to detect effect sizes in the medium-large range above d = .65. Effect size estimates will include odds ratios for completion of home testing and Cohen's d equivalents for continuous measures of putative mechanisms. A sample size of 60 allows adequate examination of effect sizes while staying within the scope of a developmental project. We recognize that only medium-large effect sizes will be likely to attain statistical significance with this sample size.

The same measures from Phase 2 will be included: feasibility of intervention/educational control, acceptability of intervention/educational control, acceptability of recruitment materials, acceptability of assessment measures, and acceptability of instructions. Additionally, we will assess by condition participants who completed the clinic forms, used the self-test, mailed the self-test, obtained test results, attended follow-up appointment, and retention rate.

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.

After participants sign the informed consent and HIPAA waiver via DocuSign, their unique ID will be entered into an Excel file by the project manager. Using Excel, participants will be randomly assigned to the intervention or educational control. Next, participants will be emailed or texted a link to the first session in their assigned condition.

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.

N/A

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.

N/A

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.).* ***For clinical tests of human biospecimens, no results may be returned unless completed in a certified lab.*** *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*.

N/A

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

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

N/A

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

N/A

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

N/A

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

N/A

e. *What happens to participants on a study in which there is a medical intervention when the study ends*? *Will participants continue to have access to the study intervention? What happens if they leave the study early?*

N/A

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

N/A

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

Data security and management plans must meet institutional standards. If you need assistance, contact [*bsph_cybersecurity@jhu.edu*]

Investigators are responsible for ensuring the security of data from the time of collection, through any transfers from one system to another, analysis, sharing, storage, and ultimate archiving and disposal. The questions below seek to elicit your plans for these protections. Feel free to add information.

1. Data Sources: Identify the source(s) of data.

- ☒ Participant/Parent-Guardian/Legally Authorized Representative
- ☐ JHM Medical Records (from Epic)

Note for JHM Data Users Only: *Please complete the* ***Data Trust Risk Tiers Calculator*** *available on the Applications and Forms page on the BSPH IRB website:* [*https://tinyurl.com/2p96md3s*] *and upload a copy of the documents to the "Miscellaneous- Other" section of your PHIRST application.*

In addition, review the ***Data Protection Attestation for Research and/or Healthcare Operations*** *at:* [*https://tinyurl.com/yszfkuur*] *and certify your attestation of compliance to those requirements.*

☐ **I certify my attestation of compliance to JHM Data Protection Requirements**

☒ Non-JHM Medical Records
☐ Outside Data Pprovider (CMS, National Death Index, Insurance Co., etc.)
☐ Other Existing Records (*please specify*):

2. Data Content: Will you collect, use, and/or record personal identifiers about study participants for any purpose? Please look at the list of identifiers in Question 3 to help answer this question. **Note: Limited Data Sets (including dates, ages, and zip codes) are considered to be "identifiable".**

☒ Yes: Continue with Question 3
☐ No: Skip to Question 6

3. Data Identification: Identify the Personally Identifiable Information (PII)/Protected Health Information (PHI) you will access/collect by checking the box(es) below for "Recruitment" and "Study Data" needs.

Recruitment	Study Data	PII/PHI to be Accessed/Collected
☐	☒	Name, signature, initials or other identifiable code
☐	☐	Geographic identifier (address, GPS location, etc.)
☐	☒	Dates (birth, death, clinical service, discharge, etc.)
☐	☒	Contact information (phone number, email address, etc.)
☐	☐	Identification numbers (SSN, driver's license, passport, etc.)
☐	☒	Health records identifiers (medical record #, insurance plan, etc.)
☐	☒	Text of clinical record notes
☐	☐	Device identifiers (implants, etc.)
☒	☐	Internet identifiers (IP address, social media accounts, etc.)
☐	☐	Biometric identifiers (fingerprints, retinal scan, voice print, etc.)
☐	☐	Audio Recordings
☐	☐	Video or full-face photographic images
☐	☐	Genomic / Genetic data
☐	☐	Other identifiers (*list here*):

4. Identifiers: If you have checked any of the boxes above, how will you protect personal identifiers?

☐ Will delete all identifiers (explain **when** you will delete identifiers):

☒ Will separate identifiers from analytic data and will store the link/code. Please explain where you will store the link/code: A password-protected document that links identifiers and participant IDs will be stored on OneDrive and will only accessible to the PI and project manager.

☐ Will use a method to make it harder to connect the data with the study participant (jiggering date, use other methods to obfuscate, etc.). *Please explain:*

5. Data Transit Plans and Protections: Identifiable data may transfer, sometimes with multiple steps, from mechanisms for collection to storage. For example, participants may complete a web-based survey, which is then downloaded to

a storage platform. Briefly identify these steps and the protections for each step (including encryption used at each step).

☐ Will delete all identifiers prior to transfer.

☒ Will separate identifiers from analytic data and will store the link/code prior to transfer. *Please explain where you will store link/code:* Data will be downloaded from Qualtrics. Immediately after download by the PI or project manager, identifers will be cut and pasted into a separate document that is password-protected and only accessibly by the PI and project manager. De-identified analytic data will be stored separately on OneDrive in a separate folder.

☐ Other (*please specify*):

6. Device(s) used for <u>data collection</u>: Identify the computing device(s) being used for identifiable data receipt/collection. Check all that apply.

We understand that resources in low resource countries may require use of systems that are not pre-approved. The following are examples of platforms/storage solutions that are **<u>not pre-approved to store identifiable information</u>** and require a risk assessment from BSPH Data Security. Do not hesitate to contact [*bsph_cybersecurity@jhu.edu*] for an assessment.

- JHU Independent Departmental Servers
- Local Computer owned by JH
- Other computers or devices owned/managed by study team members and used for other than secure web access
- USB/Portable data storage device
- Other solutions not managed by IT@JH, e.g., commercial cloud storage (Box, Dropbox, iCloud, personal OneDrive, Google Drive, Amazon storage, etc.)

☒ Provided or managed by BSPH IT

☐ Study-provided, and not managed by BSPH IT. These must include the following protective controls:

- Data encrypted while "at rest" (on a storage device)
- Security patches and updates are routinely or automatically applied
- Devices have access controls so that:
  - Each person accessing the device is uniquely identified (username)
  - Passwords are sufficiently strong to prevent compromise
  - All access is logged and recorded
  - Unauthorized access is prevented
- Approved access list is reviewed periodically for correctness

☐ Other (*please specify*):

7. Data Collection: Describe the format of data received/collected. Check all that apply.

☐ Paper/Hard Copy (must be secured in transit and placed in a secure cabinet/room)
☐ Audio recording
☐ Video recording
☐ Received directly by research team member and entered into file/database
☐ Mobile or Web App (custom developed). *Review* [*guidance*] *and provide attestation of compliance*
☐ Mobile or Web App (purchased). *Specify product and version*:
☒ Online survey. *Specify mechanism/platform*: Qualtrics
☒ 3rd party collector (*please specify*): Our community partner, Texas Health Action, will provide study-related PHI with the PI and project manager.
☐ Existing data shared with BSPH by data provider via electronic access/transfer
☐ Duplicate and backup copies will be secured with same rigor as original data
☐ Other (*please specify*):

8. Devices/Platforms used for Analysis, Storage, Processing: Identify where the identifiable or de-identified data will be analyzed/stored. Check all that apply.

☒ Pre-approved storage and analysis platforms managed by JH/BSPH for which security and risk mitigation measures are known.

Identify pre-approved storage platform(s) being used:

JHM Preferred:

☐ JH SAFE Desktop ☐ JH PMAP

Other Approved Platforms:

☒ JH One Drive/BSPH OneDrive ☐ JH IT-Managed Network Storage ☒ JHM/BSPH Qualtrics
☐ BSPH HPCC ☐ BSPH SharePoint ☐ BSPH Shares ☐ JHU REDCap
☐ MARCC-Secure Environment

☐ Platform(s) not managed by JH/BSPH, not pre-approved, and require a risk assessment review from BSPH Data Security.

- Describe the not pre-approved platform(s) you plan to use:
- Describe the technologies you intend to use (software, hardware, connectivity) with a focus on the measures taken to secure collected data along the continuum of data collection, storage, transmittal and access:

9. Access to Data and Access Controls: How will you ensure that only authorized individuals can access the data? What access controls will you put into place to ensure that only authorized individuals may access and use the data. (For example, OneDrive [*guidance*] illustrates how to share files with "people you specify". [*BSPH Shares*] addresses providing permissions to individual people.) Check all that apply. Note: If you need assistance implementing secure access controls, contact [*bsph_cybersecurity@jhu.edu*]

☒ Will provide access to data in accordance with OneDrive/BSPH-Shares guidance posted on JHU IT websites

☐ Will use secure access controls to limit access to individual-level data

☐ Will use secure access controls to provide other researchers controlled access only to aggregated study data

10. Data Sharing: Clarify if data are to be shared externally with third parties, including sponsors and other investigators, and whether only aggregated data will be shared, or if you will share individual-level data. Describe sharing and protection plans for that sharing, including the proposed use of data agreements.

Consider the following:

- *Information about your data sharing in the consent forms*
- *Information about data sharing laws in the country where data will be collected, and if they limit sharing, how you will comply with those limitations?*
- *Whether data will be shared in aggregate only, or individual level data*
- *Whether you plan to make the data publicly available, and in what form.*

☐ Will not share data with outside investigators

☐ Will make publicly available

☐ Will share with restrictions/controls

☐ Will share aggregated data only

☐ Will share individual-level data without identifiers

☐ Will deposit data into an existing data repository for future research. *Please explain*: De-identified individual data will be deposited into the Johns Hopkins Research Data Repository.

☐ Future research use and data sharing will have limited purposes. *Please explain*:

☐ Other sharing information:

11. Duration and Destruction: Explain how long data will be retained and the plan for eventual return, deidentification or destruction of data, including moving data to an archive.

A. Certificate of Confidentiality:

All NIH studies include Certificate of Confidentiality (C of C) 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://grants.nih.gov/policy/humansubjects/coc.htm*]

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

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. Include risks beyond individuals to include the study population as a group and community risks. Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan.

Discomfort or distress answering inclusion/exclusion questions, assessment questions, or completing intervention or educational control sessions. Distress about someone (e.g. abusive partner) they do not want to know discovering they are participating in the study or testing for HIV/STIs.

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.*

Participants will be informed that responses are confidential, that they can refuse to answer any particular question they do not want to answer, and that they are free to withdraw from the study at any time without penalty.

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?*

We don't expect any adverse reactions to occur.

D. *Describe the research burden for participants, including time, inconvenience, invasion of privacy in the home, out of pocket costs, etc.*

Participants will spend approximately 6 hours engaging in the entire research study in which they will be compensated. Participants will need to find time to administer the self-test kit in a private space.

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.*

Participants will be informed ahead of time both by the informed consent and the project manager that there may be sensitive topics during the intervention and to ensure that they're alone and use headphones around when they do the intervention sessions.

F. *Levels of COVID-19 community transmission will vary considerably by geography and over time, and therefore, the responses to the pandemic may also vary. The risk of COVID-19 to study staff and participants from in-person research activities can be mitigated by appropriate study procedures. If you are conducting in-person research activities, please indicate the protections you plan to implement at your research site(s):*

- ☒ Not applicable
- ☐ COVID testing of staff
- ☐ COVID testing of study participants
- ☐ Indoor masking/wearing PPE
- ☐ Social distancing for indoor activities
- ☐ Symptom screening of staff
- ☐ Symptom screening of study participants
- ☐ Vaccination of research team members
- ☐ Other procedures/comments:

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).*

Participants will be linked to Kind Clinic Virtual Services, which will provide free HIV/STI self-testing, treatment if applicable, and PrEP (if applicable). Thus, participants will be connected to sexual healthcare services, which

they can continue after the completion of the study. Select study team members will only have access to participants' PHI during the study, nothing after so participants are potentially connected with long-term sexual healthcare services.

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

Due to the inordinate HIV risk among Black women in the South, it is essential to increase HIV/STI testing among Black women with scalable and sustainable methods to increase HIV/STI testing, linkage to care, and linkage to PrEP. The results of this study can guide the development of a proposed intervention that can be tailored to other locations and for other populations at high risk for HIV. With the web-based platform, we can tailor the intervention to various populations and promote its use as a marketable strategy to increase home testing, linkage to care, and linkage to PrEP among underserved populations.

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 no payment is provided, the BSPH IRB strongly encourages providing such tokens. If yes, please describe below.

There will be no non-monetary token of appreciation.

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.

Phase 2: Those who participate in the baseline assessment will receive $10. At the end of 5 sessions there will be a post-session assessment, participants who complete this assessment will receive $50. After the follow-up assessment, participants will receive $20.

Phase 3: Those who participate in the baseline assessment will receive $10. At the end of 5 sessions there will be a post-session assessment, participants who complete this assessment will receive $50. After the first follow-up assessment, participants will receive $20. After the second follow-up assessment, participants will receive $30.

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

Phase 2: Participants will receive $80 for assessments.

Phase 3: Participants will receive $110 for assessments.

X. Study Management:

A. Oversight Plan:

1. *Describe how the study will be implemented. List all parties, including collaborators and subcontractors, who will be "engaged" in the human subjects research project and their roles .*

   Dr. Liesl Nydegger (PI): Dr. Nydegger will build the intervention, oversee recruitment and analyze the data with the assistance of the Project Manager.

   Dr. Mandy Hill (Co-I): Dr. Hill will provide input on intervention sessions.

   Dr. John Mark Eddy (Co-I): Dr. Eddy will provide input on intervention sessions.

   Camila Gaudin Gonzalez (Program Manager): Oversee the day-to-day operations of the project including intervention building, recruitment, data collection, developing and monitoring project timelines and budgets, programming the measures into Qualtrics, coordinating the intervention and data handling process for the project, and supporting the investigators as necessary throughout the project.

2. *What are the qualifications of study personnel implementing the project*?
   Both completed CITI training and this study is a continuation from a prior approved study at UT Austin an R1 institution. Both the PI and the Project Manager have post-graduate training in ethics and conducting research studies.
3. *How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research ethical protections? (Use the BSPH Ethics Field Training Guide available on the BSPH IRB website. If* the study is a clinical trial, consider using the BSPH Good Clinical Practice (GCP) For Social and Behavioral Research Field Guide).

   N/A

4. *If the BSPH PI is responsible for data collection and 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*.

   N/A

B. **Protocol Compliance and 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: [*housecalls@jhu.edu*]).

Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements. If the study team does not follow study procedure, what is your plan for reporting protocol non-compliance?

Monitoring will be conducted by the PI in consultation with the investigative team (Drs. Hill and Eddy) and the IRB. PI Nydegger will monitor and oversee all aspects of the project including recruitment, consenting, intervention processes, data security, data analysis, and management of research team members who interact with data. Drs. Hill and Eddy, and the CAB, which was put together for this study, will provide guidance to PI Nydegger to ensure all aspects of the projects conform to the approved protocol. All procedures will be monitored to ensure they conform to the approved protocol. In addition, monitoring will occur for all unforeseen circumstances that might arise and affect safety, for adverse events (e.g. that lead to drop out by the participant or termination by the investigator), and for other unexpected adverse events results from the study. Monitoring of adherence to the study protocol and emergent unanticipated adverse events will be conducted by the PI and Project Manager on an ongoing basis. This monitoring will be discussed with the research team during weekly meetings. In addition, monitoring by the IRB is conducted at the annual continuing reviews as scheduled by the IRB and upon receving reports of adverse events from the PI.

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 and what is that person's specific charge?*

   Participants will be able to contact research team members by phone through Google Voice, a secure e-mail address monitored by Johns Hopkins University, or text message via Google Voice. PHI communicated between Kind Clinic Virtual Services and the study team will be sent via encrypted email. We have been assigned a Certificate of Confidentiality and confidentiality will be protected to the extent allowable by law.

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*.

Descriptive data on behavioral outcomes, feasibility, and acceptability will be analyzed and occur with the post-session assessment, and 1- and 3-months follow-up data on a monthly basis during Phase 3. The study will consider early termination if a majority of participants report extremely negative feedback regarding the use of the HIV/STI home testing kits, severe adverse reactions after receiving positive results, or refusing to follow-up with treatment.

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

*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 Continuing Review/Progress Report.*

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

The anticipated potential adversity inherent in assessment involves situations detailed above and is addressed by the timely intervention of the PI. Serious and unexpected adverse events that are related to the study will be reported to JHSPH IRB and to NIH. The JHSPH IRB requires that events including significant events, anticipated risks and complaints about research, or non-compliance with approved protocols and procedures be reported as soon as possible always within 30 days, and compromises of personally identifiable information be reported within 2 days. Proposed changes or amendments to the protocol in general must first be requested in writing to the IRB, which will then grant or deny permission to make the requested change in protocol. In addition, the IRB requires data and safety monitoring reports be submitted on an annual basis. As we have a certificate of confidentiality, we will report if we learn about child or elder abuse or neglect, or that is someone is a clear, serious, and direct harm to self or others. We will contact child protective services, adult protective services, and/or the police.

E. Other IRBs/Ethics Review Boards:

If other IRBs will review the research, provide the name of each IRB/ethics review board and its Federal Wide Assurance number, if it has one (available on [*OHRP's Website*]). ***For federally funded studies, subrecipients MUST have a Federal Wide Assurance (FWA) number from the OHRP. The IRB overseeing the subrecipient should be registered with the OHRP. The BSPH IRB will not have oversight responsibility for international subrecipients, and generally will not oversee data collection at external U.S. institutions Please contact the*** [*BSPH IRB Office*] ***with questions.***

Non-BSPH IRB/REC	FWA Number

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

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

	BSPH	UT Austin	UT Health Science Center Houston
For federally funded studies, collaborators' FWA	00000287	00002030	00000667
Primary Grant/Contract Recipient	Nydegger		
Grant/Contract Subrecipient		Eddy	Hill
Hiring Data Collectors	Nydegger		
Training Data Collectors	Nydegger; Gaudin Gonzalez		
Obtaining Informed Consent and/or Identifiable Data	Nydegger; Gaudin Gonzalez		
Accessing/Analyzing Identifiable Data	Nydegger; Gaudin Gonzalez		
Overseeing storage, access and use of biospecimens	Nydegger; Gaudin Gonzalez		

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, and 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. Data Coordinating Center:

Complete if BSPH 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.*

Who will hold the IND?

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* [*BSPH IRB Website*]

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

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.*