## Protocol Title

A Pilot SMART Testing an Integrative Smoking Cessation Intervention for HIV Patients

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## Principal Investigator

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## 1) Objectives*

We will conduct a pilot Sequential, Multiple Assignment randomized clinical trial (SMART) incorporating nicotine replacement treatment (NRT), contingency management (CM), and mindfulness training (MT) to identify the optimal dynamic strategy to promote biomarker-confirmed smoking abstinence among people living with HIV (PLWH).

## 2) Background*

Mindfulness training (MT) is an approach that has become more widely used for the purposes of smoking cessation. MT can operationalized into two components: 1) maintaining attention on immediate experience, and 2) maintaining an attitude of acceptance toward that experience, which can improve individuals' ability to avoid absorption in maladaptive mental patterns, behaviors, and emotional reactions that lead to depression.[1,2]_ENREF_40 MT is effective in reducing both self-report and objective indices of negative affect and psychological stress.[3,4] MT also can help smokers control craving by being less emotionally reactive and less prone to relapse related to avoidance of distressing symptoms.[5] The use of MT for smoking cessation, however, has not been tested among Hispanics HIV patients who smoke. We, therefore, propose to test the feasibility, acceptability, and potential efficacy of a mindfulness smoking cessation intervention among Hispanics HIV patients that smoke. CM is an evidence-based behavioral intervention where individuals receive escalating tangible reinforcement for biologically confirmed substance abstinence.[6] CM has been successful in retaining patients in treatment and fostering stable periods of abstinence in substance use behavioral research, including tobacco.[7-9] In HIV patients, CM was feasible and effective in improving compliance to ART[10] and reducing HIV risk behaviors (e.g., unprotected sex, injection drug use).[11] CM may as well reduce the economic stressor for smoking cessation (e.g., unemployment) in HIV patients. [12,13] Yet, no studies to date tested CM to promote smoking cessation among HIV smokers. In our survey among HIV smokers, 45.7% were interested in CM to quit smoking. Therefore, CM may serve as an ideal adjunct intervention to MT to promote long-term abstinence in HIV smokers.

## 3) Inclusion and Exclusion Criteria*

### A. Inclusion Criteria

To be eligible participants should:

- Diagnosed with HIV (based on self-report).
- Be 18 years and older
- Have smoked ≥ 5 cigarettes/day in the past year

- Be interested in making a quit attempt in the next 30 days
- Own a smartphone (apple/android), and plan to keep it active for the next 6 months
- Able to consent
- Have no plans to move in the next 6 months
- Are not pregnant or planning to be pregnant in the following 6 months
- Have any condition that, in the opinion of the investigator, would compromise the well-being of the patient or the study or prevent the patient from meeting or performing study requirements

**B. Exclusion Criteria**

Participants would be excluded if they:

- Have contraindication to NRT (past month myocardial infarction, history of serious arrhythmias/or unstable angina pectoris, dermatological disorder)
- Are currently being treated for a psychiatric condition.
- Are currently being treated for smoking cessation**,** alcoholism, or illicit drug use
- Are adults unable to consent
- Are individuals who are not yet adults
- Are pregnant women
- Are prisoners

## 4) Study Design

a. Study Type – Interventional
b. Primary Purpose – Other
c. Interventional Study Model – Sequential
d. Number of Arms – 2
e. Randomized or not – Randomized
f. Open label or if blinded – Not blinded
g. Number of participants – 100

## 5) Procedures Involved*

We will recruit participants via community and clinic flyers and among participants of another on-going survey who smoke (IRB#20180269). In Stage 1, participants will be randomized into one of two groups: 1) a group mindfulness training (MT) for smoking cessation, or 2) contingency management (CM) for smoking cessation. In Stage 2 non-

responders (those who have not quit at 1 month evaluation) will be randomized to: 1) *Switch* to sequentially receive the other intervention (i.e., CM or MI) and complete the 3-month assessment; or 2) *Continue* without further intervention and complete the 3-month assessment only.

In stage 1, both groups will do the following:

- Complete a baseline survey.
- Receive 6 weeks of Nicotine Replacement Treatment (NRT) via mail
- Receive reminder/encouragement calls or texts the day before their quit date and 2 weeks after their quit date.

Arm 1: The MT smoking cessation intervention:

Participants will attend an orientation session via Zoom or in person to introduce them to mindfulness, smoking cessation, and what is covered in the group sessions. This orientation will last 60-90 minutes. They will receive twice weekly group sessions (eight total during 4 weeks) via Zoom or in person that were manualized and will be delivered in Spanish or English by a Hispanic instructor(s) experienced in MT (a single therapist with >4 years of training in MT). We will e-mail participants study materials ahead of the first group session, such as the participant study booklet. We will also communicate with participants using WhatsApp to send them reminders and links to mindfulness recordings.

The overarching theme of momentary awareness and acceptance of cravings and affect (e.g., stress, anxiety etc.) will be introduced and reinforced in complementary ways throughout the training. Each session will last 45-60 minutes.

a. *Session (1):* Will introduce participants to the concept of how smoking can become a habituated behavior triggered by an environmental, physical, or mental stimulus through associative learning. It also will explore how cravings feel in the body and how MT can help individuals become more aware of these processes.

b. *Session (2):* Will examine how thoughts, emotions and body sensations become triggers for craving and smoking and introduce a technique to 'mindfully' work with cravings (Recognize, Accept, Investigate and Note what cravings feel like as they arise; acronym: RAIN).

c. *Session (3):* Will introduce how difficult emotions perpetuate smoking as well as a standard meditation technique called loving-kindness as a way to work with them. Loving-kindness is practiced through directed well wishing, typically by repetition of phrases such as 'may X be happy.'

d. *Session (4) (quit date):* Will teach participants how cravings thwart long-term goals, and reinforce mindfulness techniques as a way to help individuals disengage from habitual responding and realign with their goals.

e. *Session (5):* Will introduce participants to mindfulness practice in everyday life, including "awareness of breath" meditation and mindful walking ("four modes of walking", during which individuals practice systematically noting

objects that they see, and then objects that they hear, then objects that they smell, and then tactile objects such as the pressure of their feet on the ground).

f. *Session (6):* Will explore the automaticity of thought, and how thoughts can lead to habitual behaviors.

g. *Session (7):* Will reinforce the concept of acceptance and its role in changing habits. It will also explore how both mental and physical actions can "plant seeds" for future actions and habits.

h. *Session (8):* Will summarize the course tools and explore ways of maintaining these in the future. Home practice will be suggested after each session as a combination of formal MT meditations (the "body scan" which teaches individuals to systematically pay attention to different parts of their bodies as a way to reduce habitual mind-wandering and strengthen their attentional capacities, loving-kindness, and awareness of breath, which through focused attention on the breath also is intended to help individuals retrain their minds from habitually engaging in self-related pre-occupations -such as thinking about the past or future, or reacting to stressful stimuli- to more present moment awareness), and informal practices (four modes of walking, mindfulness of daily activities, mindfulness of smoking, RAIN). Participant will receive meditation recordings to practice.

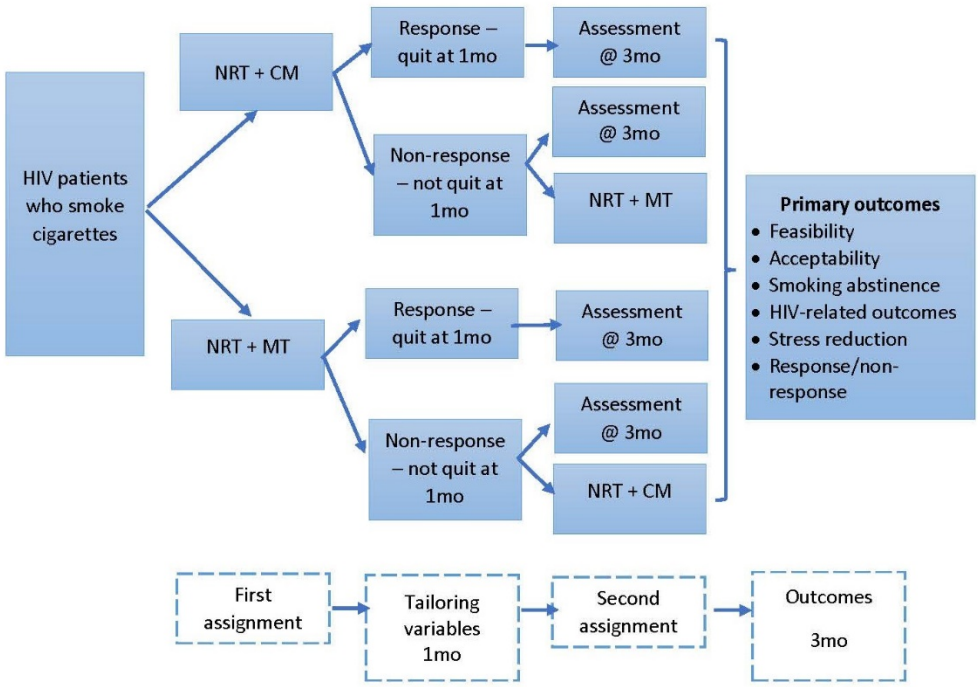
Participants will receive a weekly phone call to ask a few questions on their use of the mindfulness practices taught in the sessions. This will take about 5 minutes.

Participants will receive $20 for completing the baseline assessment, $10 for attending each of the 8 sessions, $10 for the end of the treatment assessment, and $25 for the 3-month follow up assessment (a total of $135).

Arm 2: Contingency Management (CM) Smoking Cessation Intervention

Participants in this arm will attend an orientation session via Zoom that will last 60-90 minutes. They will connect with a research associate 3 times per week for 3 weeks after quit date via zoom where they will answer a few questions about their quitting progress, report on past 7-day smoking, and provide a sample of CO to verify their smoking status after their quit date using a portable CO monitor (coVita **iCO™ Smokerlyzers®**) and/or NicoTests saliva screen test that has been mailed to them. Those who proved their abstinence (CO< 8 ppm using coVita **iCO™ Smokerlyzers®**) and/or 30 ng/mL using NicAlert) [14] will receive a cash reward. The first successful CO sample earns $5 cash, and then the reward increases by $2 for each consecutive successful CO and/or saliva sample (e.g., $5, $7, $9...). Participants also earn $2 bonus for 4 consecutive successful CO and/or saliva samples (total=$4). In all, participants can earn a maximum of $176. Participant who fail the CO and/or saliva test will not receive reinforcement and the value of the next payment will be reset to the one that was missed.

Figure (1): overview of the study design




All participants will be asked to complete an end of treatment assessment 2 weeks after the intervention ends, which will be the same as the 3-month follow-up described below. Breath CO and/or saliva sample test (for cotinine analysis) will be collected at the end of treatment assessment via Zoom for participants who report they have quit.

All participants will be asked to complete a follow-up assessment 3 months after their quit date to assess their smoking status as well as get information about concomitant smoking and NRT use, use of additional NRT or cessation drugs (e.g., bupropion), and use of other tobacco methods. Breath CO and/or saliva sample test (for cotinine analysis) will be collected at the 3-month follow-up points for participants who report abstinence. The breath sample will be collected with the portable CO monitor (coVita **iCO™ Smokerlyzers®**) and/or NicoTests saliva screening test. A cut-off of 8 ppm for CO test (using coVita **iCO™ Smokerlyzers®)** and/or ≤ 30 ng/mL for the saliva sample test (using NicoTests) will be used to determine abstinence (Benowitz et al 2002).

***Study measures***

1. Baseline Assessment: All study materials and instrument will be translated into Spanish.

- *Demographics and HIV history:* Age, race/ethnicity, birth origin, years in USA, relationship status, education, employment, income, acculturation, discrimination, self-identity, time since HIV diagnosis, HIV treatment.

Smoking status will be verified using breath carbon monoxide (CO [< 8 parts per million (ppm)], which can be determined quickly through a small, hand-held monitor and/or using a saliva screening test (cutoff concentration of ≤ 30 ng/mL), which can be determined quickly through a NicoTests saliva sample.

- *Smoking*: Smoking history, past quit attempt, motivation to quit, confidence in quitting, Fagerström test for nicotine dependence,[15] 12-item smoking self-efficacy to resist urge to smoke,[16] and 15-item Minnesota nicotine withdrawal scale (i.e., craving, irritability, anxiety, depression).[17]

- *Mindfulness skills*: The 15-item short form five facets of mindfulness questionnaire that measures MT skills related to observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience.[18]

- *Others: The 20-item Centers for the Epidemiologic Study of Depression (CES-D) scale,*[19] social support,[20] quality of life,[21] and alcohol and substance use (ASSIST).[22]

2. End-of treatment assessment (one month after quit date):

- The follow up assessment will occur at 1 months after quit date. The visit will last approximately 45 minutes.

- Information on number of sessions that was attended.

- *Acceptability:* The acceptability will be assessed by 3 items "How satisfied were you with the intervention?", "How likely are you to recommend this intervention to a friend?" and "How useful was the intervention?"

*Smoking Cessation:* Main smoking cessation outcome is 7-day point-prevalence abstinence (defined as self-report of not smoking in the past 7-days; not even a puff) and confirmed smoking cessation by expired carbon monoxide (CO) level cutoff of < 8 ppm using a coVita **iCO™ Smokerlyzer®** and/or NicoTests saliva sample of ≤ 30 ng/mL at the 1-month follow up. Secondary outcomes include the reduction in number of cigarettes smoked per day.[23,24] Relapse is defined as smoking at least once/week on two consecutive weeks.[25] These are described in more detail below.

3. Three-month Follow-up Assessment (3-month after quit date):

- The follow up assessment will occur at 3 months (+30 days) after quit date. The visit will last approximately 45 minutes.

- All baseline assessment will be re-administered except demographics.

- Information on number of sessions that was attended.

- *Acceptability:* The acceptability will be assessed by 3 items "How satisfied were you with the intervention?", "How likely are you to recommend this intervention to a friend?" and "How useful was the intervention?"

- *Smoking Cessation:* Main smoking cessation outcome is 7-day point-prevalence abstinence (defined as self-report of not smoking in the past 7-days; not even a puff) and confirmed smoking cessation by expired carbon monoxide (CO) level cutoff of < 8 ppm using a coVita **iCO™ Smokerlyzer®** and/or NicoTests saliva sample of ≤ 30 ng/mL at the 3-month follow up. Secondary outcomes include the reduction in number of cigarettes smoked per day.[23,24] Relapse is defined as smoking at least once/week on two consecutive weeks.[25] These are described in more detail below.

- *Process evaluation:* Semi-structured post-intervention evaluation interviews will be conducted with randomly selected participants to further inform our assessment of acceptability and perceived helpfulness of interventions, and identifying key areas for refining the intervention protocols (e.g., improving access, content, usability). These will be conducted in-person or via Zoom and participants will receive $25 for completing the interview.

**Primary Outcome Measure Title:** Smoking cessation - 7-day point-prevalence abstinence.

**Outcome Measure Description:**

Defined as self-report of not smoking in the past 7-days, not even a puff and confirmed by expired carbon monoxide (CO) level cutoff of < 8 ppm using a coVita **iCO™ Smokerlyzer®** and/or NicoTests saliva sample of ≤ 30 ng/mL.

**Outcome Measure Timeframe:**

4 weeks (end of treatment), and 3 months

**Secondary Outcomes**

1. Treatment-specific retention rates for study measures.
    - Defined as: Percentage of participants completing all study procedures divided by total enrolled. Coded reasons for dropouts.
    - Timeframe: 3 months
2. Treatment-specific adherence rates to study protocol
    - Defined as number of phone-call check-ins attended by each participant (4 for mindfulness training, 12 for contingency management).
    - Timeframe: 3 months

## 6) Data and Specimen Banking*

There will be no data or specimen banking.

## 7) Data Management*

The analysis of the feasibility and acceptability outcomes will be mainly descriptive. We will calculate differences in pre and post intervention measures of baseline characteristics, indices of treatment implementation, adherence, retention, and treatment perceptions and compare the differences between arms 1 and 2. Attrition analyses will compare respondents who complete all measurements to those who do not based on baseline characteristics. Direct maximum likelihood estimation and multiple imputation will be used to address incomplete data. Univariate and multivariable logistic regression models will be used to explore baseline predictors of 3-month smoking cessation and the acceptability and feasibility of the intervention. Cross-tabulations for ordinal variables and mean and corresponding 95% confidence intervals for continuous variables will be used to explore secondary outcomes including improvement in depression, smoking self-efficacy, craving, quality of life, and mindfulness skills. Although we are unpowered to detect differences by gender, we will consider exploring the gender effect on our main outcomes in our analysis. Data management for preparing data for statistical analysis and statistical analysis will be performed with SAS or R statistical software.

Qualitative analyses of semi-structured post-intervention evaluation interviews will identify emergent themes related to acceptability and specific targets for refinement of content and delivery. Interviews will be audio-recorded, transcribed verbatim, and analyzed using Nvivo. This program is designed for the storage, coding, retrieval, and analysis of qualitative data. Two complementary coding schemes will be used: 1) descriptive, which uses words or short phrases to summarize passages of data and 2) in Nvivo, in which actual language from participants is used to name concepts and themes. Extensive analytic memos will be written after each interview is conducted, coded, and throughout the analysis process to reflect on code choices, emergent themes and patterns, and conceptual models. Finally, the data will be themed, in which the final sets of codes and their meanings will be transformed into longer and more descriptive themes to organize recurrent meanings and patterns. Themes and definitions will be compared across interviews to ensure consistency and reliability.

Statistical analyses will be done using SPSS, V21, (https://www.ibm.com/analytics/spss-statistics-software).

All study data will be entered and captured by REDCap, which provides secure data capture for clinical and non–clinical research studies.

## 8) Risks to Subjects*

The risks to subjects, immediate and long range, are considered minimal. Study participants will be asked to complete questionnaires before and after receiving advice to quit smoking, either self-help materials to quit or a behavioral intervention, as well as nicotine replacement for smoking cessation. It is possible that subjects might become psychologically distressed while completing the questionnaires or be dissatisfied with the self-help information or intervention. They will be provided with transdermal nicotine patches that are available over-the-counter. Participants will be required to indicate whether they have any health conditions that may negatively interact with the patches.

To minimize the risk of psychological distress due to questionnaire completion, the measures do not contain private or potentially embarrassing items, and will take about 30-45 minutes for completion time per assessment. To minimize the risk of dissatisfaction with the intervention, we will use an established intervention that has high efficacy. To minimize risks associated with the nicotine patches, subjects will be provided with thorough education of the indications for the nicotine patch, possible side effects, and known health conditions that preclude patch use. The patches are available over the counter; thus, they do not pose a significant health risk to most people. They contain minimal amounts of nicotine (which are much less than they get from smoking), and are absent the remaining 7,000 toxins contained in cigarettes. In addition, we will refer patients with a questionable medical history to their physician or to Jackson Memorial Hospital for consultation.

Though we regard the risks of participating in this study as low, we will take every measure to ensure that every recruiter, interviewer or project personnel, is trained to handle situations sensitively and with empathy. All research staff are required to complete site mandated training on the Protection of Human Research Participants.

## 9) Adverse Events (AE) and Serious Adverse Events (SAE)

Adverse events for this study may include the following:
EXPECTED:

a. Symptoms of nicotine withdrawal, such as headaches, cravings, insomnia, anxiety, or depression.
b. Side effects of using the nicotine replacement patches, such as minor skin irritation or rash).

These expected AE will be recorded in the participant tracking database. Participants will be advised to review the materials they received on nicotine withdrawal and proper use of NRT patches. If unmanageable symptoms persist of withdrawal or NRT use

persis, participants will be advised to discontinue use of NRT and see their physician.

UNEXPECTED

c. Unexpected negative psychological reactions to practicing mindfulness.

These unexpected AE will also be recorded in the participant tracking database. If negative reactions to the mindfulness practice cannot be resolved within the group session by the trained mindfulness expert, participants will be advised see their physician. If severe reactions occur and cannot be resolved, study staff will call 911. We do not expect this SAE to occur, nor are any other SAE anticipated.

## 10) Potential Benefits to Subjects*

Individual subjects can potentially benefit from participating in the study because they will have the opportunity to make a quit attempt and the possibility of long-term smoking cessation. This is associated with a number of additional benefits including improved health, economic savings, the confidence and happiness associated with becoming an ex-smoker, and reducing their stress as a result to practicing mindfulness.

## 11) Vulnerable Populations*

This research study does not include vulnerable populations.

## 12) Setting

The primary study site is the University of Miami Miller School of Medicine Campus. Recruitment will mostly take place at UHealth and community clinics, social media (e.g., Facebook), and organizations serving people living with HIV. The consent process, participant assessments, and group meetings will take place via Zoom.

## 13) Resources Available

Our team of multi-disciplinary experts in smoking cessation, MT, and analysis is a pioneer in developing and testing novel smoking cessation interventions among high-risk populations. Drs. Asfar and Lee have long-term collaboration on several epidemiological studies and community-based cessation trials.[26-28] Dr. Asfar (PI) is a Research Assistant Professor in the Department of Public Health Sciences at the University of Miami (UM). She has more than 10 years of experience in tobacco research. She had led several clinical- and community-based smoking cessation trials.[29-32] Dr. Lee (Co-I) has been involved in tobacco research for over 20 years. Recently, he has been evaluating mindfulness-based interventions

targeting high-stress occupational groups, and he will assist Dr. Asfar in the development and testing of the proposed intervention.

## 14) Prior Approvals

N/A

## 15) Recruitment Methods

Our target sample size is up to 100 HIV patients who smoke (50 in each arm). Flyers will also be distributed at UM/HIV clinics and various community-based clinics/organizations not directly affiliated with UM/HIV, such as Jackson Health System (JHS). We will also recruit via advertisements on social media platforms.

Those interested will contact our research team to first determine eligibility or they may scan the QR code included on the study flyer to complete the screening questions independently via REDCap. Those completing the screening questions independently via REDCap will be assigned a subject ID and will then be directed to a separate form asking for their name and contact information, in case needed to be reached. If eligible, the research staff will provide an overview of the research study, and if the participant wants to participate, we will send them a link to complete the electronic informed consent and baseline survey via REDCap.

We are requesting permission to collaborate with another study, Project CHARM (IRB#20160911), which serves as a consent to contact database, to contact eligible participants. They will provide us with contact information for participants in their study who might be eligible for our study and have consented to be contacted by other studies.

Participants in arm 1 (mindfulness) will receive $20 for completing the baseline questionnaire, $10 for each session they attend, and $10 for completing the end of treatment assessment and $25 for completing the 3-month follow-up. Participants who complete the process evaluation will receive another $25.

Participants in arm 2 (CM) will receive $20 for completing the baseline, and at first successful CO and/or saliva sample earns $5 cash, and then the reward increases by $2 for each consecutive successful CO and/or saliva sample (e.g., $5, $7, $9...). Participants also earn $2 bonus for 4 consecutive successful CO and/or saliva samples (total=$4). In all, participants can earn a maximum of $176 in rewards. Participant who fail the CO and/or saliva test will not receive reinforcement and the value of the next payment will be reset to the one that was missed. Participants will receive $10 for completing the end of treatment assessment and $25 for completing the 3-month follow-up, and those who complete the process evaluation will receive another $25.

To improve recruitment, participants will be given a $10 incentive via cash, gift card, or electronic cash transfer, for each participant they refer who enrolls in the study.

To improve retention rates, participants will be contacted via text, mail, or email for study follow up reminders.

Participants can expect to be in the study for 3 months (+/- 2 months).

## 16) Local Number of Subjects

Our target sample size is up to 100 HIV patients who smoke.

## 17) Confidentiality

Multiple steps will be taken to guarantee confidentiality. All electronic surveys and forms will be entered and uploaded using REDCap. All REDCap data is securely hosted by the University of Miami's IT Department. Research IT administers project creation, user account management, and movement of projects from development to production. Authentication is performed via CaneID Authentication Service (CAS), the same institution-wide system used for a variety of applications such as mum. Other electronic data will be stored in password-protected files that only the PI and study staff will be able to access. Participants will be assigned an ID# in REDCap and a master key linking names and ID# will be kept in a separate location accessible only approved study personnel.

There are multiple levels of security once placed on the local network. All study personnel will be certified to conduct human subjects' research by the University of Miami Institutional Review Board. All data will be inspected for quality assurance prior to analysis. Prior to performing statistical analyses on quantitative data, the data will be checked, screened and verified.

### Jackson Health System additional requirement

☒ This section is not applicable because the research is not collecting health information from JHS under a waiver of authorization (without obtaining a HIPAA authorization from the participant)

If health information, including Protected Health Information and/or Personally Identifiable Information are collected from JHS without a signed authorization from the subject (with a waiver of authorization from an IRB or Privacy Board), you must agree to the following:

☐ JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research with a waiver of the requirement for an authorization under HIPAA shall only be

stored on the secured JHS SharePoint environment made available by JHS. I and the Study Team members shall not copy or store the JHS sourced personally identifiable information (PII), including protected health information (PHI) data to any other system, including any systems maintained or provided by the University of Miami. I and the Study Team shall only copy or transfer JHS-sourced data that has been properly de-identified in accordance with all requirements contained in the HIPAA Rules by removing all of the identifiers listed in the instructions for Section 15 of this protocol.

If the data obtained for this research will be acquired from a retrospective "chart review" involving health information from JHS with a waiver of authorization (without obtaining an signed HIPAA authorization from the subject) then the data and the link and/or key to each subject's identity shall only be maintained in the secure JHS SharePoint environment made available by JHS.

## 18) Provisions to Protect the Privacy Interests of Subjects

Participants can be assured that the personal information they provide will only be seen by approved research staff and that in the data their name will be replaced by an ID number. The key linking names and ID numbers will be accessed only by the PI.

In order to enhance privacy when conducting the sessions via Zoom, participants will be instructed not to share the meeting link with anyone; for the privacy of all participants to attend the session in a private setting without others in the background; to change their location if it other people come into the area; to not discuss anything shared in the session with others; and to not share any sensitive personal data during the session. Participants will be also placed in the Zoom waiting room and admitted only by the research staff.

## 19) Consent Process

Informed consent will be obtained electronically via REDCap prior to the beginning of the sessions. In the event that participants have difficulty completing the electronic consent in REDCap via Zoom, we will mail them a copy, have them sign while on Zoom, and ask them to mail it back to us. All participants will be offered a copy of the informed consent for their records.

## 20) Process to Document Consent in Writing

Participants will electronically consent to participate in this study, which will be documented in the study database kept in REDCap. A copy of consent will be

provided to participants if requested. The consent will also include information regarding who they can call if they have any questions regarding their participation in the study.

## 21) Withdrawal of Subjects

Participation in study is voluntary. Participants can elect not to answer any specific question on the survey or interview and can elect not to participate in any procedures or all procedures of the study.

## 22) Waiver of Authorization for Use and Disclosure of Protected Health Information (HIPAA)

☐ This section is not applicable, we are not requesting a waiver of authorization.

*If the research team will access patient medical records or other identifiable health information for this research without or prior to obtaining a signed HIPAA authorization from the subject or the subject's legally authorized representative (LAR), you must obtain a waiver of the requirement for written authorization from the patients to access their medical records.*

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.

☒ ***I confirm***

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

☒ ***I confirm***

1/3/2023

PI Signature Date

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