PrEP Readiness Interventions for Supporting Motivation (PRISM)

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UM-IRB

20180823: Stimulant-Using MSM and PrEP

(PRISM project)

Dr. Adam Carrico, Principal Investigator

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1) Protocol Title

Adaptive Intervention Strategies to Optimize PrEP Clinical Evaluation and Uptake in Stimulant-Using Men

2) Objectives*

The overarching goal of this formative research is to examine whether—and in what combination—contingency management (CM) and motivational interviewing (MI) can facilitate entry of stimulant-using men who have sex with men (MSM) into the pre-exposure prophylaxis (PrEP) care continuum.

Aim 1. Augment CM and MI with content to facilitate entry into the PrEP care continuum by conducting qualitative interviews with PrEP healthcare team members and stimulant-using MSM.

Aim 2. Examine the *feasibility and acceptability* of adaptive treatment strategies combining CM with MI to promote clinical evaluation for PrEP, PrEP uptake, and PrEP care retention.

Aim 3. Document implementation factors relevant the *scalability* of CM and MI such as perceptions of community-based HIV prevention providers to inform a full-scale sequential multiple assignment randomized trial (SMART) of the interventions.

3) Background*

Preliminary Data: There are no relevant preliminary data for this R34 project where the primary objective is to obtain preliminary data for a planned R01 proposal.

Significance: The CDC estimates one-in-six MSM will acquire HIV in their lifetime, including one-in-two Black MSM and one-in-four Hispanic/Latino MSM. PrEP is highly effective for preventing HIV infection, but many MSM who are at elevated risk for HIV are experiencing difficulties with initiating and remaining on PrEP. As a biomedical intervention, PrEP offers tremendous protection against HIV infection without necessitating changes in sexual behavior. PrEP can also serve as a gateway into regular HIV testing as well as comprehensive sexual and mental health care. There is an urgent need to augment as well as tailor evidence-based CM and MI interventions to facilitate entry of stimulant-using MSM into the PrEP continuum.

MSM who use stimulants have been consistently shown to be at a 3-6 fold greater risk of HIV seroconversion. Despite successful deployment of public health interventions, recent methamphetamine use doubled from 2011-2014 (from 4% to 9%) among MSM in New York City (NYC). This trend is corroborated by comparable increases in methamphetamine use in South Florida and other urban areas such that national rates are meeting or exceeding 2005 peaks. In South

Florida, the 12-month prevalence of stimulant use is among the highest nationally for MSM: 25% cocaine, 9% ecstasy, 6% crack-cocaine, and 6% methamphetamine. Stimulant use is also prevalent in ethnic minority MSM where HIV incidence is the highest. For example, we recently observed that one-in-five young black MSM in Texas reported stimulant use in the past two months.

Combining CM and MI could optimize HIV prevention in stimulant-using MSM. CM is an evidence-based substance use intervention where individuals receive tangible rewards as positive reinforcement for stimulant abstinence, which targets extrinsic motivation. One enduring concern with CM is the risk for relapse after the incentives are discontinued. Because MI explicitly targets intrinsic motivation, it could have synergistic, beneficial effects on long-term abstinence if delivered with CM. At the same time, MI alone may not adequately address structural factors (e.g., transportation) that are key obstacles to HIV prevention with stimulant-using MSM. CM incentives could amplify the benefits of MI by assisting with navigation of these structural barriers while providing positive reinforcement for behavior change.

This pilot SMART will focus on testing different schedules for the sequential delivery of these scalable motivational enhancement interventions to target sequentially linked behaviors (i.e., PrEP medical evaluation, PrEP uptake, and early PrEP care retention) to facilitate entry into the PrEP care continuum. In Phase I, we will implement formative qualitative research by conducting key informant interviews with PrEP healthcare team members and in-depth qualitative interviews with stimulant-using MSM. These data will inform our efforts to tailor the CM and MI interventions to simultaneously reduce substance use while optimizing engagement along the PrEP care continuum. In Phase II, we will conduct a pilot SMART of the sequentially delivered CM and MI interventions to examine the feasibility, acceptability, and potential scalability of these motivational enhancement approaches.

4) Inclusion and Exclusion Criteria*

Recruitment: PrEP healthcare team members will be recruited via professional networks of the study investigators to complete key informant interviews regarding barriers and facilitators to delivering PrEP to stimulant-using MSM. We will recruit stimulant-using MSM for in-depth qualitative interviews in Phase I as well as the pilot SMART of the sequentially delivered CM and MI interventions in Phase II. Participants will be recruited from a national sampling frame using social networking applications where men meet romantic and sexual partners (e.g., Scruff, Grindr). We will also recruit participants in South Florida from the community as well as through extant registries of HIV- MSM that are managed by Drs. Carrico and Safren at the University of Miami as well as Dr. Grov at the City University of New York. More detailed information regarding our recruitment plan is provided below.

Inclusion Criteria for Phase I: Participants will be included in this project based on:

- 18 years of age or older
- Sexually active MSM
- Reports using methamphetamine, powder cocaine, or crack-cocaine at least one day in the past month
- HIV-negative (self-report)
- Meets CDC criteria for PrEP eligibility

Exclusion Criteria for Phase I: Participants will be excluded if they: a) are under 18 years of age; b) are not a man who has sex with men; and c) are unable to provide informed consent at the assessment visit in English.

Inclusion Criteria for Phase II: Participants will be included in the pilot SMART based on:

- 18 years of age or older
- Sexually active MSM
- Reports using methamphetamine, powder cocaine, or crack-cocaine at least one day in the past 3 months
- HIV-negative (confirmed at baseline)
- Meets CDC criteria for PrEP eligibility
- Not currently prescribed PrEP

Exclusion Criteria for Phase II: Participants will be excluded if they: a) are under 18 years of age; b) are not a man who has sex with men; or c) are unable to provide informed consent at the assessment visit in English.

5) Procedures Involved*

Phase I – We will conduct formative qualitative data collection to support our efforts to modify the extant CM and MI protocols to include content relevant to the PrEP care continuum. Key informant interviews and focus groups with 10-12 PrEP healthcare team members (e.g., physicians, nurse practitioners, social workers, and benefits navigators) will facilitate our efforts to obtain a more nuanced understanding of barriers and facilitators to optimizing the PrEP care continuum in stimulant-using MSM. We will also ask PrEP healthcare team members to elaborate regarding how they manage the complex care needs of stimulant-using MSM (e.g., addressing problematic patterns of stimulant use, safer injection practices, and referrals to substance use disorder and mental health treatment). The qualitative

interview guide for our work with providers is attached. Because PrEP healthcare team members are completing this one time study visit in their professional role, we are requesting a waiver of signed informed consent.

Approximately 30 stimulant-using MSM (15 not currently on PrEP and 15 currently taking PrEP) will complete in-depth qualitative interviews to explore the perspective of the target population regarding the planned interventions as well as barriers and facilitators to navigating the PrEP care continuum. We will purposively sample men who are not on PrEP and men who are currently taking PrEP to gain a fuller understanding of how participants are navigating distinct aspects of navigating the PrEP care continuum (e.g., uptake versus adherence). All participants will be asked to comment on what magnitude of incentives would be necessary for promoting stimulant abstinence during thrice weekly urine screening as well as PrEP medical evaluation and PrEP uptake. The qualitative interview guide for these in-depth interviews is attached. Signed informed consent will be obtained for all from all in-depth interview participants. Stimulant-using MSM will also be asked to provide consent to become part of a consent to contact database so that our study team can inquire if they are interested participating in Phase II or other projects. Participants will consent to this in a separate signature line of the Phase I informed consent.

Procedures for conducting Phase I key informant interviews and focus groups with PrEP healthcare team members as well as in-depth qualitative interviews with stimulant-using MSM are outlined below.

Telephone screen. Stimulant-using MSM will complete a brief telephone screen to determine eligibility for completing in-depth interviews based on inclusion criteria above (see attached).

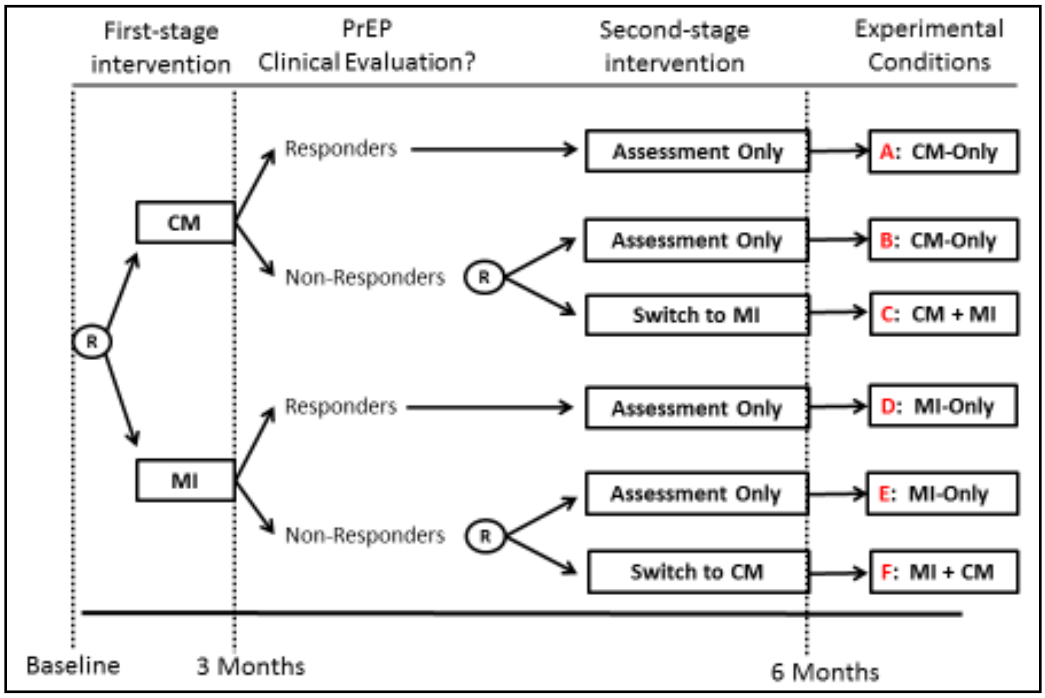
Informed consent. Participants will complete an informed consent that includes permission to re-contact participants to determine if they are interested in participating in Phase II of this project.

Key informant interviews or focus group with PrEP healthcare team members. PrEP healthcare team members will complete a 1 hour interview or join a 1 hour focus group about their experiences in providing PrEP and perceptions regarding the unique needs of stimulant-using MSM. PrEP healthcare team members will receive $100 for the key informant interview or focus group. If participants are unavailable to attend a focus group, we will schedule an individual interview with them at a place and time of their choosing.

In-depth qualitative interviews with stimulant-using MSM. In-depth interviews with stimulant-using MSM will be approximately one hour and cover topics such as history of stimulant use, attitudes and beliefs about PrEP. Those who are not on PrEP will be asked to describe on barriers and facilitators to accessing PrEP. Those who are currently taking PrEP will be asked to describe how they successfully

navigated the process of initiation and strategies they are implementing to achieve prevention effective PrEP adherence. After completing the interview, participants will complete a brief survey to assess demographic information and efforts to navigate the PrEP healthcare continuum (see attached). Stimulant-using MSM will receive $40 for completing this one time study visit.

Phase II – We will conduct a pilot SMART with 70 HIV-negative, stimulant-using MSM who meet CDC criteria for PrEP eligibility.
First Stage Intervention. After completing a baseline assessment and a brief run-in period, participants will be randomized to complete a 3-month CM intervention or a two-session MI intervention that were developed as part of our Phase I activities.
Second Stage Intervention. Three months after this first-stage randomization, participants will complete a second informed consent prior to a 3-month follow-up assessment to determine whether they are responders.
Experimental Conditions. Responders will be classified as those who have started PrEP, the primary outcome. Responders will continue with assessments only. Participants who have not responded to the initial intervention will be randomized again to either: 1) continue with assessments only; or 2) switch to the other intervention (i.e., CM+MI versus MI+CM). An overview of the pilot SMART procedures is provided in the figure below. Below we describe each of the procedures relevant to executing this pilot SMART.



Telephone screen. Stimulant-using MSM will complete a brief telephone screen to determine eligibility for enrolling in the pilot SMART based on inclusion criteria above for Phase II (see attached). This telephone screen has been modified to include items relevant to the novel coronavirus (COVID-19), which are also attached. The figure below describes the participant flow for the pilot SMART.

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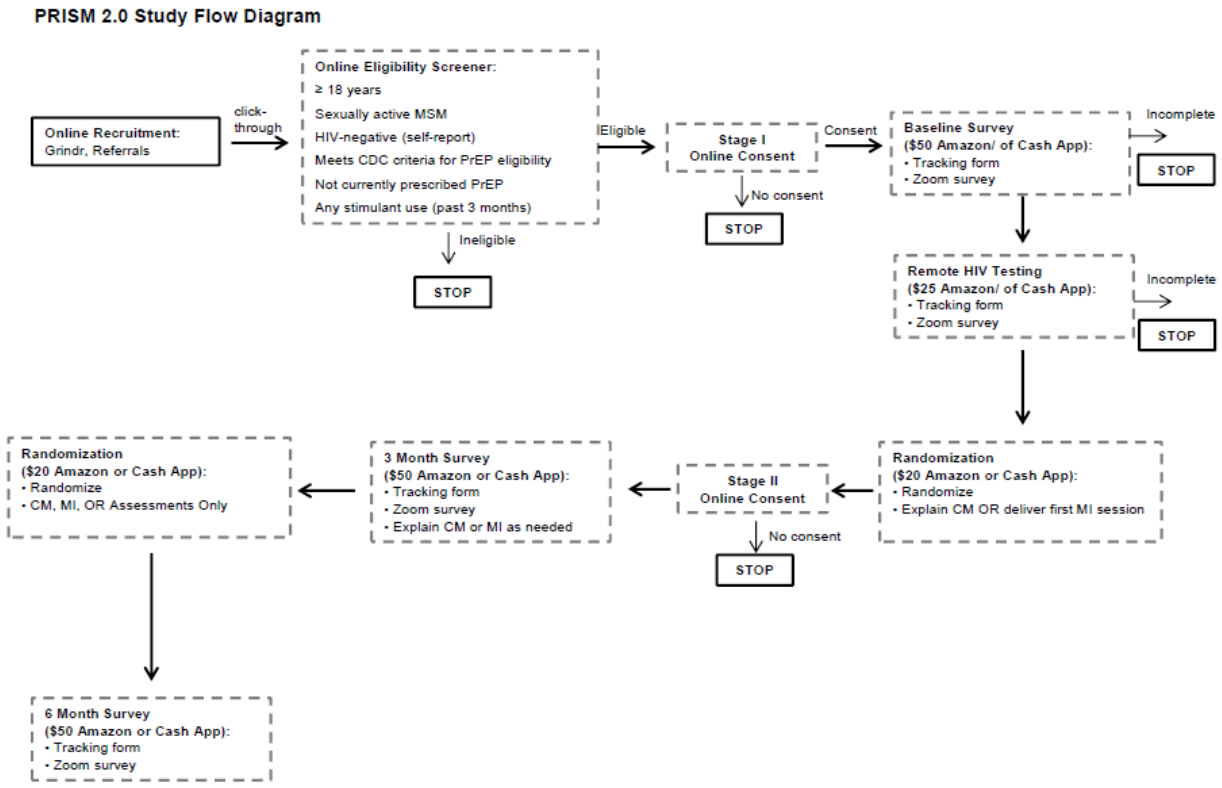

Stage 1 informed consent. Prior to the baseline assessment, participants will review an online consent with a study staff member of zoom detailing the procedures for the first three months of the pilot SMART and indicate whether they consent to participate.

We have elected implement sequential informed consents for this project for two primary reasons. First, the study procedures are complex and dependent on whether participants respond to the first-stage intervention. Sequential informed consent procedures enhance the comprehension of this complex SMART protocol. Second, because one of the interventions involves receiving CM incentives this could create a scenario where participants initially randomized to MI choose not to respond in order to have another chance to receive CM incentives in the second-stage intervention. Conducting sequential informed consenting substantially mitigates this concern because participants are not aware of the second-stage interventions until the 3-month follow-up assessment. Given these ethical and logistical concerns, we believe sequential informed consenting is a reasonable solution.

Baseline assessment. Due to the challenges presented by COVID-19, we are requesting a waiver of written consent to review the Stage 1 consent with

participants over zoom at baseline. We will follow-up with remote HIV testing. Participants will be asked to indicate whether they consent to participate in the study and continue with the baseline assessment via Zoom. The baseline quantitative and qualitative assessment includes a detailed battery of measures and a brief in-depth qualitative interview. A codebook of the baseline quantitative measures as well as the qualitative interview guide are attached. Participants will receive a $50 Amazon gift card or cash application payment for completing this assessment.

Remote HIV testing. To ensure that participants meet the inclusion criteria for Phase II, they will be asked to complete remote HIV testing by mailing in a saliva sample from a kit that our team will send to their home. Participants will receive $25 as an Amazon gift card or cash application payment for completing remote HIV testing. Those who test positive for HIV will be excluded from this trial and referred for confirmatory testing in their local community.

Non-reactive (HIV-) test results will be delivered to participants as part of their randomization visit. For those who do not respond to attempts to schedule their randomization visit, after 2 months their non-reactive HIV test results will be emailed to the email address on file via a secure, encrypted University of Miami email. This report does not contain any PHI.

All study staff also receive ongoing training and supervision from Dr. Carrico (a licensed psychologist) on delivering HIV test results and providing counseling to individuals experiencing acute distress. All staff will receive training in procedures for immediate linkage to confirmatory HIV testing. Participants residing in Miami-Dade county who are test positive for HIV will be referred for confirmatory testing and anti-retroviral therapy (ART) with Dr. Allan Rodriguez.

Randomization visit. Approximately one week after baseline, participants who are confirmed to be HIV-negative will attend a separate randomization visit. Those randomized to CM will be introduced to incentives for PrEP clinical evaluation and uptake. Participants randomized to MI will receive their first session of this intervention. All participants will receive a $20 Amazon gift card or secure cash application payment for attending the randomization visit.

CM intervention protocol. Participant randomized to CM will complete a 3-month CM protocol where they will be eligible for CM incentives for documentation that they have been evaluated for PrEP by a medical provider ($50) and filled a prescription for PrEP ($50) in the three months following randomization. Total possible CM incentives are $100 per participant, which will be provided in Amazon gift cards or secure cash application payment.

MI protocol. Participants in the MI intervention will complete two individually delivered sessions via zoom designed to enhance intrinsic motivation and self-efficacy for taking the first steps towards starting PrEP and addressing the

intersection of substance use and HIV risk. Session 1 focuses on supporting efforts of participants to be medically evaluated for PrEP. Session 2 focuses on addressing the intersection of substance use and HIV risk. A detailed protocol for this 2-session MI intervention is attached. Participants will receive a $20 Amazon gift card or secure cash application payment for completing each MI session via zoom.

Stage 2 informed consent. Prior to completing the 3-month follow-up assessment, participants will provide informed consent for the Stage 2 of the pilot SMART. This consent will clarify that participants may be invited to participate in a CM or MI intervention based on the responses to the survey questions and prior intervention assignment. Due to the challenges presented by COVID-19, we are requesting a waiver of written consent to review the consent with participants over zoom.

3-month follow-up assessment with second-stage randomization. After completing the informed consent process, we will re-administer quantitative measures from the baseline assessment via Zoom, and those who have not started PrEP will be classified as non-responders. All non-responders will complete the second-stage randomization to either: 1) continue with assessments only; or 2) switch to the other intervention (CM+MI versus MI+CM). Those randomized to receive CM or MI will receive these intervention consistent with the protocols described above. Responders will continue with assessments only. Participants will receive a $50 Amazon gift card or secure cash application payment for completing this assessment. Participants will have a 30-day window (+1 month) to complete their follow-up assessments.

6-month follow-up assessment. We will re-administer the quantitative measures from the baseline assessment and a qualitative exit interview (see attached) via zoom. Participants will receive a $50 Amazon gift card or secure cash application payment for completing this assessment. Participants will have a 30-day window (+1 month) to complete their follow-up assessments.

6) Risks

These study procedures meet the criteria for minimal risk research activities. However, possible risks include: 1) a breach of confidentiality; and 2) negative psychological reactions to study procedures.

Breach of Confidentiality. To mitigate confidentiality risks, all study files are located in a locked file cabinet in a secure filing cabinet. Web-based data collection is employed such that all data is collected and stored behind the University of Miami firewall. All participants are also informed of mandated reporting guidelines for active suicidal/homicidal ideation, child abuse, and elder/dependent adult abuse in Florida. Because this study is funded by NIH, our notice of grant award includes a Federal certificate of confidentiality for this project to protect against court-ordered disclosure of study-related information given the highly sensitive nature of

the data collected. All assessment interview and intervention activities will be conducted via zoom, which is HIPAA compliant.

Negative Psychological Reactions to Study Procedures. In our experience, the vast majority of participants experience only transient negative reactions to completing HIV testing, self-report assessments, or clinical interviews. On rare instances, participants have experienced more severe negative reactions to study procedures. Dr. Carrico is a licensed psychologist in Florida. Data collection for this project will be exclusively conducted at the University of Miami. Dr. Grov will assist with data collection in Miami and will have access to study data.

Staff will receive extensive training and supervision to assess participants for signs of acute distress during the study visits. Staff will be trained in a brief screening protocol to assess suicidal thoughts, plans and intent. Specifically, they will administer a brief screening tool only where participants display signs of acute distress. Those expressing any current plan or intent to harm themselves or someone else will be assessed further by the study PI, a licensed psychologist in Florida. The vast majority of participants displaying signs of acute distress (e.g., crying) will not report any current plan or intent. Referral sheets are available to provide linkages with community-based resources such as mental health treatment and substance abuse treatment that may assist participants with managing some of the issues that come up in their study activities. Those who test positive for HIV will be immediately linked to confirmatory testing and immediate anti-retroviral therapy (ART) with Dr. Allan Rodriguez. We will also work with Dr. Doblecki-Lewis to refer any participants who are newly diagnosed with HIV to the appropriate case management services at the Miami-Dade County Department of Health to assist these individuals with access HIV medical care.

We acknowledge that participants who learn they test positive for HIV may experience acute distress. Dr. Carrico is a licensed psychologist and we are prepared to provide immediate, on-site support to assist participants in coping with acute distress, ensure there is no imminent threat of harm to self or others, and coordinate immediate linkage for confirmatory HIV testing. We will also provide referrals for community-based mental health treatment tailored specifically to meet the needs of those who are newly diagnosed.

7) Data and Specimen Banking*

There will be no specimen banking in this modified protocol. Saliva samples provided by participants will be labeled only with he participant ID and date of receipt. These saliva samples will be tested for HIV by a collaborating laboratory and then destroyed.

8) Data Management*

All patient-reported data will be stored on a secure server and labeled with the participant ID number only. Participant files will be completed using Redcap. Any paper files will be stored in a locked filing cabinet in Dr. Carrico's office.

Because this is a pilot study, we have not conducted a formal power analysis. In fact, there is increasing recognition in clinical research methods that pilots should focus primarily upon issues relevant to feasibility and acceptability of a more definitive study, not effect size estimation.

Feasibility. To evaluate feasibility of a more definitive trial, we will monitor rates of recruitment and effort required (e.g. number of staff hours) as well as the number of screenings conducted, proportion eligible, and proportion who agree to enroll. *Feasibility of recruitment* will be operationalized as an enrollment rate of 70% or higher, an established standard in the literature. We will also record number of rescheduled and missed assessment visits, CM visits, and MI sessions to estimate staffing needs and retention protocols for a planned R01. *Feasibility of intervention delivery* will be operationalized as attending three-fourths of scheduled MI sessions (3 of 4 sessions completed on average). Although power will be limited, we will conduct independent samples t-tests to describe the average number of MI sessions attended among non-responders randomized to switch (i.e., CM+MI vs. MI+CM).

Acceptability. To measure *acceptability*, we will modify previous intervention satisfaction evaluation surveys that have been administered to methamphetamine users in Dr. Carrico's clinical research. Measures include items such as, "How satisfied were you with the program in general?" and "How likely are you to recommend this intervention to a friend who uses stimulants?" Independent samples t-tests will describe mean acceptability ratings of CM and MI among non-responders who are randomized to switch (i.e., CM+MI vs. MI+CM).

Qualitative data will also provide meaningful insights into *acceptability* of the CM and MI interventions. All interviews will be digitally audio-recorded, transcribed verbatim, and transferred to Atlas.ti 7 for analyses led by Dr. Grov. 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 vivo*, 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 more descriptive themes to organize recurrent meanings.

Quantitative Analyses. The primary outcome for the pilot SMART is PrEP medical evaluation in the six months following first-stage randomization. Secondary

outcomes will include: PrEP uptake, early retention in PrEP clinical care, CAS, stimulant use (measured via self-report), motivation for PrEP initiation, and motivation for avoiding stimulant use. Logistic regression will examine differences by arm as well as psychological predictors of the odds of PrEP medical evaluation or PrEP uptake over follow-up. Secondary outcomes involving longitudinal trajectories of continuous measures will be tested using multilevel random coefficient models (i.e., hierarchical linear modeling; HLM). Multilevel models for binary outcomes will be fitted using SAS PROC GLIMMIX with maximum likelihood estimation via adaptive quadrature. Exploratory mediation analyses will be undertaken using the logic of Kramer to estimate attenuation of the direct pathway in the presence of the hypothesized effect modifier in the regression model.

Data Safety and Monitoring Plan. The University of California, Los Angeles Data Safety and Monitoring Board in Addiction Medicine (DSMB-AM) has agreed to serve as the DSMB of record for this trial. The DSMB will hold annual meetings to monitor trial progress the DSMB chair will be notified within 72 hours of any adverse event (AE) or serious adverse event (SAE) regardless of whether it is judged to be related to study procedures by the study team. All self-report data will be collected using a secure server behind the University of Miami firewall. Any paperwork or data containing identifiers will either be in a secured cabinet in a locked office or on a password protected server. Staff receive extensive training in data management and security protocols.

9) Risks to Subjects*

- Privacy risks including a breach of confidential information
- Psychological risks including negative reactions to study measures
- Legal risks related to forced disclosure of information related to substance use
- Social and economic risks related to discrimination if there was a breach of confidential information such as substance use
- Possible injury from rectal DBS or rectal swab collection

10) Potential Benefits to Subjects*

All participants in this study will receive some form of evidence-based treatment to reduce stimulant use (i.e., MI or CM). However, we are uncertain if these interventions will yield meaningful benefits for engagement along the PrEP care continuum. The proposed research has the potential to advance our understanding of promising intervention approaches to simultaneously target stimulant use and difficulties with engagement along the PrEP care continuum in MSM. This will be one of the first trials to test potentially scalable strategies for optimizing medical

evaluation for PrEP and PrEP uptake in a high priority population of stimulant-using MSM.

11) Vulnerable Populations*

Although stimulant-using MSM are marginalized and underserved, this population is not classified as vulnerable under 45 CFR Part 46. At this time, we do not plan to conduct any study procedures with incarcerated participants.

12) Setting

All study procedures will occur at the University of Miami Miller School of Medicine. We will use a national sampling frame to recruit participants from social networking applications (e.g., Scruff, Grindr). We also plan to recruit participants from South Florida in partnership with local STI and PrEP clinics serving MSM in South Florida that are operated by the Miami Department of Health and AIDS Healthcare Foundation. Dr. Grov is an external collaborator on this project but no data will be collected at his site in New York. He will assist with data collection in Miami as needed and have access to study data.

13) Resources Available

Dr. Carrico has extensive expertise in the designing and conducting clinical research with stimulant-using MSM. He has overseen multiple protocols that collected biospecimens for specimen banking with substance-using populations.

14) Prior Approvals

This study was previously submitted to the IRB for approval as part of a just-in-time (JIT) request. We are modifying this protocol to recruit a national sample and to be conducted entirely online due to difficulties with achieving our enrollment targets in South Florida.

15) Recruitment Methods

The primary mechanism for recruiting participants will be using social networking applications (e.g., Scruff, Grindr). Participants residing in the United States and Puerto Rico will be directed to a secure Redcap survey where the phone screening questions are administered. Participants will be asked to provide their contact information (i.e., name, phone number, and email) if they wish to be contacted by the study team to learn more information.

Community-based recruitment will occur broadly in the community using palm cards and pull-tab flyers that will be distributed at bars and clubs, social media (e.g., Facebook), social networking applications (e.g., Grindr, Scruff), medical clinics that prescribe PrEP, referrals from active participants, and face-to-face recruitment at community events (e.g., Pride). Potentially eligible participants who contact the study team will complete a brief telephone screen or Redcap survey to determine eligibility. Flyers have been approved by the IRB, including recruitment banner ads that will be used on social networking applications (e.g., Scruff, Grindr).

We will also recruit men from clinical registries of HIV-negative MSM that are maintained by the PI and Dr. Safren at the University of Miami as well as Dr. Grov at the City University of New York. We will submit modifications to these protocols prior to contacting potentially eligible participants who may be interested in joining this project.

16) Local Number of Subjects

Across both phases of this project, we estimate that 20 PrEP healthcare team members and 100 stimulant-using MSM will participate.

17) Confidentiality

Consent forms and contact information will be stored electronically using Redcap (a HIPAA compliant document management system administered by the University of Miami IT). Paper forms will be stored in a locked file cabinet. All data will be stored in a password protected file and password protected server. Confidentiality of information regarding participants will be maintained. Although not specifically mentioned in 42 CFR, collection self-report measures of substance use may have important social and legal consequences. Dr. Carrico's team takes extensive precautions to safeguard confidentiality of this information (e.g., certificate of confidentiality, electronic data collection on a firewall protected server).

18) Provisions to Protect the Privacy Interests of Subjects

Study visits will be conducted online from the University of Miami Miller School of Medicine or from the homes of our study team members during COVID-19. We will secure a private office to facilitate privacy and comfort during study assessments and intervention visits. Only the study team will have access to identifying information. Consent forms will be stored electronically using Redcap where possible or signed paper copies will be stored in a locked file cabinet. All data will be stored in a password protected server.

19) Consent Process

All potential participants will be told that their participation is voluntary. Their refusal to participate or withdraw from the study will not have any effect, including

on the clinical services they receive at the University of Miami. All participants will be told the objectives of the study.

We are requesting prior approval to consent in order to conduct the study procedures via Zoom. Participants will be provided with a consent form to read and sign on their computers (where possible). If participants do not have device that allows them to sign electronically, they will indicate consent verbally. Where participants have any further questions or concerns regarding consent, these will be addressed in a private office or home of our study team members.

When questions arise or participants do not appear to understand the nature of the study, staff are trained to review the consent verbally and encourage participants to ask any questions as well as take time to consult friends or family before deciding to participate in the study. Staff are also trained to ask a series of open-ended and closed ended questions to confirm that participants comprehend the inherent risks and benefits of this project.

20) Process to Document Consent in Writing

Potential participants will be scheduled for a baseline Zoom meeting during which they will be informed that their participation is voluntary in the study. If the participant is willing, he will be provided with a brief overview of the study. Participants will be asked to click a button confirming that they consent to participate and enter their name and the date before any questions are administered.

Following the baseline assessment, those who are eligible will be asked to provide contact information. Participants will be notified that they can decline to participate in the study at any time and contact information for the study team will be provided should they wish to have their identifying information destroyed. Participants will complete a second informed consent for Stage 2 of the pilot SMART prior to the 3-month Zoom follow-up assessment.

Research staff are trained to review the consent verbally and encourage participants to ask any questions as well as take time to consult primary care provider, friends, or family before deciding to participate in the study. Staff are also trained to ask a series of open-ended and closed ended questions to confirm that participants fully comprehend the inherent risks and benefits of this project. All potential participants will be told that their participation is voluntary, and they can decline participation at any time during the study. Where participants have any further questions or concerns regarding consent, these will be addressed with the designated study staff member prior to collecting self-report data or biospecimens. Because PrEP healthcare team members are being interviewed only once and regarding their professional role, we are requesting a waiver of signed consent for key informant interviews or focus groups with these providers.

Permission to Take Part in a Human Research Study

Title of research study: Stimulant-Using MSM and PrEP (RCT Stage I)

Investigator: Adam W. Carrico, Ph.D.

The following is a short summary of this study. It will help you decide whether or not to take part. More detailed information is given later in this form.

You are being asked to take part in a research study. Doing so is voluntary. The purpose of this study is to test two interventions to assist HIV-negative men who use stimulants such as methamphetamine or cocaine with taking the first steps to start or re-start pre-exposure prophylaxis (PrEP).

If you are a good fit, you will spend about 3 months in this study**.** Today, you will be asked complete questionnaires and provide a sample of your saliva that you will mail back to us to be tested for HIV. If you are a good fit, you will be invited to participate in the first three months of the study where you will receive one of two interventions.

Taking part in the study involves some risks. Some questions asked in the study may cause you emotional discomfort. The risks of HIV testing are no different than if you were to receive these services in the community and we will provide you with the results when they are available. The interventions may cause emotional discomfort but the study team is available to talk to you about your concerns. Direct benefit cannot be promised but you will receive one of two interventions that have shown to work in research with people who use stimulants. Instead of being in this research study, you may get therapy for stimulant use from community therapists.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are an HIV-negative man who has sex with men, you report recent substance use, and you are not currently taking PrEP.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Participation is voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, please contact Dr. Adam Carrico at 305-243-6947.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). Please contact the University of Miami Human Subject Research Office at (305) 243-3195 if:

- You wish to talk to someone other than the research staff about your rights as a research subject.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to provide input concerning the research process.

Why is this research being done?

The purpose of this study is to test the potential benefits of two interventions to assist HIV-negative men who use stimulants with taking the first steps to start or re-start PrEP.

How long will the research last?

We expect that you will be in this part of the research study for 3 months.

How many people will be studied?

We expect about 70 people will be in this research study.

What happens if I say yes, I want to be in this research?

You will be asked to electronically sign this consent form to participate in this study. The rest of the form gives you more detailed information about this study.

Part 1: Eligibility Screening Interview

To participate in the intervention study, you must first complete an interview today over Zoom to look at whether you are a good fit for the study. If you are a good fit, you will be told by study staff and asked if you are interested in providing a saliva sample to be tested for HIV.

Screening Interview:

- You will be asked some questions by a study staff member over Zoom.
- You will be asked questions about your personal background, mood and the way you have been feeling, drug-using behaviors, and sexual behaviors.
- A part of this interview will ask you to describe your experiences with substance use.
- The interview will last a total of one and a half (1.5) hours.

Contact Information:

We will ask you to provide detailed contact information such as the names of people who could help us find you. If you agree, your contact information will be kept so that we can see if you are interested in future studies about HIV prevention.

If you decide to be give your information for the database, it will be kept indefinitely or until you no longer want to be included. You do not have to say yes to the database, to be in this study.

You will receive a $50 gift card or cash application payment after completing your interview.

Part 2: HIV Testing

HIV testing:

You will be asked to use the package sent from our team to mail in your saliva sample to be tested for HIV. We should be able to provide your results within a week after we receive your saliva sample. If you test positive for HIV, we may provide your preliminary HIV-positive results and your name to a linkage coordinator in your area to help you get confirmatory HIV testing and treatment. The research will not be doing this, but we can help coordinate and call medical centers and/or physicians to help get you an immediate appointment for confirmatory testing in your area.

Testing for HIV is available at other locations near you. Our team will provide referrals for HIV testing in your area if that is helpful.

Non-reactive (HIV-) test results will be shared with you during your randomization visit. If you do not complete your randomization visit or do not respond to the attempts to schedule this visit after 2 months, the results report will be emailed to your email address on file via a secure, encrypted email. This report will not contain any identifying information about you (e.g., name, DOB, address, etc.).

You will receive a $25 gift card or cash application payment after we receive your saliva sample.

Part 3: Intervention Study Activities

If you are a good fit, you will be invited to participate over three months of the study to receive one of two interventions. You will be assigned randomly, like by tossing a coin, to complete a 3-month contingency management intervention or a 2-session motivational interviewing intervention. Each of these interventions is described briefly below.

Contingency Management Intervention (CM)
Participants randomized to CM will complete the 3-month intervention.

- You will receive $50 gift card or cash application paymentfor providing evidence that you have seen a medical provider to be evaluated for PrEP.
- You will receive a $50 gift card or cash application payment for filling your prescription for PrEP medication.

Motivational Interviewing Intervention (MI)
Participants randomized to MI will complete two 60-minute counseling sessions over Zoom that focus on PrEP, substance use, and HIV risk.

- All sessions will occur over Zoom.
- All sessions will be audio recorded.
- All audio recordings are labeled only with your study ID number and kept on a secure server.
- You will receive a $20 gift card or cash application payment for each session completed.

Study Follow-up Interview & Survey (3 months):

- You will be asked some questions by a study staff member over Zoom.

- You will be asked questions about your personal background, mood and the way you have been feeling, drug-using behaviors, and sexual behaviors.
- A part of this interview will ask you to describe your experiences with substance use.
- The interview will last a total of one and a half (1.5) hours.
- You will receive a $50 gift card or cash application payment after completing your interview.
- You will have a 30-day (+1 month) window to complete your follow-up assessment.

What are my responsibilities if I take part in this research?

If you want to stop the study at any time, please notify a staff member. Because you are being asked to be in this part of the study for 3 months, staff will make many attempts to contact you to complete the scheduled visits.

What happens if I do not want to be in this research or say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

Participating in this research study may have the following possible risks:

Psychological Discomfort: Some of the questions in the interviews or discussions with study staff might make you uncomfortable; talking about your drug-using and sexual behaviors may make you feel embarrassed, angry, uneasy, or sad in some way. You are free not to answer any questions or to take part in any discussions at any time.

The PI is a licensed psychologist in Florida (PY9709) and he can assist you in coping with the preliminary HIV test results and can provide with community referrals for psychological help.

Our study team has made every effort possible to carefully manage these risks, but these steps do not guarantee that risks have been eliminated. If you have any questions or need to talk to someone, contact the study team.

What are the costs of taking part in this study?

There will be no costs to you from being in this study, other than possible transportation costs to and from the appointments.

Are there benefits to taking part in the study?

You will receive one of two interventions that have shown to work in research with people who use stimulants. There will be no other direct benefit to you from participating in this study. However, the information that you give may help us learn how to help people manage their substance use better and get PrEP healthcare services.

Will I be paid for taking part in this study?

In return for your time and effort, you will receive $50 as a gift card or cash application payment following the eligibility screening tests that you complete for Part 1 of this study. You will receive $25 as a gift card or cash application payment for completing HIV testing in Part 2 of this study. If you are eligible for Part 3 of this study, the incentive that you receive will vary based on the intervention to

which you are assigned. At the 3-month follow-up Zoom interview, you will receive a $50 as a gift card or cash application payment.

Can I get paid to refer other participants?

If you refer men who are determined to be eligible to participate in this study, you will receive a $20 as a gift card or cash application payment for each eligible referral. You may refer up to three men who are eligible for this study for a total of $60.

What happens to the information collected for the research?

The researchers will keep all study records, including any codes to your data, in a secure location at the University of Miami. Research records will be labeled with a code. A master file that links names and codes will be maintained in a separate and secure location. All electronic files containing identifiable information will be password-protected. Only the members of the research staff will have access to the passwords. At the end of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Your information may be looked at and/or copied for research or regulatory purposes by:

- The sponsor, National Institute on Drug Abuse (NIDA)
- Department of Health and Human Services (DHHS);
- other University of Miami employees for audit and/or monitoring purposes; and
- other organizations collaborating in the research.

A Certificate of Confidentiality (CoC), issued by the NIH, covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research except as described above.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute on Drug Abuse may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research, but this is your choice. The information you share will no longer be protected by the CoC.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Can I be removed from the research without my OK?

Dr. Carrico, principal investigator of the research study or the sponsor can remove you from the research study without your approval. You may be removed from the study if you are unable to follow the procedures or if it is judged to be in your best interest not to participate. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institute on Drug Abuse (NIDA), which includes salary support for the principal investigator (Drs. Carrico and Grov) and the physician on this project (Dr. Doblecki-Lewis). Dr. Susanne Doblecki-Lewis is a compensated consultant and scientific advisory board member for Gilead, the manufacturer of the only approved medication for PrEP.

MAIN CONSENT

Participant's Statement

- *I have read this form and the research study staff contact you has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered.*
- *If I have more questions, I have been told who to call.*
- *I will receive an electronic copy of this **study or other** consent form.*

By selecting below, this means you consent to participate in this research project.

☐ Yes, ***I agree to participate***.

☐ No, ***I choose not to participate***.

Your signature documents your permission to take part in this ***research***:

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

FUTURE STUDIES

We may conduct additional studies related to the study described in this form. If we do conduct these studies, we will contact you in the future to see if you would like to be part of the future study. Your participation in this study does not depend in any way on your participation on any future study.

I agree to be contacted to take part in future studies.

☐ Yes ☐ No

Your signature below documents your permission to have study staff contact you to determine if you are interested in future research.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Permission to Take Part in a Human Research Study

Title of research study: Stimulant-Using MSM and PrEP (RCT Stage II)

Investigator: Adam W. Carrico, Ph.D.

The following is a short summary of this study. It will help you decide whether or not to take part. More detailed information is given later in this form.

You are being asked to continue taking part in a research study. Doing so is voluntary. The purpose of this study is to test two interventions to assist HIV-negative men who use stimulants with taking the first steps to start or re-start pre-exposure prophylaxis (PrEP).

If you choose to take part in this phase of the study, you will spend about 3 additional months in this study**.** You will be asked to complete questionnaires. Similar to your participation during the last three months, you may receive one of two interventions.

Taking part in the study involves some risks. Some questions asked in the study may cause you emotional discomfort. The interventions may cause emotional discomfort but the study team is available to talk to you about your concerns. Direct benefit cannot be promised but you may receive one of two interventions that have shown to work in research with people who use stimulants. Instead of being in this research study, you may get therapy for stimulant use from community therapists.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are an HIV-negative man who has sex with men, you report recent substance use, and you are not currently taking PrEP.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Participation is voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, please contact Dr. Adam Carrico at 305-243-6947.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Please contact the University of Miami Human Subject Research Office at (305) 243-3195 if:

- You wish to talk to someone other than the research staff about your rights as a research subject.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to provide input concerning the research process.

Why is this research being done?

The purpose of this study is to test the potential benefits of two interventions to assist HIV-negative men who use stimulants with taking the first steps to start or re-start PrEP.

How long will the research last?

We expect that you will be in this part of the research study for 3 months.

How many people will be studied?

We expect about 70 people will be in this research study.

What happens if I say yes, I want to be in this research?

Part 1: Intervention Study Activities

Based on your responses to the study interview today, you may be assigned randomly, like by tossing a coin, 1) to continue only answering the survey, or 2) switch to the other intervention (CM+MI versus MI+CM). Each of these interventions is described briefly below.

Contingency Management Intervention (CM)
Participants randomized to CM will complete the 3-month intervention.

- You will receive $50 gift card or cash application payment for providing evidence that you have seen a medical provider to be evaluated for PrEP.
- You will receive $50 gift card or cash application payment for filling your prescription for PrEP medication.

Motivational Interviewing Intervention(MI)

- Half of participants will complete two 60-minute counseling sessions over Zoom that focus on PrEP, substance use, and HIV risk.
- All sessions will occur over Zoom.
- All sessions will be audio recorded.
- All audio recordings are labeled only with your study ID number and kept on a secure server.

<u>You will receive a $20</u> gift card or cash application <u>payment for each session completed.</u>

<u>Study Follow-up Interview (3 months)</u>:

- You will be asked some questions by a study staff member over Zoom.
- You will be asked questions about your personal background, mood and the way you have been feeling, drug-using behaviors, and sexual behaviors.
- A part of this interview will ask you to describe your experiences with substance use.
- The interview will last a total of one and a half (1.5) hours.

You will receive a $50 gift card or cash application payment after completing your interview.

What are my responsibilities if I take part in this research?

If you want to stop the study at any time, please notify a staff member. Because you are being asked to be in this part of the study for 3 months, staff will make many attempts to contact you to complete the scheduled visits.

What happens if I do not want to be in this research or say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

Participating in this research study may have the following possible risks:

Psychological Discomfort: Some of the questions in the interviews or discussions with study staff might make you uncomfortable; talking about your drug-using and sexual behaviors may make you feel embarrassed, angry, uneasy, or sad in some way. You are free not to answer any questions or to take part in any discussions at any time.

Our study team has made every effort possible to carefully manage these risks, but these steps do not guarantee that risks have been eliminated. If you have any questions or need to talk to someone, contact the study team.

What are the costs of taking part in this study?

There will be no costs to you from being in this study, other than possible transportation costs to and from the appointments.

Are there benefits to taking part in the study?

You will receive one of two interventions that have shown to work in research with people who use stimulants. There will be no other direct benefit to you from participating in this study. However, the information that you give may help us learn how to help people manage their substance use better and get PrEP healthcare services.

Will I be paid for taking part in this study?

If you are eligible to receive an intervention**,** the incentive that you receive will vary based on the intervention to which you are assigned. At the 3-month follow-up interview, you will receive a $50 gift card or cash application payment.

Can I get paid to refer other participants?

If you refer men who are determined to be eligible to participate in this study, you will receive a $20 gift card or cash application payment for each eligible referral. You may refer up to three men who are eligible for Part 2 of this study for a total of $60 cash.

What happens to the information collected for the research?

The researchers will keep all study records, including any codes to your data, in a secure location at the University of Miami. Research records will be labeled with a code. A master file that links names and codes will be maintained in a separate and secure location. All electronic files containing identifiable

information will be password-protected. Only the members of the research staff will have access to the passwords. At the end of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Your information may be looked at and/or copied for research or regulatory purposes by:

- The sponsor, National Institute on Drug Abuse (NIDA)
- Department of Health and Human Services (DHHS);
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A Certificate of Confidentiality (CoC), issued by the NIH, covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research except as described above.

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- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Can I be removed from the research without my OK?

Dr. Carrico, principal investigator of the research study or the sponsor can remove you from the research study without your approval. You may be removed from the study if you are unable to follow the procedures or if it is judged to be in your best interest not to participate. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

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Participant's Statement

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered.*
- *If I have more questions, I have been told who to call.*
- *I will receive an electronic copy of this consent form.*

By selecting below, this means you consent to participate in this research project.

☐ Yes, ***I agree to participate.***

☐ No, ***I choose not to participate.***

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	