Study Protocol

Project Title: Adapting a Peer-Delivered Behavioral Activation Intervention to Improve Adherence to MAT among Low-Income, Minority Individuals with OUD

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Contents

Abstract

The opioid use disorder (OUD) crisis has been considered an "epidemic of poor access to care" that disproportionately affects low-income, racial/ethnic minoritized individuals (Mitchell et al., 2012; Stahler et al., 2018; Samples & Mennis, 2018; Saloner et al., 2017). Recent efforts to identify gaps in OUD care using a cascade of care framework (Williams et al., 2017; Williams et al., 2018; Johnson et al., 2018) have highlighted the need to improve retention in medication for opioid use disorder (MOUD), with six month retention often below 50% (Williams et al., 2017; Williams et al., 2018; Johnson et al., 2018; Morgan et al., 2018) and even lower rates among low-income, racial/ethnic minoritized individuals (Stahler et al., 2019; Samples & Mennis, 2018; Manhapra et al., 2018; Weinstein et al., 2017). There is an urgent need to develop and evaluate innovative strategies to address barriers to MOUD retention for low-income, racial/ethnic minoritized individuals, given that retention is highly predictive of future relapse, functioning, quality of life, and mortality (Hser et al., 2007; Timko et al., 2009; Stotts et al., 2009; SAMHSA, 2014).

Peer recovery specialists (PRSs), trained individuals with their own lived experience with substance use disorder (SUD), are a promising strategy to improve MOUD retention for low-income, minoritized individuals with OUD. Utilizing peers to improve MOUD retention offers a flexible approach to address common barriers to MOUD retention, including stigma, challenges navigating services, housing instability, and other structural and psychosocial factors (Jack et al., 2017; Bassuk et al., 2016). Rapid increases in the use of PRSs nationwide demonstrates the appeal of employing them as a potentially sustainable solution to support the behavioral treatment needs in OUD care.

Yet, few evidence-based interventions (EBIs) have been evaluated for PRS delivery to promote MOUD retention. Prior research has been inconclusive regarding psychosocial interventions to support MOUD retention (Timko et al., 2016; Carrol & Weiss, 2017); to date reinforcement-based approaches, such as contingency management, have empirical support for improving MOUD retention, yet also have low adoption in community settings due to organizational and provider barriers, including cost in medically underserved areas (Timko et al., 2016; Carroll, 2015). Prior research suggests the relevance of a reinforcement-based approach to improve MOUD retention, yet the need to identify an approach that is feasible and sustainable to deliver for underserved populations (Timko et al., 2016; Dunn et al., 2013).

Behavioral activation (BA) may be a feasible, scalable, reinforcement-based approach for improving MOUD retention for low-income, minoritized individuals with OUD. BA, originally developed as an efficacious treatment for depression (Lejuez et al., 2011), aims to increase positive reinforcement by promoting engagement in adaptive, valued behaviors. By targeting increases in positive reinforcement, BA has since been found to be effective for improving SUD treatment retention (Magidson, Gorka, MacPherson et al., 2011) and preventing future relapse (Mimiaga et al., 2012; Mimiaga et al., 2019; Daughters et al., 2017) among low-income, minoritized individuals with SUD. Further, BA has improved medication adherence (i.e., for HIV) among low-income, minoritized populations with SUD (Magidson et al., 2014; Magidson et al., 2018; Daughters et al., 2010; Tull et al, 2018) as well as depression, which is a barrier to MOUD retention (Carroll, Nich, Frankforter, et al., 2018). Importantly for implementation, BA also is feasible and cost-effective using lay counselor delivery (Magidson, Lejuez, Kamal, et al., 2015; Ekers et al., 2011; Ekers et al., 2014; Richards, Ekers, McMilllan et al., 2016). Following from this prior research, BA is an ideal EBI to evaluate for improving MOUD retention using a PRS-delivered model.

This study builds upon our team's formative work (Magidson, Gorka, MacPherson, et al., 2011; Magidson et al., 2018; Satinsky, Doran, Felton et al., 2019) to adapt and evaluate BA delivered by PRSs ("Peer Activate") to support MOUD retention for low-income, minoritized individuals initiating MOUD at an outpatient, opioid treatment program in a medically underserved community in Baltimore City. Baltimore is a prime location to test innovative strategies to combat the OUD crisis, as its overdose

fatality rate is among the highest in the US, particularly for low-income, African Americans (Hogan, Rutherford, & Neall, 2017; KFF, 2017; Baltimore City Health Department, 2018). Guided by Aarons' stage model (Aarons, Hurlburt & McCue Horwitz, 2011) and Proctor's model of implementation (Proctor et al., 2011), we propose a mixed methods, hybrid Type 1 effectiveness-implementation study:

Aim: To refine a PRS-delivered Peer Activate approach for delivery at a methadone treatment (MT) program. Specific aims are:

1. To establish feasibility (primary), acceptability, and fidelity of Peer Activate in an open-label trial (n=40), and to pilot assessment procedures, including collecting preliminary MOUD outcomes (retention, abstinence). We hypothesize Peer Activate will be feasible (≥75% of patients agree to participate), acceptable (≥75% of those enrolled complete ≥75% of the 5 core sessions) and delivered by PRSs with fidelity (≥75% of a randomly selected 20% of session delivered as intended).

2. To refine and finalize training and therapy manuals/procedures based on findings.

Changes following COVID-19. On March 13th, 2020, the rapid spread of the global novel coronavirus (COVID-19) pandemic led to new emergency procedures at UMDTC which altered various clinic processes, including the frequency of MOUD distribution. Under non-emergency circumstances, methadone treatment adherence and retention must be observed in the context of daily observed dosing (i.e., daily medication dispensed at the clinic and taken by patients in front of clinic staff); however, the outbreak of the COVID-19 pandemic has given way to extreme and necessary measures of social distancing which aim to limit the transmission of this deadly virus. These widespread precautions have led to dramatic changes to MOUD dosing procedures at many treatment facilities, where supervised dosing has shifted to extended periods of take-home bottles for some patients in order to ensure the safety of the patients, treatment staff, and the wider community. As such, there is an urgent need to support MOUD adherence and retention during the unprecedented new circumstances prompted by the outbreak of COVID-19. We will administer this hybrid (remote and in-person) study in line with UMCP's human subjects research policies, Maryland state regulations, and federal guidelines surrounding safe social practices in response to COVID-19. As such, this protocol outlines distinct procedures for a hybrid delivery of the Peer Activate intervention.

Updates to COVID-19-related changes: In June 2021, UMDTC modified its guidelines regarding MOUD dosing procedures, relaxing social distancing requirements and switching many patients from extended take-home dosing to daily supervised methadone dosing. We will continue to administer this hybrid (remote and in-person) study in line with UMCP's human subjects research policies, UMDTC requirements, Maryland State regulations, and federal guidelines surrounding safe social practices in response to COVID-19.

The University of Maryland College Park (UMCP) is collaborating with the University of Maryland Baltimore (UMB) on this project. After this project received the initial IRB approval, an Authorization Agreement was put into place to cover IRB approval for UMB.

As we will be collecting information about illegal behavior and substance use, the NIH provides us with a Certificate of Confidentiality.

Subject Selection

Recruitment

The University of Maryland Drug Treatment Center (UMDTC) is located at 1001 W. Pratt St., Baltimore, MD 21223. The UMDTC MOUD program receives new admissions to the clinic Monday through Friday (excluding holidays). During the ongoing COVID-19 period, patients continue to visit the treatment center in-person for appointments such as dosing, take-home bottle collections, medical visits, and counseling sessions. While at UMDTC, patients are led to a private, sanitized room to meet with intake coordinators, doctors, and counselors or meet with these providers in sanitized space with enough room to allow for appropriate physical distancing. Throughout this study, patients will have the option to engage with researchers in-person at 1001 and/or to perform study activities by phone or computer at their home or another private location.

Patients who express interest in participating in research provide consent at intake (through UMDTC) for chart review to determine eligibility for research studies taking place at the center. All patients in the program who agree to this use of medical charts for research will be screened for study eligibility. Screening will include review of routinely collected patient information from program intake charts: intake date, age, pregnancy status, and dosing history. Patients who approach researchers directly with interest in the study or who are referred to the study by their counselors or medical providers and express interest can also be screened. Patients who are at least 18 years old, not pregnant (based on routinely performed pregnancy test at treatment intake), have expressed interest in participating in research, and meet at least one of the following eligibility criteria will have the opportunity to learn about the study:

a. have started MOUD treatment in the last 3 months, AND/OR

b. are demonstrating challenges with methadone adherence in the last 3 months, with nonadherence defined as one of the following:

    a. at least one missed methadone dose in the past 3 months as identified through clinic records, patient self-report (which can be indicated using a visual analogue scale rating of methadone adherence from 0-100%, and corroborated by a clinic counselor or provider), or counselor/provider report,

    b. at least one missing take-home bottle at the time of bottle return,

    c. screened negative for methadone in routinely administered clinic urinalysis tests,

    d. transitioned from an extended take-home bottle schedule to daily dosing schedule.

Due to variable access to communication technologies across the patient population at UMDTC (i.e., very limited smart phone or A/V technology access, and limited cell phone minute access), we will offer several ways for patients who have indicated their interest in participating in research to connect with our team as to not exclude individuals based upon lack of access to technology. Options include: 1) Direct communication via telephone, text messaging, or email, whereby researchers can contact eligible patients who have indicated that they are interested in research participation to ask if they are interested in hearing information about a study that is testing a new intervention to help people stay in treatment; 2) A pre-

recorded video introduction to the study during routine visits to UMDTC to outline the basic information regarding study participation and working with a peer; 3) A study flyer provided to eligible individuals at their dosing time which provides space for the individual to list their name and contact details and deposit the completed flyer in a lockbox checked routinely by the study staff; 4) Flagging patients through the medical record system to be informed of research team in-person presence at UMDTC and instructing them to meet researchers at the research location if they would like more information about participation. Direct communication via telephone, texting, or email utilizes contact information provided to UMDTC by the patient. In the case that a patient does not have reliable access to their own phone, contact information may include an emergency/alternative contact other than the patient themselves. The research team may use any contact information provided by the patient, including alternative/emergency contacts. If the research team contacts someone other than the patient, they will follow the specified recruitment script to provide contact information for the patient to follow up or otherwise coordinate direct communication with the patient. Interested individuals will also have the opportunity to write their name and contact details on a research study flyer at dosing and to deposit this flyer in a secure lockbox for the research team to contact them. The research team will screen and flag eligible individuals who should receive this flyer at dosing using the treatment center's HIPAA compliant softwares, Methasoft and EPIC. Inclusion of the flyer helps make sure that patients with unreliable contact details in Methasoft/EPIC or who present for dosing when researchers are not on-site still receive study information and can indicate their interest in further contact (indicating preferred contact details). Prior to and during active recruitment for this study, a researcher will occasionally be posted at the study site in order to provide information about this study to drug treatment center patients. In addition to dedicated space at the study site, the researcher may also be posted at the outdoor research booth near the front of the UMDTC building where flyers may be posted to be accessible to answer questions about the study. The researcher will be wearing a face mask and gloves and will maintain six feet of distance from other individuals at all times. A sign will be posted at the research booth instructing patients to wear a mask at all times and maintain six feet of distance when engaging with the researcher. The researcher will follow all necessary UMDTC COVID-19 precautions for in-person interaction indoors and at the outdoor research booth/tent. COVID-19 precautions outlined in the approved in-person human subjects research plan.

Before engaging in any in-person research activities on-site, all enrolled participants and patients interested in the study will be double screened for COVID-19 risk and will be required to wear the appropriate personal protective equipment (PPE). All visitors at UMDTC (including staff, patients, and visitors) are screened for COVID infection or exposure risk by the UMDTC staff using up-to-date UMMS ambulatory site protocols including temperature check. Visitors are required to wear a facemask and to pass the screener in order to gain access to the UMDTC building. In addition to this routine screening, research staff will screen study participants at all in-person visits by asking about specific symptoms of COVID-19 and possible exposure. Therefore, double screening will take place for all participants who medication in-person at 1001 before commencing any research activities. Any participant who screens positive for COVID-19 will be temporarily excluded from in-person study engagement until a later date decided upon by the research team.

Enrolled participants who experience circumstances that make them unable to regularly attend visits at UMDTC (e.g. transfer to other clinics, extended hospitalizations or time in rehabilitation facilities) may be considered for off-site, in-person encounters. The population served in this study can also experience varying phone and remote technology access, making it challenging to retain contact when they are no

longer visiting the clinic in person, even if they have expressed interest in continuing to seek peer support through this study. In order to meet needs of these research participants and support participant retention in this study, study visits may be conducted in the following ways:
-In-person encounters with participants at outdoor locations near their home, hospital, residential treatment facility, or other local setting (socially distanced with PPE use by both researcher and participant)
- In-person encounters with participants at indoor location that meets the current in-person plan space requirements (while socially distanced with PPE use by both researcher and participant)

Off-site visits will follow all of the same COVID-19 precautions as on-site visits, including screening for COVID-19 symptoms before (at scheduling) and at the time of study visit.

After discussing the study with the research team member by telecommunication (audio or video) or in-person and based on continued interest, the participant will be invited to complete the informed consent process (detailed below in Procedures) and to schedule the baseline assessment. In all cases, patients will be informed that the study provides gift card compensation for participation. The study team member will reiterate that participation in the study will in no way affect any services that they receive at UMDTC or elsewhere. They will also make the participation options, remote or in-person, clear and answer any question about COVID-19 safety concerns. The study team member will also work with the participant to understand their access to technology for study communication. The study team will work with each participant to try to accommodate their individual frequency needs (aiming for a minimum of every other week) for intervention and other study-related contact, with flexibility of timing based on each individual's dosing schedule and needs. The study team will keep a record of participant access to technology (e.g. phone minutes, texting capability, video capability, WiFi, etc.) in a UMCP REDCap database (non-identifiable information only) and in a HIPAA-compliant, UMB-based Microsoft Teams spreadsheet (includes identifiable contact information). As needed, the research team will provide information on/assistance with applying for a phone through public assistance programs and other resources available at UMDTC.

Eligibility Criteria

Participants must (1) be 18 or older and (2) have initiated MOUD at the community-based site within three months prior to study enrollment OR are demonstrating challenges with methadone adherence within the last three months indicated by one of the following:

a. at least one missing take-home bottle at the time of bottle return,

b. screened negative for methadone in routinely administered clinic urinalysis tests,

c. transitioned from an extended take-home bottle schedule to daily dosing schedule due to autonomous medication management challenges, or

d. at least one missed methadone dose in the past 3 months as identified through clinic records or patient- or counselor- report. Patients' self-reported missed doses will be corroborated with patients' counselors and/or clinic providers for consensus that the patient is struggling with methadone adherence. Patients referred to our study by their counselors will be asked if they have missed any methadone doses in the last 3 months

using a visual analogue scale to identify their level of methadone adherence from 0-100%, with below 100% indicating challenges with adherence.

Exclusion criteria will be (1) demonstrating active, unstable or untreated psychiatric symptoms, including mania and/or psychosis; (2) inability to understand the study and give informed consent in English; or (3) being pregnant at enrollment.

Active, Unstable or Untreated Psychiatric Symptoms: The study team is committed to recruiting a sample that reflects the complexity and likely comorbidity of people with moderate to severe OUD in this setting. Therefore, we will only exclude people whose concurrent mental health issues preclude ability to participate with the procedures in this study. Throughout the study, researchers will assess for active, unstable or untreated psychiatric symptoms as the presence of these symptoms during study procedures would interfere with participation. Assessment for exclusionary psychiatric symptoms can include reviewing data in medical chart (per protocol-approved access to medical records), observation during assessments and intervention sessions, and/or current symptoms detected on the MINI modules for psychosis and mania.

Inability to complete informed consent/ study in English. This study/intervention will be implemented in English only. Therefore, the capacity and willingness to give written informed consent in English, to understand the study and inclusion and exclusion criteria in English.

Pregnant Women. Pregnant women receive a different standard of care than non-pregnant patients, including more intensive services. Pregnant women are also more likely to be referred out to another program with specialized services during pregnancy. Therefore, pregnant women are excluded from this study.

Rationale

The UMDTC is a community-based, outpatient substance use treatment center affiliated with the University of Maryland (directed by co-I Dr. Aaron Greenblatt). The program provides MT to over 700 adults living in Baltimore. The program serves many people of low-income, racial/ethnic minoritized patients with OUD who struggle with MT retention. There over 500 active patients in the MT program, the majority of whom (65%) identify as Black or African American, and 83% report having earned less than $15,000 in the past twelve months. Thus, recruiting from this population is appropriate, given the aims of our study.

Enrollment Numbers

For the open-label trial, our goal is to have at least 30 patients initiate the intervention, and at least 24 completers.

Rationale for Enrollment Numbers

We will enroll at least 30 patients because we expect to have an attrition rate of approximately 20% based upon current retention rates in other research at this site and significant attrition between baseline and initiating the intervention. The minimum target size (n=30) is of patients who are receiving the intervention to be large enough to allow us to demonstrate feasibility, implementation, acceptability, and

preliminary efficacy for the intervention and also allow us to make any changes to the protocol if deemed necessary prior to collecting the full sample.

Procedures

This section outlines procedures starting with recruitment and screening, and describes the approach to intervention and assessment.

Recruitment and Screening

As stated above, recruitment will take place at the University of Maryland Drug Treatment Center (UMDTC). All patients in MOUD treatment who consent to use of medical records for research (that is, have already expressed interest in participating in research) will be screened for study eligibility by reviewing routinely collected information such as age, pregnancy status, and dosing record through chart review conducted remotely using UMDTC's medical record databases, Methasoft and EPIC. Patients who approach researchers directly with interest in learning more about the study or who are referred to the study by their counselor/provider and express interest will also be screened. Following initial intake procedures, patients who found to be eligible will have the opportunity to speak further with researchers. Eligible patients must be age 18 or older, not pregnant, interested in research, and either recently starting treatment (within the last three months), or demonstrating challenges with methadone in the last three months as indicated by one of the following:

a. have started MOUD treatment in the last 3 months, AND/OR

b. are demonstrating challenges with methadone adherence in the last 3 months, with nonadherence defined as one of the following:

    a. at least one missing take-home bottle at the time of bottle return,

    b. screened negative for methadone in routinely administered clinic urinalysis tests,

    c. transitioned from an extended take-home bottle schedule to daily dosing schedule due to autonomous medication management challenges, or

    d. at least one missed methadone dose in the past 3 months as identified through clinic records or patient- or counselor- report. Patients' self-reported missed doses will be corroborated with patients' counselors and/or clinic providers in order for consensus that the patient is struggling with methadone adherence. Patients referred to our study by their counselors will be asked if they have missed any methadone doses in the last 3 months using a visual analogue scale to identify their level of methadone adherence from 0-100%, with below 100% indicating challenges with adherence.

Patients will have the opportunity to speak with researchers in several ways. Patients may be contacted by a member of the research study team by phone, text, email, or in-person (during routine visit to the treatment center) and asked if they are interested in hearing about a study that is testing a new intervention to help people stay in treatment. Alternatively, patients may be given the opportunity to view a pre-recorded video of the team introducing the study and inviting the participant to contact the research

team by phone to indicate their interest to participate. This video will be made available on a computer located in a sanitized, private room at the treatment center during patients' routine visits to UMDTC. Interested individuals will also have the opportunity to write their name and contact details on a research study flyer at dosing and to deposit this flyer in a secure lockbox for the research team to contact them. The research team will screen and flag eligible individuals who should receive this flyer at dosing using the treatment center's HIPAA compliant softwares, Methasoft and EPIC. Researchers will use the same flagging system to indicate participants who should be informed of researcher on-site presence for in-person description of the research opportunity, when applicable.

Patients who are currently pregnant based on initial chart review will be considered ineligible for the study. Eligible patients who begin the study and become pregnant while enrolled will remain engaged in the study. Each participant will be engaged in the study for a maximum period of approximately three months; during this period, we do not expect early pregnancy (i.e. in the first trimester) to affect study participation and the intervention presents no additional risk to pregnant women. Standard procedures for pregnancy care at UMDTC will be followed and participants will be referred for subsequent care as needed (which typically begins starting in later pregnancy) following the three months of participation in this study. Patients will also be informed that the study provides gift card compensation, that their participation is voluntary, and that participation has no impact on their treatment at UMDTC or at any other location.

After discussing the study with a research team member, and based on patient continued interest, patients will be invited to provide verbal consent for study participation via phone, video teleconferencing, or in-person. In-person participants will be offered paper copies of the consent form and UMB COVID Risk Statement for their records. Remote participants will be offered a digital copy of the consent form and UMB COVID Risk Statement via text or email or a physical copy provided at the dosing window during a routine visit to the clinic. Eligible participants who successfully complete the informed consent process will be given a unique identification number. This number will be used in place of their name for the remainder of the study.

Interested, eligible, and consented participants will then be scheduled to complete the Baseline assessment by phone (including Google Voice), by the video-conferencing platform (e.g. Zoom), or in-person, depending on participant availability and preference. Phone or video-based assessments may need to be shorter than in-person assessments; thus, we have streamlined and reordered our assessments to prioritize the most important measures first. This will allow us to gather the most important data earliest during the remote assessments in case a participant experiences difficulties with technology or is unable to continue the remote assessment for some other reason (such as a family emergency). Baseline measures can include demographic characteristics and history of substance use treatment (Demographics and Other Information questionnaire, Economic Resource Utilization), measures of MOUD adherence (MOUD Adherence and Retention: Chart Extraction, Ira Wilson's Self-Report Adherence Measure, Barriers to Adherence of Medication for Opioid Use), measures of problems related to substance use (Short Inventory of Problems-Revised and the Tobacco, Alcohol, Prescription medications, and other Substance Tool), substance use frequency and severity (timeline follow back [TLFB]), other mental and physical health characteristics (Patient Health Questionnaire-8, Generalized Anxiety Disorder 2-Item, TCU HIV/AIDS Risk Assessment for HIV, SF-8 Health Survey, PROMIS Pain Intensity – Scale, PROMIS Pain Interference – Short Form 6b, Clinical Characteristics, and Pittsburgh Sleep Quality Index (PSQI)),

readiness for change (SOCRATES-8D), social support (Multidimensional Scale of Perceived Support, Substance Use Stigma Mechanisms Scale, and Methadone-Maintenance Treatment Stigma Mechanisms Scale), Mini-International Neuropsychiatric Interview (MINI) for DSM-5 Mania Module and Psychosis module, and current activities (Behavioral Activation for Depression Scale-Short Form, the Environmental Reward Observation Scale). The measures listed above can be found in the HEAL Measures document. Please also reference the Intervention Flow Diagram for a visual timeline of measure use. Patients who are deemed ineligible following the full baseline assessment due to lower than moderate opioid use or current psychotic or manic symptoms will be provided additional resources and may continue with usual care at the center.

At all stages of recruitment, we will reiterate that participation or non-participation will not influence the patient's treatment, resources, or other relationships with UMDTC.

Intervention and Assessments

Following completion of the baseline assessment, the participant can meet with the PRS for up to 12 BA sessions (5 core content sessions and 7 review sessions) that can be scheduled based on individual treatment plans and particular participant needs based on distinct methadone dosing schedules, with the aim of a minimum session frequency of every other week. These sessions will be held either remotely or in-person at the drug treatment center, depending on participant availability and preference. Based on participant needs and preferences, the PRS may provide a second check-in between BA sessions. The additional check-in will focus on challenges and barriers that participants are experiencing in their methadone treatment. These sessions can be conducted via phone (including telephone, Zoom, or Google Voice), videoconference (Zoom), or in-person at the drug treatment center. Participants can conduct remote sessions from their homes or other preferred private locations. In-person sessions will take place at 1001 (the drug treatment center) and follow all UMDTC COVID-19 precautions for in-person interaction at this site.

The study interventionist will be a trained and supervised PRS who will receive training in protocol and intervention procedures. Supervision session between the PRS and a research team member (overseen by a licensed clinical psychologist on the research team) will take place approximately weekly. The peer hired as the study interventionist will be a Maryland Certified Peer Recovery Specialist (CPRS). CPRS certification is managed by Maryland Department of Health and requires 46 hours of training, 500 work hours in peer recovery support, and 25 hours of documented supervision under a registered peer supervisor.

Throughout the treatment program, the PRS will attempt to work with the patient approximately twice monthly (at a minimum). These sessions will occur in-person or via phone or over Zoom, a cloud-based video-conferencing system hosted by UMCP which allows for participants to call-in via phone or computer. Call administrators are able to record and store audio from a call on a local drive. Phone sessions will be recorded using Zoom or a hand-held recorder, in-person sessions will be recorded using a hand-held recorder, and all recordings will be saved to UMCP Box folder before they are deleted from the recording device. In order to further protect participant privacy, no audio recording will take place through a cloud platform. Sessions will be audio-recorded for supervision and to assess for treatment fidelity. This is noted in the consent process, and participants can refuse audio-recording at any time

(refusal of audio recording does not preclude participants from continuing to be part of the study). The PRS will reiterate before conducting each session that the audio-recording is for research purposes only, will not include any identifiable information, and will be kept confidential. Zoom security functions include a Waiting Room in which individuals can be screened before the call administrator allows them to join the call, and a Lock Meeting function which allows the administrator to block new participants from joining. Depending on different participants' needs, the timing of PRS meetings are expected to vary and will generally last up to half an hour to an approximate maximum of one hour. The PRS role is often flexible, particularly for patients who are poorly engaged in care. We will document how and when sessions take place (method of communication, locations of PRS and participants, time of day) to further our understanding of how the PRS role can optimize participant engagement in treatment.

In order to assess MOUD retention and treatment adherence, we will extract routinely-collected data from patient medical charts (maintained by UMDTC) at each BA session and assessment, with collected data consisting of MOUD intake date, clinic attendance, counselor appointments, dosing, dose volume, any notes on patient dosing, any breathalyzer results, any urinalysis or other drug testing results, and we will ask participants about any changes to their enrollment in treatment programs. This use of medical records is outlined in the consent form. At each BA session, participants will complete two items on the Ira Wilson's Self Report Adherence Measure.

During the approximately weekly or biweekly sessions, the PRS will determine the participants' specific circumstances and needs and will draw upon intervention components accordingly. Intervention components can include: Life Steps to identifying and overcoming day-to-day barriers to treatment, SMART goal identification and work, case management with the treatment facility, and modified Behavioral Activation (BA) to support retention in treatment. The PRS will complete/update the intake goals and follow-up goals with the participant during sessions to keep track of the participants' individual plans moving forward. PRS can also work through BA modules during sessions and review material as needed. After sessions, the PRS will complete a fidelity assessment to indicate which components were addressed. Specifically, the approach can focus on the following six elements: (1) psychoeducation regarding substance use, (2) treatment rationale, (3) identification of treatment barriers and solution planning, (4) identification of valued life areas to guide activity selection, (5) monitoring of current activities, (6) scheduling of new activities, and (7) tracking of actual behaviors and subsequent substance use behaviors.

If a participant misses BA sessions and/or dosing, the PRS will continue to follow up with the participant to assess barriers, concerns, and try to continue treatment.

Members of the research team may attend regularly scheduled UMDTC "teamlett" meetings held between the participant's counselor and attending physician at 1001. The purpose of these meetings is for the treatment team to review the patient's case and address any challenges faced in the treatment program. Research team attendance at these meetings will allow researchers to track the participant's engagement in the program, and may help inform how the intervention can further meet the participant's needs.

As part an effort to coordinate study enrollment with other IRB-affiliated research studies at the study site, the research team will share the enrollment status of participants with other IRB-affiliated researchers at the same study site. Researchers will be able to see participants' involvement in other

studies at this site. This information will be shared via a secure, central UMB-hosted server that is only accessible to other UMB IRB-affiliated researchers at the study site. No other participant information or study participation details will be shared.

With participant permission, all sessions will be audio recorded for supervision purposes and for fidelity assessments. A trained, independent rater will review approximately 20% of audio-recordings from sessions. The independent rater will fill out fidelity measures based on these session recordings for later comparison with the PRS's self-reported fidelity.

At the approximately 6-week and approximately 3-month follow-ups, a trained member of the research team will complete remote or in-person (depending on participant availability and preference) assessments with the participant. We anticipate that phone or video-based assessments may need to be shorter than in-person assessments; thus, we have streamlined and reordered our assessment measures to prioritize the most important measures for this study. This will allow us to gather the most important data earliest during the remote assessments in case a participant experiences difficulties with technology or is unable to continue the remote assessment for some other reason (such as a family emergency). The approximately 6-week midpoint assessment will be a brief assessment of factors that we hypothesize may change during the course of the intervention. Measures that can be used in this assessment include Treatment Program Status, MOUD Adherence and Retention: Chart Extraction, Ira Wilson's Self-Report Adherence Measure, Barriers to Adherence of Medication for Opioid Use, Short Inventory of Problems-Revised, TLFB, Patient Health Questionnaire-9, Substance Use Stigma Mechanisms Scale, Methadone-Maintenance Treatment Stigma Mechanisms Scale, Behavioral Activation for Depression Scale or Behavioral Activation for Depression Scale-Short Form, and the Reinforcement-Punishment Inventory or the Environmental Reward Observation Scale. The posttreatment assessment measures can include the same measures as the baseline assessment with the exception of no Demographic and other Characteristics Questionnaire and no MINI psychosis and mania modules. The posttreatment assessment can also include the Treatment Program Status form and the JHU Feasibility and Acceptability measure. The JHU Feasibility and Acceptability measure assesses for the participant's satisfaction with working with the PRS and important barriers and facilitators to implementation of the intervention.

After completing the posttreatment assessment (approximately 3 months after baseline), participants will be invited to complete a qualitative exit interview which will ask them about their experience in the treatment. Exit interview can take place by phone, video, or in-person. Participants who have dropped out of the program early will also be invited to complete the midpoint assessment, posttreatment assessment, and exit interview over the remaining period of the planned study timeframe (an intent-to-treat approach) or at their earliest convenience. The exit interview will take place immediately following the posttreatment assessment or may be scheduled within approximately one week. Because this interview will ask about the participants' experiences with the PRS, the interview will be conducted by a trained member of the study staff and the participants' responses will not be shared with the PRS. The participant will be asked for their consent for the interview to be recorded. They will be assured that audio recording will be used for research purposes only. The recording will be uploaded to UMCP's Box folder immediately following the session, and the audio file will be deleted from the recording device.

As stated above, posttreatment assessment will take place at approximately three months after baseline, at which point participants who have not yet completed 12 intervention sessions may choose to continue meeting with the interventionist approximately weekly until they reach a maximum of 12 sessions or until they choose to discontinue intervention (whichever occurs first). Those participants will be offered another, optional posttreatment assessment and exit interview, also compensated with $25 and $15 gift cards (respectively).

It will take approximately 30-60 minutes to complete the baseline assessment, approximately 15-30 minutes to complete the midpoint assessment, approximately 30-60 minutes to complete the posttreatment assessment, and approximately 30 minutes to complete the posttreatment exit interview. The participant will receive $25 (gift certificate) for completing the baseline, $15 for completing the abbreviated midpoint assessment, a $25 gift certificate for completing the posttreatment assessment, and $15 for completing the exit interview. Compensation for the baseline and posttreatment assessments may be broken up into more than one day ($10 gift card for completing the first day of the assessment and $15 gift card for completing the remainder of the assessment) if the assessment is paused and resumed another day for any reason. Participants may receive physical gift cards or e-gift cards via email, text, mail, or may pick up their gift cards through a no-contact method at UMDTC. Researchers will coordinate with UMD and UMDTC to determine an acceptable method of remote payment delivery to participants without direct social contact between researcher team and participants.

We recognize that meeting with participants remotely or in person may both present new challenges to participation, including cost associated with using their own device for session contact or cost of attending sessions when not scheduled for dosing. We also understand that participants may also face additional transportation costs when presenting in-person to the drug treatment center during COVID-19. As such, participants will receive compensation in the form of gift cards for each session attended to cover transportation and/or telecommunication costs. Gift cards of $5 per session will be provided to participants after each session attended for the duration of the study. Total gift card compensation for intervention session attendance (above the compensation for assessment participation) will have a maximum of $60, reflecting attendance of 12 maximum sessions.

During this period when telecommunications are heavily relied upon due to COVID, it is increasingly important to ensure that patient contact details are up-to-date. In order to promote uninterrupted communications between researchers and participants and improve retention and tracking of a hard-to-retain sample, we will provide incentives for participants to confirm their contact details. Participants will receive $5 gift cards for each week that they confirm their up-to-date contact details. These gift cards will be provided after each contact verification, with a total possible amount of $120 if the participant contacts the research team weekly for up to 24 weeks of the study.

For any remote call with the participant, the research team will document the participant ID number, researcher name, location of research team member, location of participant, means used (telephone or computer), start and end time, quality of call (excellent, minor issues, significant impediment), and any barriers to effective communication in a database. For any in-person session (assessment or intervention session), researchers will follow procedures outlined in the IRB-approved in-person human subjects protocol.

Risks

During the aftermath of the COVID-19 pandemic, the health and safety of participants, researchers, and UMDTC staff is a primary focus. The study team will work with participants to determine preference for in-person or remote participation in assessment and intervention sessions. Participants will have the option of either in-person or remote engagement throughout the study. The study team will also ensure that remote interviews are conducted within the participant's existing daily routine, ensuring participants are not exposed to settings or situations that will put them at any additional risk for viral exposure. Participants will complete study sessions by phone or video conferencing at their home, preferred private location, or in a private room at UMDTC during routine visits to the treatment clinic for other appointments (intake, dosing, bottle pick-up, medical visit, telehealth visit). In-person study sessions will take place either in a private space (tent) outdoors or in a room at UMDTC. Any necessary changes to this protocol will be made based on UMCP policy and State/Federal regulations in response the status of the COVID-19 pandemic.

The risk from research interviews is minimal and relatively uncommon. During assessments, participants may be uncomfortable discussing their drug use, depression, and other mental health symptoms. Participants may become frustrated and tense when they encounter difficulty when completing these measures. Careful planning and observation of the participant's response to these sessions will allow the testing to be completed with a minimum of discomfort. The research team will be trained by Dr. Magidson to be vigilant and sensitive to these signs of participant distress using role plays, didactics, and ongoing supervision and training in order to minimize any potential discomfort at ensure staff competence to detect and address participant distress. Participants will take breaks when necessary to help alleviate any discomfort. Participants will be reminded that they can refuse to answer any questions that make them uncomfortable and may take breaks whenever they are needed.

Behavioral Activation (BA) is a minimal risk intervention; however, the study population, adults with OUD, is a group with potential to report symptoms of depression or anxiety. BA sessions may cause some temporary anxiety or distress due to discussing drug use and attempts to maintain abstinence. Through Maryland Peer Recovery Specialist Certification, the PRS interventionist will have received training to recognize signs of distress. We will take specific precautionary steps to protect against related risks to participant wellbeing. Researchers will contact one of the licensed psychologists on the team (Drs. Magidson, Bennett, or Seitz-Brown) if a participant is in distress or reports current suicidality during interviews at any of the study assessment time-points or BA sessions (in-person or remote). If a research staff member, in consultation with the on-call psychologist, determines that a participant is at active and imminent risk for suicide (determined using the Suicide Risk Assessment form), we will follow the preferred safety procedures at the treatment center including contacting a UMDTC professionals (e.g., social workers, nurses, doctors) while the participant waits with the researcher (in person) or the participant remains on the phone with the researcher (remote). In the unlikely event that the research team is concerned about the participant's immediate safety while the participant is not at 1001, emergency services will be contacted and UMDTC staff will be notified. The researcher will work to stay in direct communication with the participant until emergency services have arrived at their location. The study PI will be immediately notified of any such occurrence once the participant is safe.

Special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, and institutionalized individuals will not be enrolled in this study. All interventionists will be watchful

regarding the participant's status, and any concerns will be discussed with the Principal Investigators (PIs) and MOUD team as needed. It will be made clear to participants during informed consent that they are free to terminate participation in the project at any time without any penalty.

There is a risk of breach of confidentiality if the online REDCap system at the University of Maryland College Park or the HIPAA compliant PHI software from the University of Maryland Baltimore is broken into. We will take the necessary precautions to minimize these risks to the best of our ability. All data will be coded with an ID number that is unique. All data including information from chart reviews, therapist reports and laboratory results will be labeled by ID only. Only the study team will have access to the link between the ID and participant's name. Data containing names and personal information will never be included in published materials. Electronic data files with identifiable information will be maintained separately from other data files and will only be used for administrative purposes (e.g., preparing aggregate reports to share with the study team). Participant identifiers and related PHI will be stored on secure servers, in a password protected file, accessible only by study staff and via a password protected computer. All personnel will receive certification in human subjects' protection prior to beginning work on this project.

There is a possible risk to confidentiality if telecommunication services (telephone, Google Voice or Zoom) are breached. In order to minimize this risk, the phone number provided to participants will be a secure, study-only UMD line with a passcode protected voicemail system that is only accessible by the study team. Participants' voice mails will be deleted once their contact details are updated on a secure, HIPAA compliant UMB drive (Sharepoint or Microsoft Teams). When using Zoom, security features will be in place to ensure that only the intended participant are allowed to join the call. All recordings of Zoom calls will be recorded to a local drive, uploaded into a secure UMCP Box folder, and deleted from the local drive upon upload. Prior to recording sessions, researchers and participants will discuss telecommunication guidelines to agree on appropriate behaviors and privacy expectations (e.g. remaining in one place during the session, ensuring both researcher and participant are in private spaces, etc.).

During trial assessments or BA sessions, it is possible that information may be disclosed about childhood abuse and neglect experiences and/or alleged perpetrators of abuse. We are aware of our obligation to report, and will follow the University System of Maryland's Policy on the Reporting of Suspected Child Abuse and Neglect and the State of Maryland's mandatory child maltreatment reporting laws to the extent that reporting does not violate any applicable federal rules or policies. For this study, we state explicitly our responsibility to report in the body of the consent form.

There is a slight risk of potential for coercion (compensation). Compensation is linked to completion of research assessments as well as attendance of intervention sessions. The small, $5 compensation for intervention session attendance is intended to offset any potential cost incurred as a result of participants using their own devices for remote communication. Participants will be reimbursed $25 for completing the longer assessments. Open-label trial participants will receive $25 for completing each major assessment, $15 for abbreviated assessments, and $15 for exit interviews for a total possible amount of $80 (baseline, midpoint, posttreatment assessments, and exit interview). As described above, some participants may also be offered another posttreatment and exit interview with an additional possible $40. We will support telecommunication or transportation costs with $5 gift card compensations per BA

session so that utilities or transportation do not present any additional cost burdens to participants, with up to a maximum of $60 for 12 sessions attended. We will provide participants with incentives for updating contact information with $5 gift cards for each week that participants contact the research team to verify contact details, with up to a maximum of $120 provided for up to 24 possible weekly contact verifications. The maximum compensation for this study accumulates to $260 with all sessions, assessments, and contact verifications completed. This compensation is modest and reasonable for the tasks being requested and are consistent with other clinical intervention research trials.

Other risks: One risk in this study related to SUD and its treatment is the stress of and symptoms associated with withdrawal; these will be monitored and treated by the MOUD prescriber and any worsening of these identified by the study team or study interventionists will be reported to the MOUD prescriber (clinical staff at UMDTC).

Throughout the study, the PIs and members of the research team will ensure strict adherence to study procedures according to the IRB-approved protocol. Should there be any protocol deviations or unanticipated problems, a PI will notify the UMCP IRB.

Because study sessions may be conducted virtually with participants and researchers at separate locations, the research team will be trained to exhibit hypervigilance when monitoring verbal, audible, and visual signs of participant distress. Researchers will discuss these signs in trainings and during weekly meeting discussions. The study interventionist will be a trained and supervised PRS who will receive training in procedures for responding to symptoms and in safety protocols designed as part of this study. Close supervision will be provided by the PI and co-Is who are licensed psychologists (Magidson, Bennett, and Seitz-Brown) as well as UMDTC director (Greenblatt) who is a co-I. The PRS will be watchful regarding the participant's status, and any concerns will be discussed with the Principal Investigator (PI) and treatment center as needed. It will be made clear to participants during informed consent that they are free to terminate participation in the project at any time without any penalty.

Adverse Events (AEs) are any untoward or unfavorable occurrence in a study participant, including any abnormal signs, symptoms, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research. Serious Adverse Events (SAEs) include any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, or is another condition which investigators judge to represent significant hazards. Unanticipated Problems (UPs) are defined as any incident, experience, or outcome that is unexpected (in nature, severity, or frequency), related or possible related to participation in the research, and suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

For reporting of AEs and SAEs, the interventionist or other member of the research team will immediately notify a principal investigator. The investigator (Dr. Magidson or Dr. Bennett) will determine how to classify the event. AEs or SAEs will be classified according to severity, expectedness, and potential relatedness to the study intervention. Severity classifications will be: mild, moderate, or

severe. Classification will be informed by the severity of the event and the degree of inconvenience or interruption of the participant's daily activities. Expectedness classifications will be: unexpected or expected. Unexpected classification will occur when the nature or severity of the event is not consistent with the information about the individual, the population, or the intervention. Relatedness classifications will be: definitely related, probably related, possibly related, or not related. Classification will be informed by temporal sequence and known/expected response patterns.

After determining the severity of the event and whether study-related, this information will be communicated to the rest of the UMCP research team. The UMCP team, under Dr. Magidson's supervision, will complete UMCP IRB's Problem Event Form and submit to the IRB. Unanticipated SAEs that are definitely or possible related to the study will be reported to the IRB within two business days once reported to the PI. The expedited Problem Event report will be followed by a detailed, written report as soon as possible. All other AEs will be collected on an AE form. AEs will be communicated to the PIs during weekly study meetings and a summary will be reported to the IRB with annual review. UPs that impact risks to study participants or others will be reported to the IRB within two business days. Deaths will be reported by study staff to the PIs (Dr. Magidson and Dr. Bennett) immediately, and undergo expedited reporting to the IRB, within one business day of being reported to the PI.

Benefits

There are no direct, guaranteed benefits to the participants. However, it is possible that receipt of BA will result in improved MOUD outcomes and reduce drug use for participants.

From a broader perspective, this study may significantly add to the field by increasing our understanding of ways to integrate evidence-based behavioral interventions to support MOUD adherence through PRS delivery. Supporting MOUD outcomes could help to promote greater recovery in communities hit hard by the opioid crisis, particularly in low-income, underserved areas, such as our study site in Baltimore.

Confidentiality

For this study, we will ensure the separation of de-identified participant data from protected health information (PHI) by storing data in separate locations. De-identified data will be stored using secure, password-protected software hosted on UMCP servers (e.g. REDCap and Box). At UMCP, all participant information will be referenced using participant identification numbers. De-identified participant responses to study measures will be collected and stored using REDCap, a software toolset and workflow methodology for electronic collection and management of data. De-identified audio recordings and transcripts will be stored on secure, password-protected UMCP Box folders. All identifiable PHI will be stored on Sharepoint and/or Microsoft Teams, both secure, HIPAA compliant drives at UMB. For participant record keeping and chart review purposes, all PHI (including date of birth) will be linked to participant identification numbers on Sharepoint and/or Microsoft Teams. Only the investigators/authorized staff will have access to the REDCap database, the Box folder, and the Sharepoint and/or Microsoft Teams drives.

At initial screening through chart extraction, we will not collect any data for individuals who are deemed ineligible after MOUD program initiation (by MOUD program staff). We will only keep a record of number of screenings completed and reasons for ineligibility.

We will need to collect names and demographic information for participants who complete consent. Once collected, data will be de-identified. The file containing the information that links participant names to their IDs will again be stored in password-protected files on the HIPAA compliant, secure UMB drives. Only investigators will have access to this file. The key linking identifiable information to the participant ID will be destroyed five years after publication of study results.

Audio-recordings will be uploaded to UMCP's Box folder immediately following the session, and the audio file will be deleted from the recording device. These computer audio files will be secured by Box dual authentication and only accessible by authorized study personnel. The purpose of the audio-recordings will be explained to all participants and we will obtain both informed consent and authorization for recording. Participant confidentiality will be respected.

Once data are collected, all data will be de-identified, i.e. names will be removed and participants will be assigned ID numbers.

As part of the informed consent process, participants will be advised that they may decline to answer any questions. This will provide participants with the assurance of confidentiality around sensitive personal information relating to substance use and mental health. All personnel working on the project will be educated about the importance of respecting participants' rights to confidentiality. Investigators will all complete and maintain ethical and CITI training. All study personnel will be appropriately trained in the ethical conduct of human subjects' research.

Prior to recording sessions, researchers and participants will discuss telecommunication guidelines to agree on appropriate behaviors and privacy expectations (e.g. remaining in one place during the session, ensuring both researcher and participant are in private spaces, determining a plan for lost contact, etc.).

Audio-recordings for participant exit interviews be transcribed by trained members of the UMCP research team (IRB-approved staff member or student with up-to-date CITI training) or a secure transcription service. The study team may use one of the following transcription services to assist in transcription: Otter.ai, which uses artificial intelligence technology and syncs data over an encrypted connection and stores it in a secure data center that has both physical and electronic security. When the user deletes the recording, there will be no record retained by AISense; Home Row, Inc., which offers military-grade 128-bit Secure Socket Layer (SSL) encryption security in transit and 256-bit AES at rest. Their typists are carefully vetted industry veterans who work under strict non-disclosure agreements, and all audio files are promptly and permanently deleted from servers as each project is completed. Audio files are de-identified, saved only using participant ID numbers. Any inadvertent disclosure of personally identifiable information will be redacted upon transcription. A trained member of the study team will use the service for assistance but still check and correct any errors in the transcriptions from the service.

Study files will be maintained until five years after the publication of study results in line with the guidelines of the American Psychological Association.

Due to Maryland law, we will disclose to the appropriate individuals and/or authorities any information

that comes to our attention concerning child abuse or neglect, or thoughts of harm to self or others, or if a court of law ensures, a subpoena for the research records.

Consent Process

This protocol will utilize a verbal consent process and meets criteria for a waiver of written consent as follows:

(1) The research involves no more than minimal risk to the subjects.

IRB determination of risk for initial protocol application is MINIMAL and protocol updates present no additional risk to participants.

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Participants will receive the same information about their rights and autonomy to participate or not participate in research without any effect on their treatment or any other opportunities.

(3) The research could not practicably be carried out without the waiver or alteration.

Due to COVID-19 precautions, continuation of a hybrid (in-person/remove) protocol, and the time-sensitive nature of the research question, the altered consent process remains necessary to protect the health and safety of both participants and study staff. Because we will continue to offer participants with the option to conduct study activities remotely, we will administer verbal consent consistently across all remote and in-person participants. In-person participants will be offered paper copies of the consent form for their records. Remote participants will be offered a digital copy of the consent form via text or email or a physical copy provided during a routine visit to the clinic.

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

We are requesting a verbal consent process. This process does not involve additional information given to participants after participation.

The consent process will take place after a participant is deemed potentially eligible based on initial screening questions and expressed interest in participation and before a potentially eligible participant proceeds with the baseline assessment. Participants will be reminded that they can stop participating in the study at any time, and that all aspects of this study are voluntary.

A trained research staff member will conduct the informed consent. Consent will be taken by reading consent forms to the participants over the phone, Google Voice, virtual conferencing platform (Zoom), or in-person. The researcher will read the consent form and the UMB COVID Risk Statement to the participant “word for word” or paraphrase – whichever makes the participant most comfortable. Prior to providing verbal consent, participants will be given the chance to ask questions, and the researcher or trained designee will answer all the questions, making sure that the participants are satisfied and comprehend study procedures. Participants will also be informed about the voluntary nature of the study, and their right to withdraw at any point. If the participant refuses to consent, they will be considered a

refusal and therefore ineligible for the study. The researcher or trained designee must witness verbal consent by the participant during the phone, web-based call, or in person.

Before the participant can provide verbal consent, the participant: 1) should verbalize understanding; 2) should be given the opportunity to ask questions; 3) should be given time to hear the consent; 4) should report all questions were answered to their satisfaction; and 5) must correctly answer the evaluation to provide consent document. When completing the evaluation to give consent form, the researcher or trained designee will ask questions 1 through 3 to ensure that the participant understands the risks, understands what will be expected of him/her, and understands that they may drop out at any point during the study.

After verbal consent is provided for both the study consent form and UMB COVID Risk Statement, the researcher will document participant ID number, researcher initials, verbal consent date and time, location of research team member, location of participant, means used (telephone, computer audio at UMDTC, or in-person), start and end time, quality of call (if remote), alternative form of communication established (if remote), and any barriers to effective communication in a database. This information will be stored in a secure, HIPAA compliant UMB drive (Sharepoint or Microsoft Teams).

All study personnel will be appropriately trained in the ethical conduct of human subjects research and will be required to recertify annually.

Conflict of Interest

None

HIPAA Compliance

All protected health information (PHI) will be stored on UMB's HIPAA compliant data storage server or as paper records in double-locked space at UMCP to which only authorized research personnel have access. Confidentiality is assured as participants will be identified on all study materials by only a participant number and date of visit. By recording the electronic study data in this manner the information is considered 'de-identified', and therefore, compliant with the Standards of Privacy of Individually Identifiable Health Information ("Privacy Rule") of the Health Insurance Portability Act of 1996 ("HIPAA").