FOREward Together: Training Peer Recovery Coaches to Promote Retention and Adherence to MOUD

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Approved Protocol

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STUDY TITLE: Training Peer Recovery Coaches to Promote Retention and Adherence to Medications for Opioid Use Disorder among Low-Income Adults

1. STUDY AIM, BACKGROUND, AND DESIGN ABSTRACT

Low-income and racial/ethnic minorities suffer disproportionately from substance use disorders, evidencing consistently lower rates of critical treatment outcomes, including treatment engagement and retention[1]. While these individuals exhibited a need for evidence-based care prior to the pandemic[2], low-income, racial/ethnic minority populations have been disproportionately affected by COVID-19[3], as have persons with SUDs[4].

Peer Recovery Coaches (PRC) are individuals with lived-experiences with substance use who have been certified by the state to assist in treatment recovery[5]. Because of similarities between PRCs and substance use clients, PRCs can overcome many of the barriers that clients face to engaging and staying in SUD treatment, such as stigma[6]. The goal of the current project is to conduct an open-label pilot trial to examine the feasibility, acceptability and accessibility of a PRC-led intervention to support retention in SUD care.

This project proposes to develop a novel and sustainable model for improving retention in SUD treatment by training PRCs to deliver an evidence-based intervention (EBI), Behavioral Activation (BA). BA seeks to increase the positive reinforcement patients experience from their natural environment by promoting prosocial and valued experiences. BA has been found to improve substance use treatment retention and adherence, as well as medication adherence in low-income individuals with HIV/AIDS. To that end, we propose the following goal: to evaluate the preliminary feasibility, acceptability, and effectiveness of the PRC- delivered BA approach. We will conduct an open-label clinical trial (*n*=40) of the adapted PRC-delivered BA intervention and training protocol in a representative agency in Detroit, MI serving a low-income, predominantly African-American population. Findings from this phase of the project will be used to re-adapt the manual and training procedures.

2. SUBJECT POPULATION AND ELIGIBILITY

The Detroit Recovery Project (DRP) is located in Detroit, Michigan. The DRP offers a variety of services to their clientele, including, though not limited to, case management, medication for opioid use disorder (MOUD), and peer recovery support. All CDC COVID-19 guidelines are practiced at the DRP. Throughout this study, patients will have the option to engage with researchers in-person at DRP and/or to perform study activities by phone or computer at their home or another private location.

All DRP visitors who are at least 18 years old, and meet criteria for a SUD will have the opportunity to learn about this study from DRP staff, and if interested, will be referred to research staff to learn more about and potentially enroll in the study. Due to variable access to communication technologies across the patient population at DRP (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 research staff 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) Direct in-person communication; 3) A study flyer provided to eligible individuals by DRP staff 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. Direct communication via telephone, texting, or email utilizes contact information provided to DRP 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 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 and to deposit this flyer in a secure lockbox for the research team to contact them or give this flyer to DRP staff.

Before engaging in any in-person research activities on-site, all enrolled participants and patients interested in the study will be screened for COVID-19 risk and will be required to wear the appropriate personal protective equipment (PPE). All visitors at DRP (including staff, patients, and visitors) are screened for COVID infection or exposure risk by the DRP staff using up-to-date protocols including temperature check. Visitors are required to wear a facemask and to pass the screener in order to gain access to the DRP building. Therefore, screening will take place for all participants. Any participant who screens positive will be excluded from in-person study engagement and will be engaged virtually.

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 ClinCard compensation for participation (see Recruitment Script). The study team member will reiterate that participation in the study will in no way affect any services that they receive at DRP or elsewhere and will emphasize that they may participate through tele-sessions if this would work best for them or due to 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 treatment 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 HFHS REDCap database (non-identifiable information only) .As needed, the research team will provide information on/assistance with applying for a phone through public assistance programs and other resources available at DRP.

a. Eligibility Criteria:

Participants must (1) meet criteria for SUD; and (2) be over the age of 18.

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

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 SUD 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 monitor for active, unstable or untreated psychiatric symptoms as the presence of these symptoms during study procedures would interfere with participation. Monitoring 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.

b. Rationale: The DRP is a community-based, outpatient substance use resource center. The program provides SUD treatment services to adults living in the Detroit metropolitan area. The program serves many people of low-income, racial/ethnic minority patients with SUD who struggle with treatment retention. Thus, recruiting from this population is appropriate, given the aims of our study.

c. Enrollment Numbers: For the open-label trial, we will enroll a maximum of 40 patients.

d. Rationale for Enrollment Numbers: We will enroll up to 40 patients because we expect to have a retention rate of 80% based upon current retention rates in other research at this site. The minimum target size (n=32) is 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.

3. STUDY PROCEDURES

Recruitment and Screening:
As stated above, recruitment will take place at the Detroit Recovery Project (DRP). All patients with SUD will be given the opportunity to learn more about this study from DRP staff, who will refer patients to research staff if interested. Patients will 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. Interested individuals will also have the opportunity to write their name and contact details on a research study flyer and to deposit this flyer in a secure lockbox for the research team to contact them.

Patients will be informed that the study provides ClinCard compensation, that their participation is voluntary, and that participation has no impact on their treatment at DRP or at any other location.

All DRP patients who present with SUD are referred at intake; for new patients, a small battery of assessments will be integrated into the intake in order to assess eligibility. The baseline will then be finished by a researcher if the potential participant is eligible, interested and consents to participation. After discussing the study with a research team member, and based on patient continued interest, participants will be offered paper copies of the consent form for their records.. 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. Baseline measures can include demographic characteristics and history of substance use treatment, measures of treatment adherence, measures of problems related to substance use, substance use frequency and severity, other mental and physical health characteristics, readiness for change, quality of life, social support and current activities. The measures to assess the topics listed above can be found in the 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 (see Resource List document) 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 DRP.

Intervention and Assessments:
Following completion of the baseline assessment, the participant can meet with the PRC approximately 8 BA sessions that can be scheduled based on individual treatment plans and particular participant needs, with the aim of a minimum session frequency of every other week. Following treatment completion, participants will be able to schedule up to 4 booster sessions to provide further assistance with addressing barriers to treatment. 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 PRC 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 SU treatment. These sessions can be conducted via phone (including telephone, Zoomvideoconference (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 DRP or other mutually convenient locations and follow all necessary COVID-19 precautions outlined in the approved in-person human subjects research proposal. Participants may also choose to participate in these virtual sessions at DRP during routine visits to the treatment center with the peer at a separate location. These procedures will follow the current telehealth practices and protocols being used at DRP.

The study interventionist will be a trained and supervised PRC who will receive training in protocol and intervention procedures. Supervision sessions between the PRC and DRP clinical supervision staff will take place approximately weekly, with inclusion of key personnel as needed (I.e. Drs. Felton, Magidson and/or Seitz-Brown). The supervisor will utilize recordings of intervention sessions while supervising the PRS. The peer hired as the study interventionist will be a Michigan Certified Peer Recovery Specialist (CPRS). CPRS certification is managed by Michigan Department of Health and requires 56 hours of training.

Throughout the treatment program, the PRC will attempt to work with the patient weekly. These sessions will occur in-person or via phone or over Zoom, a cloud-based video-conferencing system 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 UMB Box folder before they are deleted from the recording device. In order to further protect participant privacy, no audio recording will be saved to 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 PRC 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 PRC meetings are expected to vary and will generally last up to half an hour to an approximate maximum of one hour. The PRC 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 PRC and participants, time of day) to further our understanding of how the PRC role can optimize participant engagement in treatment.

In order to assess SUD retention and treatment adherence, research staff will extract routinely-collected data from patient medical charts (maintained by DRP) at each BA session and assessment, with collected data consisting of intake date, clinic attendance, counselor appointments, engagement in psychosocial services, any breathalyzer results, any urinalysis or other drug testing results, and, when applicable, MOUD dosing, dose volume and any notes on patient dosing. We will ask participants about any changes to their enrollment in

treatment programs (see Treatment Program Status, MOUD Adherence and Retention: Chart Extraction in Measures document). 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 PRC 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 PRC 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. The PRC can also work through BA modules during sessions and review material as needed. After sessions, the PRC will complete a fidelity assessment to indicate which components were addressed (see the Fidelity measure guide in the Measures document). 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, the PRC will continue to follow up with the participant to assess barriers, concerns, and try to continue treatment.

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. This rater may be a research team member who is located at the University of Maryland, College Park. The independent rater will fill out fidelity measures based on these session recordings for later comparison with the PRC's self-reported fidelity (see Fidelity measure in Measures document).

At the approximately mid intervention and post-intervention, a trained member of the research team will complete remote or in-person (depending on participant availability, COVID-19 protocols, and participant 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 difficulty 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 are listed in the Intervention Flow document. The post-treatment assessment measures can include the same measures as the baseline assessment with the exception of no Demographic and other Characteristics Questionnaire. The post-treatment assessment can also include the Treatment Program Status form, Working Alliance Inventory Short Revision and the JHU Feasibility and Acceptability measure, to assess the participant's satisfaction with working with the PRC and important barriers and facilitators to implementation of the intervention.

After completing the posttreatment assessment, participants will be invited to complete a qualitative exit interview which will ask them about their experience in the treatment (see Exit Interview Guide). 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 PRC, the interview will be conducted by a trained member of the study staff and the participants' responses will not be shared with the PRC. 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 UMB's Box folder immediately following the session, and the audio file will be deleted from the recording device.

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. All compensation for study related activities will be in the form of a reloadable ClinCard. The participant will receive $10 (ClinCard) for completing the baseline, $15 for completing the midpoint assessment, a $25 ClinCard for completing the posttreatment assessment, and $25 for completing the exit interview. Total compensation for baseline assessment, midpoint assessment, posttreatment assessment, and exit interview will be up to $75.

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 other services at DRP. 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 ClinCards for each session attended to cover transportation and/or telecommunication costs. $10-25 per session will be provided to participants after each session attended for the duration of the study. We have chosen to incrementally increase compensation as sessions persist in order to encourage long-term retention. Participants will receive $10 per session for BA 1-2, $15 per session for BA 3-4, $20 per session for BA 5-7, and $25 for BA 8. Total compensation for intervention session attendance (above the compensation for assessment participation) will have a maximum of $135, reflecting attendance of the 8 sessions.

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 RedCap. For any in-person session (assessment or intervention session), researchers will follow procedures outlined in the IRB-approved in-person human subjects protocol.

Data analysis:

Quantitative data will involve pre- to-post t-tests and will utilize multiple imputation to handle missing data if deemed appropriate and necessary.

Qualitative data will be analyzed using thematic analysis, and the coding team will iteratively develop a codebook outlining themes, sub-themes, and definitions in the transcripts. The codebook will be modified as new concepts arise.

4. ANTICIPATED RISKS

During the COVID-19 pandemic, the health and safety of participants, researchers, and DRP 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. If participants elect to meet remotely with the peer, they will complete remote study sessions by phone or video conferencing at their home, or other preferred private location.

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.. The research team will be trained by Dr. Felton to be vigilante 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 problematic substance use/SUD, 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. ThroughMichigan Peer Recovery Specialist Certification, the PRC 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. Felton, Magidson, 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, suspects 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 DRP staff 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 DRP, emergency services will be contacted and DRP 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, 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 treatment 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 Henry Ford Health Systems, or Box through the University of Maryland, College Park. 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, or Zoom) are breached. In order to minimize this risk, the phone number provided to participants will be a secure, study-only issued phone. Only study personnel will have access to the phone. Participants' voice mails will be deleted once their contact details are updated on a secure, HIPAA compliant HFHS drive (Box). 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 State of Michigan'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. Participants will be paid $10 for the baseline assessment and intervention sessions 1-2, $15 for intervention sessions 3-4 and the midpoint assessment, $20 intervention sessions 5-7, and $25 for intervention session 8, the post-treatment assessment and exit interview. The maximum compensation for this study accumulates to $260 with all sessions, assessments, and the exit interview 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 participant's treatment team at the DRP and any worsening of these identified by the study team or study interventionists will be reported to the DRP.

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 HFHS 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 (Felton or Magidson) as well as DRP clinical supervisor (Walker). 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. Felton or Dr. Magidson) 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 research team. The research team, under Dr. Felton's supervision, will complete HFHS 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. Felton and Dr. Magidson) immediately, and undergo expedited reporting to the IRB, within one business day of being reported to the PI.

5. ANTICIPATED BENEFITS

There are no direct, guaranteed benefits to the participants. However, it is possible that receipt of BA will result in improved treatment 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 treatment adherence through PRC delivery. Supporting SUDoutcomes could help to promote greater recovery in communities hit hard by substance use, particularly in low-income, underserved areas, such as our study site in Detroit.

6. RENUMERATION/COMPENSATION

Open-label trial participants will receive $10 for the baseline assessment and intervention sessions 1-2, $15 for intervention sessions 3-4 and the midpoint assessment, $20 intervention sessions 5-7, and $25 for intervention session 8, the post-treatment assessment and exit interview. The maximum compensation for this study accumulates to $260with all sessions, assessments, and the exit interview completed. This compensation is modest and reasonable for the tasks being requested and are consistent with other clinical intervention research trials.

7. COSTS

Participation in this study may involve transportation and parking costs. These costs will not be the responsibility of the investigator, however, we will compensate participants per session in order to indirectly offset costs.

8. ALTERNATIVES

The alternative is that subjects do not have to participate in the research and continue in treatment as usual.

9. CONSENT PROCESS AND DOCUMENTATION

A trained research staff member will conduct the informed consent. The researcher will read the consent form aloud to the participant and ensure that the participant understands key points from the consent form and what is being asked of them in participation. Participants may also choose to read the consent form themselves. Prior to giving their informed 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 (see Evaluation to Sign Consent Form). 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.

Before written consent is given, the participant: 1) should verbalize understanding; 2) should be given the opportunity to ask questions; 3) should be given time to read the consent; 4) should report all questions were answered to their satisfaction; and 5) must correctly answer the questions on the evaluation to sign consent document. When completing the evaluation to sign 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 them, and understands that they may drop out at any point during the study.

After written consent is given, the participant will be given a copy of consent form with signature blocks removed. Consent forms will be locked in a secure location at the Detroit Recovery Project.

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.

10. WITHDRAWAL OF SUBJECTS

Subjects may voluntarily withdraw from the study at any time with no penalty themselves or their healthcare or insurance plans/benefits. In the event of safety concerns and/or due to the participant having exceptional difficulties with completing the questionnaires, the PI may decide to withdraw the participant from the study.

11. PRIVACY AND 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 and HFHS servers (e.g. REDCap and Box) and in double-locked rooms at the DRP. At DRP, 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. Only the investigators/authorized

staff will have access to the REDCap database and the Box folder.

We will immediately destroy initial screening checklists for individuals who are deemed ineligible after DRP program initiation. 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 RedCap file. 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 digital recorder. 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.

All physical data, including filled out questionnaires, will be stored at the DRP in locked drawers. 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.

Audio-recordings for participant exit interviews be transcribed by trained members of the research team (IRB-approved staff member or student with up-to-date CITI training). Any inadvertent disclosure of personally identifiable information will be redacted upon transcription.

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 Michigan 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.

Important HIPAA Concerns

If you will be using, disclosing or accessing the health record (medical record, mental health or substance abuse records, etc) for research purposes, then HIPAA applies. If you are accessing medical records or PHI for screening purposes, HIPAA regulations apply and investigators will need to obtain prospective HIPAA authorization or apply for a waiver of HIPAA authorization for the screening activities, as applicable, depending on the nature of the study.

If accessing PHI for screening purposes and providing written authorization, describe how authorization will be obtained for the screening portion, who will obtain it or request and justification for a request for HIPAA waiver for recruitment purposes. If you are requesting waiver of HIPAA for screening purposes,

describe the confidentiality procedures that will be used.

For more information on HIPAA authorization guidance, visit: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html

NOTE: You may also need to obtain a waiver of documentation of informed consent (ie, signed consent) for screening purposes if you do not meet the requirements for waiving consent provided in the Consent Process section.

12. DATA AND SAFETY MONITORING PLAN

All of the materials collected are for research purposes only, and data will be kept in strict confidence. No information will be given to anyone without permission from the subject. Confidentiality will be ensured by use of unique identification codes. All data, whether generated in the laboratory or at the bedside, will be identified with a randomly generated identification code unique to the subject.

In the course of conducting the questionnaires, we may learn about mental illness symptoms including suicidal ideation and/or intent, or other risks of harm. A research emergency protocol will be followed to detect, assess, and refer/triage persons to the most appropriate existing, non-research crisis resource available to them. In addition, the PI will be responsible for internal data monitoring on a scheduled basis including review of protocol deviations, adverse events, unanticipated problems, eligibility/screening and the informed consent process. Finally, the project team will meet regularly to assure that all confidentiality procedures are being maintained.

Data security will be maintained by limiting access to the minimum number of research team members required to complete the aims. A secure computer folder and password protected files, maintained on a secure server, will be used to store data. Data will be accessed any time a new participant enrolls or completes an assessment and we will ensure no identifying information is linked to answers. No identifiable data will be published or disclosed to third parties. At the end of the study, identifying information will be destroyed. Data collected from interviews and surveys will be stored until after all publications are completed.

The research team will be thoroughly trained on the research protocol and procedures. A Manual of Procedures will be developed for project staff to reference. Protocol deviations/violations and Unanticipated Adverse Events will be communicated to the IRB per HFHS IRB policy by the Project Coordinator or PI and again reported at continuing review. The Project Coordinator will maintain records of approved protocol, initial IRB submission, and approved materials and tracking system and will make amendments to protocol/materials for approval by IRB when warranted.

Unanticipated Problems and Adverse Events

If applicable, describe process for reporting any unanticipated problems and adverse events to the IRB

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. Felton or Dr. Magidson) 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.

13. QUALIFICATIONS OF THE INVESTIGATOR(S)

- Dr. Julia Felton – Licensed clinical psychologist; Multiple funded research projects; published research work on PRCs
- Dr. Jessica Magidson (University of Maryland, College Park - Collaborator) – Licensed clinical psychologist; Multiple funded research projects published research work on PRCs
- Dr. CJ Seitz-Brown (University of Maryland, College Park - Collaborator) – Licensed clinical psychologist; Multiple funded research projects published research work on PRCs

14. REFERENCES

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