# Research Protocol – 2024-0862

## Pilot evaluation of a peer recovery support program adapted to target retention in clinic-based medication for opioid use disorder treatment

Version: 5 08 2025

Principal Investigator: Melissa Poulsen
100 N. Academy Ave.
Danville, PA 17837
570-214-9322

## TABLE OF CONTENTS

# 1 ABBREVIATIONS USED IN THE PROTOCOL

| Abbreviation | Term |
|---|---|
| AE | Adverse Event |
| CRS | Certified Recovery Specialist |
| EHR | Electronic Health Record |
| GIRB | Geisinger Institutional Review Board |
| HIPAA | Health Insurance Portability and Accountability Act |
| IRB | Institutional Review Board |
| MOUD | Medication for Opioid Use Disorder |
| MRN | Medical Record Number |
| OUD | Opioid Use Disorder |
| PACDC | Phenomic Analytics and Clinical Data Core |
| PHI | Protected Health Information |
| PI | Principal Investigator |
| PRS | Peer Recovery Support |
| RCT | Randomized Controlled Trial |
| SAE | Serious Adverse Event |

## 2 ABSTRACT

Drug overdoses are at record levels in the US, driven primarily by the ongoing opioid use disorder (OUD) epidemic. Medications for opioid use disorder (MOUD) have been shown to safely and effectively treat OUD, reduce overdose and overdose death, and facilitate long-term recovery. However, retention in MOUD treatment often falls short of the 6-12-month duration necessary for sustained recovery, and early termination from MOUD is a risk factor for overdose. Peer recovery support (PRS; i.e., support services provided by trained "peers" with lived experience of addiction and recovery) holds substantial promise as a strategy for improving retention in MOUD, yet virtually no rigorous research has been conducted on its effectiveness in this setting. To fill this gap, the proposed project will pilot test a PRS program that was developed in collaboration with community partners for use in outpatient clinical addiction treatment settings. The pilot test will be conducted in two of Geisinger's outpatient addiction treatment clinics to assess the feasibility of implementing the PRS program and of the study procedures. Information gathered during the pilot study will inform refinements to the PRS program and study components for a future clinical trial that will evaluate the effectiveness of the PRS program in increasing retention in MOUD treatment.

## 3 BACKGROUND AND SIGNIFICANCE

Opioid use disorder (OUD) is a public health crisis, contributing to substantial mortality and morbidity via an epidemic of opioid overdose. In 2021, approximately 108,000 overdose deaths were recorded in the US [1], with 70% associated with synthetic opioids [2]. Opioid overdose deaths will continue to rise without effective interventions [3]. Overdose death is just one devastating outcome of OUD, which impacts ~2.7 million Americans ages 12 and up [4]. Innovative and creative scientific efforts are needed to combat the >130 daily deaths and economic burden to society of $786.8 billion annually resulting from OUD in the US [5-7].

Medications for opioid use disorder (MOUD) are essential to responding to the opioid epidemic, with maintenance treatment a critical component of their life-saving potential. MOUD—including methadone, buprenorphine, and naltrexone—are the standard of care for OUD, greatly reducing risk for overdose and facilitating long-term recovery [8]. Maintenance MOUD treatment is most effective for preventing relapse to opioid misuse and subsequent overdose [8]. However, many patients who initiate MOUD fall short of effective treatment durations, increasing overdose risk. Many patients only take buprenorphine and naltrexone for 30-60 days [9-13], while research supports a minimum of 6-12 months for sustained recovery [14,15]. Median retention in MOUD at six months is just 57%, but as low as 19% in some settings and populations [16]. Early treatment discontinuation is linked to deleterious outcomes, including relapse, overdose, and all-cause mortality [17-19], and prevents patients from achieving long-term OUD remission [20]. Patients with OUD often follow a cyclic pattern of initiating MOUD followed by return to opioid misuse. This is a risky cycle, as fatal overdose is common during the first month following MOUD dropout [21].

Patient engagement in MOUD is influenced by modifiable risk and protective factors. In prior qualitative research with Geisinger patients with OUD, we identified multilevel barriers and facilitators to MOUD engagement including attitudes toward MOUD, motivation, mental health comorbidity, stigma around OUD/MOUD, social support, a therapeutic environment, and access barriers [22]. Findings were consistent with prior studies [23, 24-30], highlighting common constraints to MOUD retention faced by patients from diverse settings. Risk factors for dropout are compounded in rural areas due to a lack of MOUD providers, low acceptability of MOUD

among providers and patients, and poor access to recovery support services [31]. Little research has focused on efforts to improve this health disparity.

Innovative and cost-effective approaches to target modifiable risk factors for MOUD dropout are an imminent need. In a dynamic modeling analysis of public health strategies to reduce opioid overdose deaths in the US, recovery supports—particularly peer recovery support (PRS)—were identified as having the greatest potential to reduce projected overdose deaths [32]. PRS is defined as non-clinical mentoring, education, and support services provided by trained "peers" with lived experience with addiction and recovery. PRS offers patient-centered, non-stigmatizing support that may help overcome the aforementioned barriers to MOUD engagement through emotional, informational, instrumental, and affiliational support [33]. Evidence suggests PRS has the potential to address many of the barriers to MOUD treatment retention, with positive effects on internalized stigma, self-efficacy, recovery capital (internal and external assets to sustain recovery), and social determinants of health such as housing stability [34-38]. Working one-on-one with patients, peers can help troubleshoot logistical barriers to MOUD engagement while providing encouragement and hope [39].

The question of whether PRS services can be utilized to improve treatment retention in MOUD has yet to be empirically tested [40]. Observational studies provide preliminary support, having found that MOUD patients who used PRS services were more likely to attend medical appointments related to OUD [41]; display improved buprenorphine treatment engagement and opioid abstinence [42]; and attend clinical appointments, including therapy [43]. However, the design of these studies precludes disentanglement of person-level characteristics that might account for both PRS utilization and positive treatment outcomes. Additional support comes from an open label pilot trial that found that patients in methadone treatment who received a PRS- delivered intervention were more likely to be retained in treatment than a comparison cohort [44]. These studies suggest PRS has promise for improving MOUD retention but highlight the need for randomized trials.

In sum, although PRS has strong potential to improve retention across a range of MOUD settings, no rigorously designed studies have documented the effectiveness of PRS for this purpose, despite calls for more rigorous research [45,40,46,47]. Further, little is known about

PRS program characteristics that may be most effective in improving MOUD retention, and the OUD field has largely lacked patient input in developing strategies to improve treatment outcomes [48]. The proposed project addresses weaknesses in rigor of previous studies [40]. Motivated by research findings [22] demonstrating enthusiasm for embedding PRS into the outpatient addiction medicine program at Geisinger, the proposed pilot study will evaluate the feasibility of a PRS program that was developed by the study team in collaboration with community partners for the MOUD setting. The pilot test results will inform a future randomized controlled trial (RCT) to determine the PRS program's impact on MOUD retention. The project has great potential to advance the design of MOUD programs to improve MOUD retention, ultimately leading to fewer overdoses and overdose deaths.

# 4 SPECIFIC AIM

This is a pilot study with goals of evaluating the feasibility and acceptability of: 1) implementing a PRS program adapted to support patient engagement in MOUD in Geisinger's outpatient addiction treatment clinics; and 2) the study procedures (e.g., assessments, incentives, recruitment methods, etc.). Information gathered during this pilot study will inform refinements to the PRS program and study components for a future clinical trial that will evaluate the effectiveness of the PRS program in increasing patient retention in MOUD.

# 5 STUDY DESIGN

## 5.1 Description

This pilot study will implement a PRS program with a small number of patients newly receiving MOUD at Geisinger to test the program's feasibility and acceptability. The program will be delivered by a Certified Recovery Specialist (CRS; a person with personal, lived experience with substance use disorder recovery and specialized training and certification to deliver support to individuals in their recovery) in two of Geisinger's addiction medicine clinics (in Scranton and Wilkes-Barre). We will collect data to assess the feasibility of administering the program and of our research processes, and to identify areas where improvements can be made to prepare for a large clinical trial.

## 5.2 Study Population

The target population for this study includes adult patients who initiate MOUD at the Geisinger addiction medicine clinics in Wilkes-Barre and Scranton.

### 5.2.1 Approximate Number of Subjects

Up to 25 Geisinger patients will participate in the pilot study.

### 5.2.2 Inclusion Criteria

- Adult ≥ 18 years of age
- Initiated MOUD at one of the Geisinger addiction medicine clinics in Wilkes-Barre or Scranton within the past 45 days
- Willing to participate in the PRS program
- Able and willing to provide consent

### 5.2.3 Exclusion Criteria

- Received MOUD at any of the four Geisinger addiction medicine clinics in the 90 days prior to the treatment initiation date
- Not proficient in English

## 5.3 Recruitment

Participants will be recruited from the pool of patients initiating MOUD treatment in two of Geisinger's outpatient addiction medicine clinics (in Scranton and Wilkes-Barre). All patients meeting eligibility criteria will be recruited.

Potential participants will be identified via Geisinger's electronic health record (EHR) using a process employed by the study team in prior studies. Specifically, a data broker will use an automated algorithm to identify eligible patients (i.e., adults who have initiated MOUD at one of the two clinics in the past 45 days). Patients meet criteria for initiation of MOUD at Geisinger if they receive an order for a qualifying medication (buprenorphine or naltrexone) for the treatment of OUD and have not received MOUD at one of Geisinger's four addiction medicine clinics in the previous 90 days. In this way, patients may be recruited if they are returning to treatment after a treatment lapse of at least 90 days. The data broker will send a list of eligible patients and their contact information to the study team weekly. Information for eligible patients will be

delivered via secure email to Geisinger study staff. This information will include the variables needed to identify, verify, and contact potential patients, including:

- MRN
- Name
- Contact information (email address, phone numbers, address)
- Enrollment in MyGeisinger patient portal
- Demographics (age, sex, race, ethnicity, insurance type)
- Addiction medicine encounter dates and specific department/clinic
- Medications ordered for OUD treatment and dates
- Duration since a past encounter in any of Geisinger's addiction medicine clinics

A Study ID will be generated for all eligible patients to protect their privacy and confidentiality. A consistent Study ID will be maintained for each eligible patient to connect study data collected via various methods (i.e., participant assessments and interviews as well as EHR data, as described in **section 5.4.4**). A file containing identifiers (i.e., MRN, name, contact information) will only be used for recruitment and for keeping a link between MRN and Study ID. This password-protected database will be kept separate from other study data and will be stored on Geisinger's secure network.

A member of the approved Geisinger study team may manually screen patient records in Epic to confirm eligibility or identify updated contact information. Study staff completing such screening will be trained on chart reviewing in Epic.

The study team will contact eligible patients to invite them to participate in the study as soon as they are identified by the data broker. Patients will be invited to participate via email, patient portal (MyGeisinger) electronic message, phone, and/or mailed letter depending upon the type of contact information available for each patient within the EHR. Multiple methods of contact may be used to reach each patient. Follow-up emails/MyGeisinger messages may be sent if patients do not respond to initial attempts. Similarly, study staff may call patients up to 5 times during initial recruitment efforts. MyGeisinger recruitment messages were reviewed and approved by Digital Engagement. All proposed recruitment and reminder materials are outlined in Table 1

below and included as study attachments. The study team recently recruited the same patient population at Geisinger for a survey study and achieved a 29% enrollment rate using a similar process (GIRB# 2021-0744). In-clinic recruitment by research staff may also be considered if other methods are not successful. To encourage participation, clinic staff will be provided with study flyers to distribute to eligible patients. The flyers were developed in collaboration with Geisinger Marketing and contain details about the study and information about how to contact a study team member for more information. To ensure that potential participants can be reached, the study team will also utilize mailed recruitment letters. Once data is received from the data analyst, the study team will prepare a mailing using an IRB-approved recruitment letter. Within this population, it is feasible that phone numbers and email addresses are incorrect and thus the mailed letter will accompany the other recruitment methods listed above. The recruitment letter will contain a URL and QR code that the potential participant can use to learn more about the study or enroll if they so choose.

Information about the study will be provided to patients through an online survey link in REDCap, where participants will also provide informed consent, provide information that will be needed for randomization in the future trial (to assess feasibility of collecting this information), and complete a baseline assessment of potential risk factors for dropout and moderators and mediators of the effectiveness of the PRS program on MOUD retention. Potential participants can review the study information and consent document on their own time to determine whether they are interested in participating. A phone number and email address will be provided so that patients who wish to discuss the study or consent process can reach study staff. If patients are contacted by phone, research staff will explain the study and direct them to the online consent form and baseline assessment. If patients prefer, the baseline assessment can be completed with the research staff member over the phone, with electronic consent obtained first. Participants will also be asked to provide additional methods of contacting them to facilitate retention (e.g., a friend or family member's phone number, an alternative email address). This information will be stored with the original recruitment data.

Participants who complete the consent will be prompted by email, text message, MyGeisinger message, phone, and/or letter to complete the follow-up assessment after initiating MOUD (see Table 1 and study attachments). The first form of communication used to contact them will

depend upon how they were successfully contacted for recruitment and the information they provide regarding how best to contact them in the future, though multiple methods may be used.

Follow-up text messages will only be sent to participants who opt-in to receive text messages during the consent process. The consent form informs participants that they may be contacted via text by the study team and communicates the risks related to text messaging (i.e., standard text messaging rates will apply, a person other than the participant may see the text). In the consent document, participants can opt-in to receive text messages. Text messages will be sent via REDCap using the Geisinger ISO-approved platform and will contain a minimum amount of information in case someone other than the participant views the message. The study team received approval from Digital Engagement for the text messages.

To encourage participation, clinic staff will be invited to briefly mention the study to eligible patient participants at their next appointment. A member of the Geisinger study team will email a list of patients identified as eligible for the study to the appropriate clinic staff each week, along with a basic description of the study. The staff members will then have the option to mention the study to the eligible patient participants whenever they are seen next, either as the patient checks in for or out of their appointment. A simple statement from the staff member, such as "you may be eligible for a study that is currently happening at Geisinger related to your treatment here—if so, you will receive an email or phone call from the study team soon," will lend legitimacy to the study. Clinic may also provide a flyer to eligible patient participants (described above).

Table 1. PEERS recruitment and reminder attachments

| **Mode of communication** | **Initial recruitment** | **Reminder to complete baseline (BL) questionnaire** | **Reminder to complete follow-up (FU) questionnaire** |
|---|---|---|---|
| | | *For consented participants* | |
| Email | Recruitment email | BL reminder email | FU reminder email |
| MyGeisinger | Recruitment MyG letter | n/a | FU reminder MyG letter |
| Phone | Recruitment telephone and voicemail script | BL reminder telephone and reminder script | FU reminder telephone and voicemail script |
| Text | n/a | BL reminder text script | FU reminder text script |

| | | | |
|---|---|---|---|
| Letter | Recruitment Letter | n/a | FU reminder letter |
| Flyer | Recruitment flyer | n/a | n/a |

## 5.4 Study Duration

### 5.4.1 Approximate Duration of Subject Participation

Individuals will participate in the pilot study for up to a maximum of 6 months, during which time they will participate in the PRS program. Study participation begins with consent and enrollment in the PRS program, soon after patients initiate MOUD treatment at Geisinger. They will complete an online study assessment at enrollment (baseline), an interview after 1-3 months of PRS program participation, and a second online study assessment after MOUD initiation (follow-up). Collection of outcome data from patients' EHRs will also occur at post-treatment initiation.

### 5.4.2 Approximate Duration of Study

The pilot study will be completed in approximately 12 months. The end of the study is the end of all participants' 6-month PRS program participation.

### 5.4.3 Peer Recovery Support Program

After completing recruitment procedures and obtaining informed consent, participants will be offered services from a CRS (i.e., the PRS program). This will entail a CRS meeting one-on-one with the patient at regular intervals (e.g., weekly) to provide support to the patient for up to a 6-month period. CRS services are patient-centered and driven by a patient's own recovery goals, thus the frequency, timing, duration, modality (in-person, phone), and location of meetings (in the clinic or in a community setting such as a coffeeshop) are flexible and determined collaboratively by the CRS and patient. These meetings can involve the CRS providing emotional support; helping patients to identify their recovery assets, goals, and barriers; guiding patients in creating a recovery plan; helping patients to increase their coping skills; and assisting patients in connecting to community and recovery resources. The PRS program will not pose any risk over and above usual outpatient addiction treatment services. Patients who are not enrolled in the study will not be offered CRS services, as this service is paid for by grant funding.

The grant timeline will only allow for participants to meet with the CRS for up to 6 months. This duration is consistent with other programs that offer CRS services as part of case management

for a substance use disorder. Part of the role of the CRS is to help patients connect with other recovery resources; thus, the CRS for this study will help participants establish other supports during the 6-month PRS program.

### 5.4.4 Data Collection Procedures

Data collection for this study will include the following activities: 1) online participant assessments at baseline and follow-up; 2) participant interviews following 1-3 months of PRS program participation; 3) EHR data for all patients eligible for the study; 4) CRS and clinical staff feedback; and 5) completion of study logs. Data from assessments, participant interviews, and the EHR will be linked to individuals using their Study ID to avoid use of identifiers (e.g., MRN). A consistent Study ID will be maintained for participants across data sources (assessments, interviews, EHR) via the password-protected recruitment database (described in **section 5.3**) that will contain MRN and Study ID and will be stored separately from study data, on Geisinger's secure network.

#### 5.4.4.1 Online participant assessments

Participants will be asked to complete online assessments of potential risk factors for dropout and moderators and mediators of the effectiveness of the PRS program on MOUD retention via REDCap at study enrollment (baseline) and after initiating MOUD (follow-up). Consented participants may also complete the questionnaires over the phone with a study team member. Participants will be asked to complete the baseline assessment at the time of consent and will be recontacted to complete the follow-up assessment, as described in Recruitment. Participants will complete measures on a range of topics including illicit drug use, treatment intentions and expectations, beliefs about MOUD, barriers to treatment retention, mental health diagnoses, recovery capital, stigma, social support, hopefulness for the future, self-efficacy to abstain from opioid use, social determinants of health, readiness for change, reasons for and motivation to quit substances, coping strategies, medication satisfaction, recovery progress, and feasibility of completing the assessments. See baseline questionnaire and follow-up questionnaire attachments for specific items. Participants will be compensated for their time with a $40 gift card for the baseline assessment and a $75 gift card for the follow-up assessment.

#### 5.4.4.2 Participant interviews

Telephone/video interviews will be completed 1-3 months after participants enroll in the study and will focus on their experience with the PRS program, including barriers to PRS program participation and perceived patient-centeredness and helpfulness of the program in staying engaged in MOUD. See interview guide attachment for specific topics. Study staff trained on qualitative interviewing techniques will complete the interviews. Interviews will be 30-60 minutes in duration. They will be audio-recorded and transcribed verbatim. Participants will be compensated for their time with a $50 gift card for interview participation.

#### 5.4.4.3 Electronic health record data

We will obtain information from EHRs for all patients identified as eligible for participation in the study by the data broker. This includes all adult patients who initiated MOUD at one of Geisinger's addiction treatment clinics in Scranton or Wilkes-Barre in the past 45 days (from time of data pull) but had not received MOUD at one of Geisinger's four addiction medicine clinics in the previous 90 days. Participants will be informed of the use of their EHR data during the informed consent process. Using EHR data will reduce participant burden, as these measures will not need to be included in the assessments and will provide greater accuracy than self-reported data. Most data will be collected for the study period (baseline through follow-up), though some historical data will be required to determine patient's prior treatment history for OUD, such as encounters and medication orders related to addiction treatment, and co-occurring health conditions. EHR data will be used to evaluate patients' baseline and co-occurring conditions that may impact their treatment outcomes and thereby moderate the effect of PRS services and to determine primary and secondary outcomes.

We will obtain EHR data for all patients eligible for the study to assess bias in who participates in the study, a critical aspect of assessing study feasibility and improving recruitment methods to reduce these biases in the future randomized trial. This includes patients who do not respond to recruitment attempts but excludes patients who specifically decline participation. During the consent process, patients who decline active participation in the study will be given an opportunity to consent to share their medical record information. If they consent, we will also obtain EHR data for these patients. Patients who consent to full study participation or to sharing EHR data will receive a $15 gift card.

EHR data to be collected includes:

- Demographics (age, sex, race, ethnicity)
- Insurance type
- Utilization and encounter location data, including but not limited to encounters at the four outpatient addiction medicine clinics
- Medication orders, including but not limited to medications used to treat OUD
- Laboratory measures, including but not limited to drug toxicology screening results
- Addiction Severity Index data
- Mental health diagnoses (e.g., depression, anxiety, bipolar, post-traumatic stress disorder)
- Substance use disorder diagnoses, including opioid use disorder, alcohol use disorder, tobacco use disorder, cocaine use disorder, cannabis use disorder, and other substance use disorders
- Additional clinical data (e.g., body mass index, comorbidity scores, comorbid conditions)
- Clinical notes (outpatient, inpatient, emergency department), including progress notes from the CRS and participant interactions that are documented in EPIC. In the standard of care, it is the policy that CRS interactions are documented in EPIC to assist with aligning care between the patient's care team.
- Dates
- Residential address (for geocoding purposes)

Mental health data are necessary to meet the aims of the study, as we hypothesize that mental health diagnoses are key factors that influence patient engagement in MOUD. Mental health diagnoses are highly prevalent among patients with OUD. For example, prior studies of Geisinger patients have reported that 35% of patients with an opioid overdose had a diagnosis for a mental health condition (depression, anxiety, psychosis, personality disorder, drug/alcohol use disorder), and among patients with prescription opioid dependence, 14% had alcohol dependence, 43% had tobacco dependence, 51% had major depressive disorder, 20% had anxiety disorder, 22% had post-traumatic stress disorder, and had 33% had antisocial personality disorder.

A member of the approved study staff may also manually screen patient records in Epic to extract additional information from encounter notes, such as the reason for discontinuing treatment at the addiction medicine clinic. This will be particularly important for participants who do not complete the follow-up assessment, which we hypothesize will be subject to selection bias (with patients being more likely to respond if they have remained in treatment). Study staff completing such screening will be trained on chart reviewing in Epic.

Participants will be geocoded based on their response to an assessment item regarding the location of their current residence; if data are missing, and for non-participating eligible patients, we will use the address from the EHR. This will allow us to determine geographic factors that influence MOUD retention and study participation bias such as rurality and distance from clinic.

#### 5.4.4.4 CRS and clinical staff feedback

Feedback from the CRS and CRS supervisor will be solicited throughout the pilot phase during regularly scheduled meetings and will focus on what is working well (or not) about the PRS program and in which areas the CRS needs additional training and support. After all pilot participants have completed two months of the PRS program, we will engage clinicians and staff working in the Scranton and Wilkes-Barre addiction treatment clinics in debriefing meetings to solicit feedback pertaining to PRS program adoption. Feedback will be strictly about the program, not about individual patients or participants in the study. The study team will document feedback from the CRS, CRS supervisor, and clinic staff, which will be used to improve the program.

#### 5.4.4.5 Study logs

Additional information will be obtained through study logs, including: 1) a database of eligible patients to track participation, which will contain demographic and clinical information obtained through the EHR (described in 5.4.4.3) and thus allow us to compare characteristics of those agreeing and declining participation, as well as reasons for declining study participation when provided; 2) the CRS's interactions with study participants (e.g., dates, lengths, and modalities of meetings; general topics covered during meetings); and 3) observations made by the research team regarding the success of various trial processes (e.g., coordination with addiction medicine clinic and staff; obtaining retention outcomes from the EHR). The study logs will be used only for the purposes of documenting the dates, lengths, and modalities of

interactions, and the general focus of the interaction (e.g., "set recovery goals") without documenting details during these interactions.

### 5.5 Primary Endpoints

The primary endpoints for the pilot study pertain to the feasibility and acceptability of the PRS program and study procedures. These data will be used to make refinements in advance of a future randomized controlled trial evaluating MOUD retention outcomes. Pilot study endpoints include:

- Proportion of eligible patients who enroll, biases in enrollment, and barriers to participation
- Feasibility of data collection procedures (e.g., assessments), including successful attainment of EHR-based measures
- Participant acceptability of data collection procedures (i.e., assessments) and incentives, and completion rates of assessments
- Feasibility of PRS program delivery, including adequacy of CRS training and program implementation challenges
- CRS and clinic staff acceptability of the PRS program
- Fidelity of CRS to PRS program protocol and adaptations made by CRS
- Participant acceptability of the PRS program
- Degree of patient participation in CRS meetings

### 5.6 Analysis

Quantitative and qualitative data analyses will be led by the study MPIs and carried out by members of the study team.

#### 5.6.1 Analysis Plan

The goals of the analysis are to integrate qualitative and quantitative data and information collected about the pilot processes to 1) assess feasibility of a future clinical trial; 2) identify deficiencies and strengths related to reach, effectiveness, adoption, and implementation of the PRS program, CRS training/supervision, and trial logistics; and 3) to generate ideas for refinements.

Quantitative data analysis will be descriptive, focusing on the proportion of patients who enroll in the study, complete each assessment, and participate in the PRS program; demographic and clinical differences between study participants and non-participants; the number and duration of PRS program sessions completed with each participant; and participant satisfaction ratings.

Qualitative interviews will be audio recorded and transcribed verbatim. To analyze the qualitative data, given the applied nature of the pilot evaluation and the short timeframe for completing it, we will utilize a rapid qualitative data analysis approach, the RADaR ("rigorous and accelerated data reduction") technique, which is advantageous for small pilot projects. This process streamlines data analysis through production of a series of data tables that are systematically analyzed and reduced, ultimately producing a condensed and concise presentation of textual data that can be rapidly coded and interpreted.

We will present the pilot evaluation results to community partners for discussion of potential refinements to the PRS program, peer training/supervision plan, and trial design. Based on their feedback, refinements will be made for board member approval in advance of the future randomized controlled trial.

### 5.6.2 Sample Size Considerations

We will recruit at least 12, and up to 25 patients for the pilot study, a sample size that is feasible in the time frame and that will provide sufficient data on feasibility and feedback to refine the program.

## 5.7 Data Management

### 5.7.1 Data Collection and Storage

Only IRB-approved study staff will have access to data collected for this research. All data will be stored on Geisinger's secure network. A data use agreement will be put in place to share deidentified baseline/follow-up assessment data and interview data with study team members at the University of Connecticut Health Center.

### 5.7.2 Records Retention

Records of data generated during this study and stored will not be de-identified. Data will be kept indefinitely and can be used for other IRB approved research.

# 6 PROTECTION OF HUMAN SUBJECTS

All personnel collecting and manipulating data will have completed Human Subjects Research Training with the Collaborative Institutional Training Initiative (CITI). All research staff also receive extensive confidentiality training as part of their job training. Further, MPI Poulsen will meet with staff regularly to ensure strict compliance with the Data and Safety Monitoring Plan (DSMP). Only study personnel (investigators and research staff) will have access to research data. No data will be released to other agencies unless the participant signs a release of information. Finally, a DSMP is provided to describe monitoring of and responses to adverse events. All GIRB and regulatory procedures will be followed.

## 6.1 Informed Consent and HIPAA Authorization

Potential participants will be recruited by research staff through patient portal message, email, or phone, as described in the Recruitment section above. These various modes of communication will direct patients to an online survey in REDCap, where they will be provided with information about the study and the informed consent document. The informed consent document will explain the purpose of the study, its risks and benefits, and will emphasize the voluntary nature of the research and that the patient's decision to participate in no way affects their treatment at Geisinger (see consent document attachment). Potential participants will have time to review the consent document before electronically signing it. Following the consent document and before the signature page, we will provide patients with options to 1) enroll in the study (directing them to the electronic signature page); 2) decline participation but agree to share their medical record information (directing them to a separate electronic signature page); 3) request a study team member to contact them so they can get more information; or 4) fully decline participation (and provide a reason for doing so, if they choose). See study attachment detailing these "pre-consent" options. The consent document will also provide a study phone number and email address for patients to contact us to ask questions or discuss the study. A copy of the consent document will be provided to each participant by email or mail.

Before any procedures specified in this protocol are performed, a participant must:

- Be informed of all pertinent aspects of the study and all elements of informed consent.
- Be given time to ask questions and to consider the decision to participate.

- Voluntarily agree to participate in the study.
- Electronically sign and date a GIRB-approved informed consent document.

We are requesting a partial waiver of HIPAA Authorization for recruitment purposes to identify potential participants via an EHR data pull. The data pull will be used to call, email, or send a MyGeisinger message to contact potential patient participants. This research could not be practically conducted without the waiver requested, as in-person clinic recruitment would be burdensome for study staff as well as for clinic staff whose workflow may be interrupted.

We are also requesting a full waiver of HIPAA authorization and a waiver of consent to access medical record information for patients who are identified as eligible for the study but who do not respond to recruitment attempts. The study team is requesting this data as it is vital to better understanding the differences between patients who choose to enroll in the research and those who do not. These data will facilitate evaluation of potential sample bias and can inform modifications to our recruitment methods. This evaluation of bias could not be practically conducted without the waivers requested, as individuals who do not respond to recruitment attempts are highly unlikely to respond to attempts to have them sign an authorization/e-consent. We will not obtain medical record information for patients who specifically decline participation, unless they consent to sharing their medical record information, as described in section 5.4.4.3.

### 6.2 Potential Risks/Benefits and Protection of Human Subjects Against Risks

**Potential Risks**

Potential risks to participants include inadvertent identification of the participant as having a substance use disorder or receiving treatment for a substance use disorder to other individuals during recruitment processes (e.g., to household members); perceived coercion to participate; potential distress if information obtained during the assessments were released to outside parties; and physical or psychological discomfort due to assessment questions.

To protect against (1) inadvertent identification of the participant as having a substance use disorder or receiving treatment for a substance use disorder to other individuals during recruitment processes, we will ensure that recruitment materials do not specifically mention participant's condition or treatment. Rather, recruitment messages (emails, text messages, etc.) will refer to "recent treatment" the participant received at Geisinger. Information about the nature of the study will only be divulged by phone (once research staff have confirmed the participants' identity) or once patients log into the REDCap survey to learn about the study.

To protect against (2) perceived coercion to participate, patient participants will be informed that their decision to participate will not impact their treatment at the addiction medicine clinic or at Geisinger. The voluntary nature of the study will also be emphasized in the consent process.

To protect against (3) potential distress if information obtained during the assessments were released to outside parties, data will be linked to participant Study ID number rather than by name or MRN. For interview data, audio-recordings will be transcribed and de-identified. Once transcripts are reviewed for validity, audio-recordings will be deleted. Transcripts will be stored within a secure computing environment at Geisinger. All direct identifiers (e.g., names, contact information) will be removed and replaced with participant Study ID numbers. A link between Study ID and identifiers will be kept in a separate password-protected database, as previously described. No information will be provided about patients enrolled in this study to anyone outside of the research team, except in emergency situations (e.g., subject deemed a threat to themselves or others) or as required by law. To further protect confidentiality, as per NIH regulations, the study will automatically have a Certificate of Confidentiality (CoC) from the U.S. Department of Health and Human Services (DHHS). While such Certificates do not prohibit making voluntary disclosures, they provide researchers with protection from voluntary and involuntary disclosures that might be required or requested by state or local authorities.

Regarding data management and storage, most data from patient participants will be collected using REDCap, a secure, on-line platform. Survey forms will be identified by Study ID numbers, not patient identifiers. All other study data, including EHR data, will be stored in databases on Geisinger's password protected secure server. Additional protections for data safety are described in the DSMP.

To protect against (4) physical or psychological discomfort due to assessment questions, the consent document will emphasize to participants that they may choose not to answer any component of the assessments. It will also clearly state that the participant has the right to withdraw from this study at any time.

**Benefits**

Participants may benefit from the peer recovery support program, as it is designed to provide additional support to patients to assist in their recovery from opioid use disorder. Participants may indirectly benefit from the research in that the information gained from the study will help understand and potentially improve strategies for improving retention in MOUD treatment. Improving MOUD retention and reducing treatment dropout would have substantial benefits to individuals, families, clinics, and society.

# 7 SAFETY MONITORING

MPIs Poulsen and Zajac, co-investigators, and study team personnel will provide safety oversight for the study. They will review safety data monthly and make any decisions about modifications of the study. The monitoring plan includes tracking participant safety and demographics, monitoring the safety of the data, and monitoring and appropriately reporting adverse events (AEs). Study staff will be trained to identify risks to safety for participants. Given the low-risk nature of the study and the low likelihood of serious adverse events related to or possibly related to the study, the data and safety monitoring plan will be carried out by MPIs Poulsen and Zajac. SAE and AE reporting requirements will be adhered to in accordance with Geisinger and NIDA guidelines. A localized AE/SAE database will be maintained and available for GIRB review upon request.

## 7.1 Adverse Event Reporting

Clinical AEs will be monitored throughout the study. No specific AEs are anticipated for this study. Due to the nature of this study, the study team has a reasonable expectation that no AEs will be related to study procedures or participation in the PEERS program.

## 7.2 Serious Adverse Event Reporting

Types of expected SAEs in this patient population are as follows: (a) onset of clinically significant suicidal intent or action; (b) onset of clinically significant homicidal intent or action; and (c) deterioration of physical or mental status to an extent that renders need for inpatient medical treatment. If there is any doubt about whether an AE constitutes an SAE, the information is treated as an SAE. All SAEs will result in the completion of a Serious Adverse Event Form, which is sent within 24 hours to the Project Manager. All deaths and study-related or possibly related SAEs will be reported immediately to the PI and to NIH within 48 hours.

All 1) study-related SAEs and 2) possibly study-related SAEs that may place participants at greater risk than previously recognized will be reported within five business days of becoming aware of the occurrence to the GIRB. The study will be temporarily stopped if it is determined that SAEs potentially related to the study occur in ≥5% of the sample. At this point, consultation with NIH and the GIRB will be sought. If it is determined that procedures need to be changed prior to resuming the trial, revised procedures will be approved by NIH and the GIRB prior to implementation. Due to the low-risk nature of the study, it is anticipated that there is a low likelihood of any SAEs occurring because of study participation.

### 7.3 Recording and Reporting

A participant's SAEs will be recorded and reported from the signing of the informed consent form to the end of study participation in accordance with GIRB policy guidelines. Detailed information will be collected about all SAEs, and a database of all SAEs will be maintained by the Project Manager. The SAE database will be available for GIRB review upon request. The database will include the date and time of onset of the SAE and the outcome (to the degree known); the study team member who reported the SAE; and whether the SAE was related to study participation. Once per month, in research team meetings, all SAEs will be reviewed that occurred over the previous month. Per NIH guidelines, any serious SAE that results in death will be reported to the NIH within 48 hours regardless of whether or not the SAE is considered to be study related.

### 7.4 Data Monitoring Plan

All research staff will be thoroughly trained and supervised regarding administration of participant assessments, handling of electronic health record (EHR) data, and completion of all necessary forms. Data will be collected via online assessments completed by participants and from the EHR, and consent will be obtained electronically. Therefore, there will be no paper copies of research data. All data will be stored on Geisinger's secure server and will be accessible only to appropriate project staff. Study ID numbers, not participant names, will be used to identify and link all assessments and other data collected. Geisinger's computing and data storage systems are protected from outside access by firewall systems.

## 8 REFERENCES

1. Spencer MR, Minino AM, Warner M. Drug overdose deaths in the United States, 2011-2021. Hyattsville, MD: National Center for Health Statistics;2022.
2. CDC. Drug overdose deaths in the U.S. top 100,000 annually. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm. Published 2021. Accessed 01/11/2022.
3. Humphreys K, Shover CL, Andrews CM, et al. Responding to the opioid crisis in North America and beyond: recommendations of the Stanford–*Lancet* Commission. The Lancet. 2022;399(10324):555-604. doi: 10.1016/S0140-6736(21)02252-2.
4. SAMHSA. Key substance use and mental health indicators in the United States: results from the 2020 national survey on drug use and health. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration;2021.
5. Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and opioid-involved overdose deaths - United States, 2013-2017. Morbidity and Mortality Weekly Report. 2019;67:1419-1427. doi: http://dx.doi.org/10.15585/mmwr.mm675152e1.
6. Ciccarone D. The rise of illicit fentanyls, stimulants and the fourth wave of the opioid overdose crisis. Current Opinion in Psychiatry. 2021;34(4):344-350. doi: 10.1097/yco.0000000000000717. PubMed PMID: 00001504-202107000-00004.
7. Murphy SM. The cost of opioid use disorder and the value of aversion. Drug and alcohol dependence. 2020;217:108382. doi: 10.1016/j.drugalcdep.2020.108382. PubMed PMID: 33183909; PMCID: PMC7737485.
8. SAMHSA. Medications for Opioid Use Disorder. Rockville, MD: Substance Abuse and Mental Health Services Administration;2021.
9. Gordon AJ, Lo-Ciganic WH, Cochran G, et al. Patterns and Quality of Buprenorphine Opioid Agonist Treatment in a Large Medicaid Program. Journal of addiction medicine. 2015;9(6):470-477. doi: 10.1097/adm.0000000000000164. PubMed PMID: 26517324.
10. Jarvis BP, Holtyn AF, Subramaniam S, et al. Extended-release injectable naltrexone for opioid use disorder: a systematic review. Addiction. 2018;113(7):1188-1209. doi: 10.1111/add.14180. PubMed PMID: 29396985; PMCID: PMC5993595.
11. Morgan JR, Schackman BR, Leff JA, Linas BP, Walley AY. Injectable naltrexone, oral naltrexone, and buprenorphine utilization and discontinuation among individuals treated

for opioid use disorder in a United States commercially insured population. Journal of substance abuse treatment. 2018;85:90-96. doi: 10.1016/j.jsat.2017.07.001. PubMed PMID: 28733097; PMCID: PMC5750108.

12. Samples H, Williams AR, Olfson M, Crystal S. Risk factors for discontinuation of buprenorphine treatment for opioid use disorders in a multi-state sample of Medicaid enrollees. Journal of substance abuse treatment. 2018;95:9-17. doi: 10.1016/j.jsat.2018.09.001. PubMed PMID: 30352671; PMCID: PMC6354252.
13. Stein BD, Sorbero M, Dick AW, Pacula RL, Burns RM, Gordon AJ. Physician Capacity to Treat Opioid Use Disorder With Buprenorphine-Assisted Treatment. Jama. 2016;316(11):1211-1212. doi: 10.1001/jama.2016.10542. PubMed PMID: 27654608; PMCID: PMC5257276.
14. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. Journal of addiction medicine. 2015;9(5):358-367. doi: 10.1097/adm.0000000000000166. PubMed PMID: 26406300; PMCID: PMC4605275.
15. National Quailty Forum. Behavioral health 2016–2017: technical report. U.S. Department of Health and Human Services;2017.
16. O'Connor AM, Cousins G, Durand L, Barry J, Boland F. Retention of patients in opioid substitution treatment: A systematic review. PLoS One. 2020;15(5):e0232086. doi: 10.1371/journal.pone.0232086. PubMed PMID: 32407321; PMCID: PMC7224511.
17. Santo T, Jr., Clark B, Hickman M, et al. Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-analysis. JAMA Psychiatry. 2021;78(9):979-993. doi: 10.1001/jamapsychiatry.2021.0976. PubMed PMID: 34076676; PMCID: PMC8173472.
18. Glanz JM, Binswanger IA, Clarke CL, et al. The association between buprenorphine treatment duration and mortality: a multi-site cohort study of people who discontinued treatment. Addiction. 2023;118(1):97-107. doi: https://doi.org/10.1111/add.15998.
19. Bentzley BS, Barth KS, Back SE, Book SW. Discontinuation of buprenorphine maintenance therapy: perspectives and outcomes. Journal of substance abuse treatment. 2015;52:48-57. doi: 10.1016/j.jsat.2014.12.011. PubMed PMID: 25601365; PMCID: PMC4382404.

20. Williams AR, Nunes E, Olfson M. To battle the opioid overdose epidemic, deploy the 'Cascade of Care' model. In. Health Affairs blog2017.
21. Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. BMJ. 2017;357:j1550. doi: 10.1136/bmj.j1550.
22. Poulsen MN, Asdell PB, Berrettini W, McBryan K, Rahm AK. Application of the COM-B model to patient barriers and facilitators of retention in medication treatment for opioid use disorder in rural Northeastern United States: A qualitative study. SSM - Mental Health. 2022:100151. doi: https://doi.org/10.1016/j.ssmmh.2022.100151.
23. Kahn LS, Wozniak ML, Doscher T, Moore C, Vest BM. Treatment Experiences Among People Who Use Opioids: A Social Ecological Approach. Qualitative Health Research. 2022;32(8-9):1386-1398. doi: 10.1177/10497323221104315. PubMed PMID: 35645402.
24. Beharie N, Kaplan-Dobbs M, Urmanche A, Paone D, Harocopos A. "I didn't feel like a number": The impact of nurse care managers on the provision of buprenorphine treatment in primary care settings. Journal of substance abuse treatment. 2022;132:108633. doi: https://doi.org/10.1016/j.jsat.2021.108633.
25. Filteau MR, Kim FL, Green B. "It's more than Just a Job to Them": A Qualitative Examination of Patient and Provider Perspectives on Medication-Assisted Treatment for Opioid Use Disorder. Community Ment Health J. 2021. doi: 10.1007/s10597-021-00824-7. PubMed PMID: 33844126.
26. Granerud A, Toft H. Opioid dependency rehabilitation with the opioid maintenance treatment programme - a qualitative study from the clients' perspective. Subst Abuse Treat Prev Policy. 2015;10:35. doi: 10.1186/s13011-015-0031-4. PubMed PMID: 26374128; PMCID: PMC4571127.
27. Lai S, Li E, Silverio A, DeBates R, Kelly EL, Weinstein LC. "It's a place that gives me hope": A qualitative evaluation of a buprenorphine-naloxone group visit program in an urban federally qualified health center. Subst Abus. 2021;42(4):858-864. doi: 10.1080/08897077.2021.1876202. PubMed PMID: 33492204.
28. Notley C, Blyth A, Maskrey V, Pinto H, Holland R. Exploring the Concepts of Abstinence and Recovery Through the Experiences of Long-Term Opiate Substitution Clients. Subst Abus. 2015;36(2):232-239. doi: 10.1080/08897077.2014.941085. PubMed PMID: 25127184.

29. Scorsone KL, Haozous EA, Hayes L, Cox KJ. Overcoming Barriers: Individual Experiences Obtaining Medication-Assisted Treatment for Opioid Use Disorder. Qualitative Health Research. 2020;30(13):2103-2117. doi: 10.1177/1049732320938689. PubMed PMID: 32691670.
30. Hewell VM, Vasquez AR, Rivkin ID. Systemic and individual factors in the buprenorphine treatmentseeking process: a qualitative study. Substance Abuse Treatment, Prevention, and Policy. 2017;12(1):3. doi: 10.1186/s13011-016-0085-y.
31. Lister JJ, Weaver A, Ellis JD, Himle JA, Ledgerwood DM. A systematic review of rural-specific barriers to medication treatment for opioid use disorder in the United States. Am J Drug Alcohol Abuse. 2020;46(3):273-288. doi: 10.1080/00952990.2019.1694536. PubMed PMID: 31809217.
32. Stringfellow EJ, Lim TY, Humphreys K, et al. Reducing opioid use disorder and overdose deaths in the United States: A dynamic modeling analysis. Sci Adv. 2022;8(25):eabm8147. doi: 10.1126/sciadv.abm8147. PubMed PMID: 35749492; PMCID: PMC9232111.
33. Sharon Reif, Lisa Braude, D. Russell Lyman, et al. Peer Recovery Support for Individuals With Substance Use Disorders: Assessing the Evidence. Psychiatric Services. 2014;65(7):853-861. doi: 10.1176/appi.ps.201400047. PubMed PMID: 24838535.
34. Anvari MS, Kleinman MB, Massey EC, et al. "In their mind, they always felt less than": The role of peers in shifting stigma as a barrier to opioid use disorder treatment retention. J Subst Abuse Treat. 2022;138:108721. doi: 10.1016/j.jsat.2022.108721. PubMed PMID: 35067397; PMCID: PMC9167238.
35. Ja DY, Gee M, Savolainen J, Wu S, Forgahni S. Peers Reaching out Supporting Peers to Embrace Recovery (PROSPER): A final evaluation report. San Francisco, CA: DYJ, Inc. for Walden House, Inc. and the Center for Substance Abuse Treatment, Substance Aubse and Mental Health Services Administration;2009.
36. Kamon J, W. T. Montpelier, Vermont: Evidence-Based Solutions;2013 Recovery coaching in recovery centers: What the intial data suggest: A brief report from the Vermont REcovery Network.
37. Kelley A, Steinberg R, McCoy TP, Pack R, Pepion L. Exploring recovery: Findings from a six-year evaluation of an American Indian peer recovery support program. Drug

Alcohol Depend. 2021;221:108559. doi: 10.1016/j.drugalcdep.2021.108559. PubMed PMID: 33548899.

38. Vayshenker B, Mulay AL, Gonzales L, West ML, Brown I, Yanos PT. Participation in peer support services and outcomes related to recovery. Psychiatr Rehabil J. 2016;39(3):274-281. doi: 10.1037/prj0000178. PubMed PMID: 26882529.
39. Stack E, Hildebran C, Leichtling G, et al. Peer Recovery Support Services Across the Continuum: In Community, Hospital, Corrections, and Treatment and Recovery Agency Settings - A Narrative Review. J Addict Med. 2022;16(1):93-100. doi: 10.1097/adm.0000000000000810. PubMed PMID: 33560695; PMCID: PMC8339174.
40. Gormley MA, Pericot-Valverde I, Diaz L, et al. Effectiveness of peer recovery support services on stages of the opioid use disorder treatment cascade: A systematic review. Drug and Alcohol Dependence. 2021;229:109123. doi: https://doi.org/10.1016/j.drugalcdep.2021.109123.
41. Mills Huffnagle S, Brennan G, Wicks K, Holden D, Kawasaki S. A comparison of patients with opioid use disorder receiving buprenorphine treatment with and without peer recovery support services. Journal of Substance Use. 2022;27(3):266-271. doi: 10.1080/14659891.2021.1938265.
42. Magidson JF, Regan S, Powell E, et al. Peer recovery coaches in general medical settings: Changes in utilization, treatment engagement, and opioid use. J Subst Abuse Treat. 2021;122:108248. doi: 10.1016/j.jsat.2020.108248. PubMed PMID: 33509420.
43. Zuccarini MM, Stiller C. The Effect of Peer Support on Treatment Engagement for Opioid Use Disorder. J Am Psychiatr Nurses Assoc. 2022:10783903221128062. doi: 10.1177/10783903221128062. PubMed PMID: 36254384.
44. Magidson JF, Kleinman MB, Bradley V, et al. Peer recovery specialist-delivered, behavioral activation intervention to improve retention in methadone treatment: Results from an open-label, Type 1 hybrid effectiveness-implementation pilot trial. Int J Drug Policy. 2022;108:103813. doi: 10.1016/j.drugpo.2022.103813. PubMed PMID: 35932644; PMCID: PMC9590100.
45. Eddie D, Hoffman L, Vilsaint C, et al. Lived Experience in New Models of Care for Substance Use Disorder: A Systematic Review of Peer Recovery Support Services and Recovery Coaching. Frontiers in Psychology. 2019;10. doi: 10.3389/fpsyg.2019.01052.

46. Bassuk EL, Hanson J, Greene RN, Richard M, Laudet A. Peer-Delivered Recovery Support Services for Addictions in the United States: A Systematic Review. J Subst Abuse Treat. 2016;63:1-9. doi: 10.1016/j.jsat.2016.01.003. PubMed PMID: 26882891.
47. Reif S, Brolin MF, Stewart MT, Fuchs TJ, Speaker E, Mazel SB. The Washington State Hub and Spoke Model to increase access to medication treatment for opioid use disorders. Journal of Substance Abuse Treatment. 2020;108:33-39. doi: https://doi.org/10.1016/j.jsat.2019.07.007.
48. Salazar ZR, Vincent L, Figgatt MC, Gilbert MK, Dasgupta N. Research led by people who use drugs: centering the expertise of lived experience. Substance Abuse Treatment, Prevention, and Policy. 2021;16(1):70. doi: 10.1186/s13011-021-00406-6.