Title: Social Work Assistance and Stipends for Housing (SASH)

March 18, 2025

NCT05803603

IRB Application, Study Protocol and included Statistical Analysis Plan.

UNIVERSITY of MARYLAND BALTIMORE

[redacted]

Date: Tuesday, March 18, 2025 10:42:36 AM Print Close

HP-00100771 Introduction Page_V2

Introduction Page

1 *Abbreviated Title:
SASH

2 *Full Title:
Social Work Assistance and Stipends for Housing (SASH): Improving Outcomes for Homeless Patients Receiving Methadone for Opioid Use Disorder

3

*Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF6708A33C00
Name: v2_Introduction Page

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Max Spaderna

CITI Training: ID00009551

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● No

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Heather Fitzsimons

CITI Training: ID00015826

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● No

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View Jewell Benford	no	no	Research Team Member	no	ID00002390
View Aaron Greenblatt	yes	yes	Sub-Investigator	no	ID00008817
View Hannah Smith	no	no	Research Team Member	no	ID00020303

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
The principal investigator will devote 5% FTE conducting and completing this project over 12 months.

2 * Describe the facilities where research procedures are conducted:
The study will take place at the University of Maryland Addiction Treatment Program (ATP), a certified substance use treatment program that collocates substance use treatment, medical care, wellness programs, and research.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
The principal investigator, Max Spaderna, is a board-certified psychiatrist with eight years of experience as an attending psychiatrist. One of the investigators, Aaron Greenblatt, is the medical director of the ATP, and another investigator, Samuel Little, is an Associate Dean at the School of Social Work. The ATP is staffed with physicians trained in a variety of fields including Internal Medicine, Family Medicine, and Psychiatry, and it is staffed with PhD-trained psychologists, social workers, and certified substance use counselors. A member of the clinic social work team will carry out the study's social work intervention and manage the housing vouchers on behalf of the participants. The entire social work team is supervised by a LCSW-C. All the staff involved with this study will be accessible to the participants if emergent issues need to be addressed.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
Regularly scheduled meetings before and during the study will ensure everyone involved in the study is aware of the study's protocols, research procedures, and responsibilities.

ID: VIEW4DF83CB976400
Name: V2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

○ Yes ● **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

○ Yes ● **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

○ Yes ● **No**

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ● **No**

6 * Institution(s) where the research activities will be performed:

- ☐ University of Maryland, Baltimore
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☐ VAMHCS
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)
- ☐ National Study Center for Trauma and EMS
- ☐ Univ of MD Cardiology Physicians at Westminster
- ☐ Nursing Homes in Maryland
- ☐ University of Maryland Biotechnology Institute
- ☐ Maryland Department of Health
- ☐ Maryland Proton Treatment Center

- [ ] Mount Washington Pediatric Hospital
- [ ] Institute of Marine and Environmental Technology (IMET)
- [ ] Other Sites
- [x] **University of Maryland Medical System (Select below)**

* UMMS Sites:

- [x] **University of Maryland Medical Center**
- [ ] UMMC Midtown Campus (formerly Maryland General Hospital)
- [ ] UM St. Joseph Medical Center
- [ ] UM Baltimore Washington Medical Center
- [ ] UM Capitol Region Health
- [ ] UM Charles Regional Medical Center
- [ ] UM Shore Medical Center at Easton
- [ ] UM Shore Medical Center at Chestertown
- [ ] UM Shore Medical Center at Dorchester
- [ ] UM Shore Emergency Center at Queenstown
- [ ] UM Shore Regional Health
- [ ] University of Maryland Rehabilitation & Orthopaedic Institute (formerly Kernan Hospital)
- [ ] UM Upper Chesapeake Health
- [ ] UM Upper Chesapeake Medical Center
- [ ] UM Harford Memorial Hospital
- [ ] University of Maryland Community Medical Group

ID: VIEW4DFB70DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

Funding Information

1 *Indicate who is funding the study:

- [ ] Federal
- [ ] Industry
- [x] **Department / Division / Internal**
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 *What portion of the research is being funded? (Choose all that apply)

- [ ] **Drug**
- [ ] Device
- [x] **Staff**
- [x] **Participant Compensation**
- [x] **Procedures**
- [ ] Other

3 Please discuss any additional information regarding funding below:
The funding is from a grant from the University of Maryland Center for Addictions Research, Education, and Service (CARES).

ID: VIEW4DF85DF452400
Name: v2_Funding Information

Research Protocol

1 * Do you have a research protocol to upload?

○ Yes

● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E00563F6D000
Name: v2_Research Protocol

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

Exempt Categories

You indicated on the "Risk Level" page that this study is Minimal Risk.

1 * Please review the following categories to determine if your research may be Exempt from IRB oversight. If you believe that your study qualifies as Exempt, select the Category under which it qualifies. If your research does not qualify as Exempt, select **"The research does not qualify as Exempt".**

☐ **Category 1**: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

☐
i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

Category 3: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

☐
i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

☐
i. The identifiable private information or identifiable biospecimens are publicly available.
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Category 6: Taste and food quality evaluation and consumer acceptance studies:

☐
i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

☑ **The research does not qualify as Exempt.**

ID: VIEW8D50FF499486A05
Name: v2_Exempt Categories

HP-00100771 Type of Research_V2

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- ☐ Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- ☐ Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- ☐ Use of device(s) whose use is specified in the protocol
- ☑ **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- ☐ Sample (Specimen) Collection and/or Analysis (including genetic analysis).
- ☑ **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- ☐ None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

● Yes ○ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

SASH is a feasibility study that will provide an intervention to improve opioid use disorder (OUD), quality of life (QOL), and housing outcomes for homeless patients receiving medications for opioid use disorder (MOUD). To achieve these goals, monthly housing vouchers of $650 that can be used for a broad range of temporary housing included in a list of resources compiled by the study will be used on behalf of the patients in this study. These vouchers will be accompanied by Social Work assistance to find permanent housing which will last the full 12 months of the study. SASH will recruit 8 OUD patients receiving MOUD who are struggling with homelessness, defined as living in an emergency shelter or a place not meant for habitation instead of a fixed, regular, and adequate nighttime residence. This definition is consistent with the one used by the U.S. Department of Housing and Urban Development. The patients will be recruited from the University of Maryland Addiction Treatment Program (ATP), a certified substance use treatment program that provides MOUD and collocates medical care, wellness programs, and research. Patients will be eligible for SASH if they experienced homelessness during at least 15 of the 30 days preceding the dispensing of the first month's stipends.

A member of the clinic social work team will start managing the vouchers on behalf of the patients in September 2022. During the first six months of SASH, each monthly voucher of $650 will be used to find temporary housing included on a list compiled by the study. The type of housing on this list could include rooms in a private dwelling, hotel rooms, or living spaces shared with roommates. In addition to receiving these vouchers, each patient throughout the 12 months of the study will attend regularly scheduled meetings at the ATP with member of the clinic social work team from the University of Maryland Addiction Treatment Program (ATP). During these meetings, the member of the clinic social work team will help house the patient and connect the patient with resources aimed at securing permanent housing, which could include obtaining permanent housing vouchers; connecting the patient with government agencies and services that help individuals struggling with homelessness; or obtaining benefits for which the patient is eligible.

ID: VIEW/E02605CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:
We hypothesize that opioid use disorder, quality of life, and housing outcomes for homeless patients receiving medications for opioid use disorder would improve if they could access temporary housing options such as a room in a private dwelling, a hotel room, or a housing arrangement with roommates. This could be achieved by using monthly housing vouchers to assist patients in securing temporary housing and social work assistance to address housing and unmet social needs.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:
This is a feasibility study to determine whether it is achievable to use monthly housing vouchers to secure temporary housing and social work assistance to address housing and other unmet social needs for patients receiving medications for opioid use disorder. All the participants in this study will receive housing vouchers and social work assistance. During the first six months of the study, monthly housing vouchers of $650 will be managed by member of the clinic social work team on behalf of the participants in the study. The vouchers can be used for a wide range of temporary housing options included on a list compiled by the study. During the twelve months of the study, participants will meet with member of the clinic social work team at the Addiction Treatment Program to address housing and unmet social needs. The meetings will occur at least monthly and will be a requirement for the participants to benefit from the vouchers.
The principal investigator will conduct a chart review of the methadone doses that participants receive in the 3-month period before the study, between Months 3 and 6 of the study, and between Months 9 and 12 of the study. The review of methadone doses will calculate the number of doses participants received and took home with them instead of receiving at the clinic. In addition to a review of methadone doses, the principal investigator will review the results of the urine toxicology tests for the participants in the 3-month period before the start of the study and monthly during the study.
Participants will complete two surveys at Day 0, Month 6, and Month 12 of the study: the OUD Checklist, which rates opioid use disorder symptoms based on the DSM-5 criteria, and the SF-36, which measures quality of life. At Months 6 and 12, participants will complete qualitative interviews to determine how the vouchers and social work assistance impacted their financial and social well-being, and whether the SASH intervention was useful in combating homelessness. Data on the methadone doses, results of the urine toxicology tests, surveys, and qualitative interviews will be stored in a password-protected database. The principal investigator will calculate the percentage of days participants are homeless during the 6-month period when vouchers are distributed and at Month 12 of the study. The percentage of days participants are homeless will be calculated from data collected by the member of the clinic social work team . These data will be stored in a password-protected database.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:
Homelessness continues to be a crisis in the United States. It is estimated that on a single night in 2020, approximately 580,000 people were experiencing homelessness, and nearly four in ten were living in unsheltered locations. Between 2019 and 2020, the number of people experiencing homelessness increased by 2 percent, while the number of people staying outdoors increased by 7 percent. Baltimore has also experienced the effects of homelessness: in 2020 an estimated 2,193 people were homeless on any given night in the city. This crisis particularly affects individuals diagnosed with a psychiatric illness or substance use disorder (SUD), who experience a high prevalence of being homeless. Being homeless has been associated with greater emergency department usage,4 longer and more expensive hospitalizations, a reduced quality of life (QOL), and an increased risk of mortality. For individuals with opioid use disorder (OUD), homelessness adds an extra layer of burden that negatively impacts their health outcomes. Homeless individuals with OUD are less likely to access evidence-based OUD treatment like pharmacotherapy and are more likely to overdose on opioids.
Fortunately, providing housing to homeless individuals can greatly improve health outcomes. Over time, reducing homelessness has been shown to decrease emergency department visits, hospital days, and health care costs. Providing housing to homeless individuals has also been shown to benefit individuals with severe psychiatric illness and SUD. The documented benefits of ending homelessness lend support to the Housing First model, which advocates for providing permanent housing to homeless individuals without requiring their participation in services, a contrast to previous models that made participation in services a prerequisite for receiving housing. Studies have demonstrated the health, QOL, and financial benefits of the Housing First model, but the model's emphasis on obtaining permanent housing can act as a barrier for getting homeless individuals off the streets and out of shelters. Although obtaining permanent housing for individuals is the desired outcome, this is often difficult to achieve because there is a shortage of housing vouchers, and landlords are hesitant to accept tenants with these vouchers. These impediments might be lessened, however, if the housing options available were expanded to include temporary housing like rooms for rent, hotel rooms, and housing arrangements with roommates.
A subset of the OUD population in dire need of interventions to combat homelessness are patients receiving methadone for OUD (MOUD), whose prevalence of homelessness might be as high as 25 percent. It is imperative to find interventions that can house this vulnerable population, as homelessness increases the risk of discontinuing life-saving MOUD. These are especially needed during the fentanyl epidemic, which has caused a rise in overdoses and deaths that have disproportionately affected Black Americans, who experience worse OUD outcomes as a result of systemic racism. Studies investigating the effects of housing homeless individuals on MOUD outcomes are mixed. A secondary analysis of a Housing First intervention was not associated with improving the dispensing of MOUD. However, another study that provided permanent housing to homeless individuals receiving MOUD found that their rate of retention in methadone treatment was 2.5 times higher than a matched group of homeless individuals receiving MOUD who were not given housing.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:
The impact of SASH will be significant. Many patients receiving medications for opioid use disorder (MOUD) are homeless and lack the resources to obtain housing, a predicament that negatively impacts their medical and opioid use disorder (OUD) care. By benefiting from the vouchers for temporary housing and receiving assistance from the member of the clinic social work team, patients could experience an improvement in their OUD, which could lead to several downstream health benefits including fewer opioid overdoses, improved psychiatric symptoms, and better social functioning. While previous studies have shown the benefits of providing permanent housing to patients receiving MOUD, none have investigated the benefits of providing temporary housing assistance to these patients. The outcomes of SASH would be written in a manuscript that would be submitted for publication to a high-impact Addiction Medicine journal. The results of SASH would also be used as pilot data to apply for the Pilot Health Services and Economic Research on the Treatment of Drug, Alcohol, and Tobacco Use Disorders R34 grant. This grant would develop the trial design, study protocols, and data analysis used in an R01 grant that would compare patients receiving the intervention with matched controls. We would submit the R34 grant for the February 16, 2024, application date.

ID: VIEW/E02605EA0C00
Name: v2_Justification, Objective, & Research Design

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

Providing housing to homeless individuals can greatly improve health outcomes. Over time, reducing homelessness has been shown to decrease emergency department visits, hospital days, and health care costs. Providing housing to homeless individuals has also been shown to benefit individuals with severe psychiatric illness and substance use disorder. The documented benefits of ending homelessness lend support to the Housing First model, which advocates for providing permanent housing to homeless individuals without requiring their participation in services, a contrast to previous models that made participation in services a prerequisite for receiving housing. Studies have demonstrated the health, quality of life, and financial benefits of the Housing First model, but the model's emphasis on obtaining permanent housing can act as a barrier for getting homeless individuals off the streets and out of shelters. Although obtaining permanent housing for individuals is the desired outcome, this is often difficult to achieve because there is a shortage of housing vouchers. Particularly affected are patients receiving methadone for opioid use disorder (MOUD), whose prevalence of homelessness might be as high as 25 percent. Studies investigating the effects of housing homeless individuals on MOUD outcomes are mixed. A secondary analysis of a Housing First intervention was not associated with improving the dispensing of MOUD. However, another study that provided permanent housing to homeless individuals receiving MOUD found that their rate of retention in methadone treatment was 2.5 times higher than a matched group of homeless individuals receiving MOUD who were not given housing.

References

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2. Baltimore City Continuum of Care. Point-in-Time Count Report. Published online 2020. Accessed February 25, 2022. https://drive.google.com/file/d/197okMLOAT9BZXYNux|SI_DXeVmNPnKcc/view
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2 If available, upload your applicable literature search:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E02605A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

During the first six months of the study, a member of the clinic social work team, on behalf of the patients, will manage monthly vouchers of $650 that can be used for temporary housing options from a list compiled by the study. These vouchers will be dispensed at the beginning of the month, and member of the clinic social work team will ensure these are used solely for housing purposes. The participants will meet with the member of the clinic social work team at least once a month for twelve months. These meetings could be scheduled as frequently as several times a week depending on the issues needing to be addressed for the participants. Social work assistance is already available to patients at the Addiction Treatment Program, but the social work assistance offered in this study would be more intensive and tailored specifically to the needs of the study participants. Because these meetings would address issues that would keep participants housed after the study ends, participants will be encouraged to schedule these meetings more frequently than once a month.

The goal of these meetings would be to ensure participants remain housed after the housing vouchers and study ends. The meetings could accomplish this goal in several ways. The member of the clinic social work team would conduct a needs assessment on the participants to determine barriers to stable housing and the sources of income are already available to the participant. A member of the clinic social work team could help participants obtain benefits for which they are eligible like Social Security Income. Participants could also take part in employment-training services that would allow them to be hired for jobs and gain income. Once the participants are housed, member of the clinic social work team could address issues placing them at risk for losing their housing such as resolving disputes with their landlords or teaching the participants budgeting strategies to manage their income and rent. The member of the clinic social work team would help the participants apply for permanent housing vouchers from the city of Baltimore so that the participants remain housed once the study is over. Attending meetings with the member of the clinic social work team will be required for the housing vouchers to be used on behalf of the participant, and participants will be removed from the study if they miss more than 50 percent of scheduled meetings with the member of the clinic social work team.

It is hypothesized that the stability provided by the housing vouchers and the meetings with member of the clinic social work team would allow participants to remain stably housed after the study ends. There is a possibility that the $650 housing voucher would not be enough to obtain temporary housing for the participants. The member of the clinic social work team could address this situation by helping the participants obtain sources of income such as benefits for which the participant might be eligible or helping the participant find employment. Participants might also have other sources of income through employment or government benefits that could supplement the $650 housing vouchers. Once the housing vouchers end, the next six months of meetings with the member of the clinic social work team would be dedicated to maintaining housing and obtaining permanent housing for the participants. If study participants are not housed by the end of the study or if they become homeless long after the study ends, then the participants would still have access to the social work assistance available to all patients at the ATP. This assistance can help connect patients at the ATP to housing resources, obtain benefits for which they are eligible, find temporary housing, or apply for permanent housing vouchers.

The principal investigator will conduct a chart review of the methadone doses that participants receive in the 3-month period before the study, between Months 3 and 6 of the study, and between Months 9 and 12 of the study. The review of methadone doses will calculate the number of doses participants received and took home with them instead of receiving at the clinic. In addition to a review of methadone doses, the principal investigator will document results of the urine toxicology tests for the participants in the 3-month period before the start of the study and monthly during the study. Participants will complete two surveys at Day 0, Month 6, and Month 12 of the study: the OUD Checklist, which rates opioid use disorder symptoms based on the DSM-5 criteria, and the SF-36, which measures quality of life. At Months 6 and 12, participants will complete qualitative interviews to determine how the vouchers and social work assistance impacted their financial and social well-being, and whether the SASH intervention was useful in combating homelessness. Data on the methadone doses, urine toxicology tests, surveys, and qualitative interviews will be stored in a password-protected database.

The principal investigator will calculate the percentage of days participants are homeless during the 6-month period when vouchers are distributed and at Month 12 of the study. The percentage of days participants are homeless will be calculated from data collected by the member of the clinic social work team. These data will be stored in a password-protected database. If there are concerns for the well-being of any of the participants in the study, including if a participant expresses thoughts to harm their self or others, then the principal investigator Max Spaderna, a board-certified psychiatrist, will be notified to address the situation. If there are medical concerns, one of the study investigators Aaron Greenblatt, a Family Medicine physician, will be notified to address the situation. If the situation involves a potentially life-threatening emergency, then the participant will be sent to the Emergency Department.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):

All the participants will be currently receiving methadone for opioid use disorder treatment at the Addiction Treatment Program.

3 * Describe the duration of an individual participant's participation in the study:

Participants will participate in the study for 12 months.

4 * Describe the amount of time it will take to complete the entire study:

The study will take 15 months to complete the study and data analysis.

5 * Describe any additional participant requirements:

Participants will be recruited for the study if they are receiving methadone from the Addiction Treatment Center at the University of Maryland and are struggling with homelessness, which will be defined as living in an emergency shelter or a place not meant for habitation instead of a fixed, regular, and adequate nighttime residence for at least 15 of the 30 days preceding the first month of the study.

ID: VIEW4E02806858400
Name: v2_Study Procedures

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:
The study will recruit eight participants. This is a feasibility study, so the results will be used as pilot data to apply for a larger grant.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:
All the participants in this study will receive the intervention. The participants will not be compared with a matched control group. Comparisons of the percentages of missed and take-home methadone doses will be completed in the 3-month period before the study, between Months 3 and 6 of the study, and between Months 9 and 12 of the study. Comparisons will be completed of the results of the urine toxicology tests in the 3-month period before the start of the study and each month during the study. Comparisons will be completed for the OUD Checklist and SF-36 scores at each of the three time points. The analyses will determine how the study interventions impacted outcomes for opioid use disorder treatment, quality of life, and housing.

ID: VIEW4E02800052800
Name: v2_Sample Size and Data Analysis

HP-00100771 Sharing of Results_V2

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:
The results will not be shared with either the participants or anyone not involved in the study. The results would be written in a manuscript, but none of the participants would be identifiable by name, and all the data would be de-identified.

ID: VIEW4E02608CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [x] **Key informant or semi-structured individual interviews**
- [ ] Focus groups or semi-structured group discussions
- [x] **Audio or video recording/photographing**
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations
- [x] **Psychosocial or behavioral interventions**
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [ ] Other psychosocial or behavioral procedures

ID: VIEWAE09416F57600
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:
OUD Checklist Score
SF-36
Homeless Days Review Form

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
Homeless Days Review Form(0.01)	7/6/2022 10:39 AM	7/6/2022 10:39 AM
SF-36 Form.pdf(0.01)	5/2/2022 10:02 AM	5/2/2022 10:02 AM
OUD Checklist.pdf(0.01)	5/2/2022 10:02 AM	5/2/2022 10:02 AM

3 * What is the total length of time that each survey is expected to take?
The OUD Checklist will take 10 minutes, the SF-36 will take 15 minutes, and the Homeless Days Review Form will take 10 minutes..

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)
● Yes ○ No

5 * Do any questions elicit information related to the potential for harm to self or others?
● Yes ○ No

5.1 If Yes, what procedures are in place to assure safety?
All interviews will be conducted in a private room with only the participant and research staff conducting the patient present. If a participant makes any statement or exhibits any behavior concerning for self-harm, then the principal investigator Max Spaderna, who is a board-certified psychiatrist, will be notified by the interviewer. If the participant is deemed an acute risk for self-harm, then the study team would ensure the patient goes the Emergency Department for a safety evaluation. If after discussing the situation, the situation is deemed not to require an emergency evaluation, then the team can work with the participant to address any unmet psychiatric needs including referring the participant to outpatient psychiatric treatment, which is available at the 1001 clinic. All data will be stored in a password-protected database.

ID: VIEW4E69460F5EC00
Name: v2_Surveys/Questionnaires

HP-00100771 Interviews_V2

Interviews

You indicated that this study involves key informant or semi-structured individual interviews.

1 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., illegal activities)
● Yes ○ No

2 * Upload a copy of the interview script or guide that will be used to guide the interviews:

Name	Created	Modified Date
SASH Qualitative Interview Guide(0.01)	6/21/2023 8:45 AM	6/21/2023 8:45 AM

3 * What is the individual duration of each interview and what is the entire duration of the interviews?
Each interview will take 30 minutes. Given that there are 8 participants in the study and each participant will be interviewed twice, the enter duration of the interviews will be eight hours.

4 * How will the interview responses be recorded and by whom?
The interviews will be recorded on a password-protected computer and stored in a password-protected database.

5 * Do any questions elicit information related to the potential for harm to self or others?
○ Yes ● No

5.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E0947A633C00
Name: v2_Interviews

Audio or Video Recording/Photographs

You indicated that this study involves audio or video recording/photographing.

1

*Indicate the type of recording (check all that apply):

- ☐ Video
- ☑ **Audio**
- ☐ Still Photo
- ☐ Other

1.1

If Other, specify:

2

*What is the purpose of the recording? (i.e., for therapeutic purposes, to establish treatment fidelity, or to establish reliability of assessments)

The purpose of audio-recording the interviews is to ensure accuracy of the responses of the participants.

3

*Could the recording be likely to cause discomfort in participants or cause harm if their confidentiality were breached?

○ Yes ● **No**

4

*How will individuals' identities be protected?

The responses from these interviews will be stored on a password-protected computer accessible only to staff involved in the study.

ID: VIEW4E094C128C800
Name: v2_Audio or Video Recording / Photographs

Behavioral Intervention

You indicated that this study involves psychosocial or behavioral interventions.

1 * Describe the intervention (duration, number of sessions, focus, etc.):

Starting in September 2022, monthly housing vouchers will be managed by member of the clinic social work team on behalf of the eight participants in the study. During the first six months of the study, the member of the clinic social work team will use the monthly $650 vouchers to obtain temporary housing included on a list compiled by the study. The type of housing on this list could include rooms in a private dwelling, hotel rooms, or living spaces shared with roommates. In addition to receiving these stipends, each participant throughout the 12 months of the study will attend regularly scheduled meetings at the ATP with a member of the clinic social work team from the University of Maryland Addiction Treatment Program (ATP).

During these meetings, the member of the clinic social work team would conduct a needs assessment on the participant to determine barriers to the participant's receiving and remaining in stable housing. The social work assistance provided at these meetings would be more intensive than what is usually provided at the ATP, and the assistance would be individualized to the needs of the participants. A member of the clinic social work team would help participants obtain sources of income by obtaining government benefits for which the participants are eligible or helping the participants gain employment. They would address issues placing the participants at risk for losing their housing such as disputes with their landlords or difficulties budgeting finances. They would also help the participants apply for permanent housing vouchers from the city of Baltimore so that the participants are housed once the study ends. The meetings will be scheduled at least monthly, but participants will be encouraged to schedule these more frequently.

A member of the clinic social work team would administer the surveys documenting the percent of days participants are homeless. A member of the clinic social work team could keep written notes for supervision or treatment purposes, but no other written documentation from these meetings would be kept for study or research purposes. The results of the surveys would be uploaded to a password-protected electronic database. After the results of these surveys are uploaded to the password-protected database, any written documentation of these surveys will be discarded in receptacles designated for destroying documents with patient-health information. Written documentation for the member of the clinic social work team would not contain any information identifying the participants to ensure confidentiality. Any written documentation needed by the member of the clinic social work team that contained information identifying the participants would be kept at the ATP in a locked cabinet accessible only to staff associated with the study.

Once the housing vouchers end, the next six months of meetings with the member of the clinic social work team would be dedicated to maintaining housing and obtaining permanent housing for the participants. If study participants are not housed by the end of the study or if they become homeless long after the study ends, then the participants would still have access to the social work assistance available to all patients at the ATP. This assistance could help connect participants to housing resources, apply for benefits for which they are eligible, obtain temporary housing if needed, or apply for permanent housing vouchers.

ID: VIEW4E0BC12A9F800
Name: v2_Behavioral Interventions

HP-00100771 Data Collection_Record_V2

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

- ☐ Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
- ☑ **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?

○ Yes ● **No**

3 * Will the data be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW/1E0E25A8CA400
Name: v2_Data Collection / Record Review

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

- [x] **Medical records**
- [ ] Medical images
- [ ] Commercial (for profit) entity
- [ ] Publicly available records
- [ ] Schools
- [ ] Other

1.1 If Other, please specify:

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.

We will have information on names, dates of birth, and doses of methadone. The information will be stored in a password-protected database to protect the confidentiality of participants. Only study investigators will have access to this database.

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date
Form for Review of Methadone Doses(0.02)	6/24/2022 1:03 PM	6/24/2022 1:06 PM
Form for Review of Days Homeless(0.01)	6/24/2022 1:05 PM	6/24/2022 1:05 PM
Form for Review of Urine Toxicologies(0.01)	6/24/2022 1:03 PM	6/24/2022 1:03 PM

ID: VIEW4E0E26B043800
Name: v2_Prospective Data

HP-00100771 Clinical Trial Registration_V2

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?
(●) Yes ( ) No

2 * Has this trial been registered?
(●) Yes ( ) No

ID: VIEW4E0936F075C00
Name: v2_Clinical Trial Registration

HP-00100771 Clinical Trial Registration Info_V2

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
● Yes ○ No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
○ Yes ○ No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT05803603

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
30

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
8

Worldwide - the number being enrolled total at all sites (including local enrollment):
8

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn Infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 to 88 years (Adult)**
- [ ] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

*Are you excluding a specific population, sub-group, or class?

○ Yes ● No

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E619C1D000
Name: v2_Participant Selection

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [x] **Economically/Educationally Disadvantaged**
- [ ] None of the above

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

HP-00100771

Vulnerable Populations Economically or Educationally Disadvantaged_V2

Vulnerable Populations - Economically/Educationally Disadvantaged

You indicated that economically or educationally disadvantaged persons are included in this study.

1 * Describe how you will prevent undue influence or coercion with this population.
Participation in this study will be voluntary, and the study team will not use any coercion to convince patients at the 1001 clinic to enter the study. The decision to participate or continue participation in the study will not affect the treatment that participants receive at the Addiction Treatment Center. Participants who decide not to participate in the study will still be eligible for the social work assistance provided at the 1001 clinic, which could address their housing and other unmet social needs.

2 * Describe the additional safeguards that have been included in the study to protect the rights and welfare of these participants.
Participants will undergo an informed consent process, during which participants will be given the opportunity to ask any questions or bring up any concerns about the study. The information from this study will not be given to anyone outside of the study, and it will not be used in the treatment participants receive at the Addiction Treatment Center.

ID: VIEW8D68FCA58796D9B
Name: v2_Vulnerable Populations - Economically/Educationally Disadvantaged

HP-00100771 Eligibility_V2

Eligibility

1 *Do you have an existing Eligibility checklist(s) for this study?
○ Yes ● No

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
There are no items to display		

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Participant must be receiving methadone for opioid use disorder treatment at the University of Maryland Addiction Treatment Center.
View	2	Participant must be living in an emergency shelter or a place not meant for habitation instead of a fixed, regular, and adequate nighttime residence for at least 15 of the 30 days preceding the first month of the study.
View	3	Participant expects to continue receiving methadone treatment at the Addiction Treatment Program at the University of Maryland for at least a year.

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Participant is unwilling to meet with the member of the clinic social work team at the Addiction Treatment Center for regularly scheduled appointments to address their housing and other unmet social needs.
View	2	Participant expects to have their own housing within the next three months.
View	3	Participant expects to enter an intensive outpatient substance use program that has supportive housing within the next three months.
View	4	Participant has either children or dependents living with them.

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00100771_5 v5-17-2023-1684328253454(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

HP-00100771 Recruitment_V2

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):
Participants will be recruited from the Addiction Treatment Program (ATP) at the University of Maryland. The Principal Investigator Max Spaderna and ATP Medical Director Aaron Greenblatt will lead recruitment. Copies of the pre-screening questionnaire will be placed near locked research-from drop boxes located in the waiting areas of the clinic and collected by designated research staff. ATP staff will also be made aware of the study and may refer patients to either these drop boxes or to research staff. Research staff that connect with an interested candidate will have the person complete the pre-screening questionnaire, which will be forwarded to either Max Spaderna or Aaron Greenblatt. Candidates who pass the pre-screening criteria will be discussed at a meeting with the study investigators to determine which eight candidates would be most appropriate for the study. Criteria to decide the eight candidates for the study would include commitment to receiving methadone treatment at the ATP, suspected likelihood the candidate would be able to attend the meetings with the member of the clinic social work team, and likelihood the candidate will remain homeless without receiving the study interventions. After being chosen, the eight candidates will be contacted and informed about being chosen for the study. If the candidate is interested in taking part in the study, then a designated staff member of the study will schedule a time to meet with the candidate to review the Informed Consent Form for the study. The candidate will be enrolled in the study once they agree to the Informed Consent Form. If the candidate does not agree to join the study, then the study investigators will meet to choose another candidate for the study.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):
Enrollment in the study will be voluntary, and participants will be made aware that they do not have to accept the member of the clinic social work team managing the housing vouchers and social work assistance. All participants will undergo an informed consent process to ensure they understand the risks and benefits of the study. If prospective candidates for the study decide not to participate, the opioid use treatment and social work assistance they already receive at the ATP will not be affected.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] PI
- [x] Study Staff
- [ ] Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
Criteria for SASH Recruitment(0.01)	6/21/2023 10:11 AM	6/21/2023 10:11 AM

ID: VIEW4E0BCAA0A5C00
Name: v2_Recruitment

HP-00100771 Advertising_V2

Advertising

1 * Will you be using advertisements to recruit potential participants?
◯ Yes ● No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/ seriousness of the risk, and the provisions for minimizing the risk:

The risks participants could experience through their involvement in this study are a breach of confidentiality, a loss of privacy, and participant discomfort.

Breach of confidentiality: All information from the study about patients will be stored in a password-protected database that will only be accessible to staff members associated with the study. Any physical data that cannot be stored on a computer will be stored in a locked cabinet in a secure location at the Addiction Treatment Program. Only staff directly involved in the study will have access to this physical data.

Loss of Privacy: The informed consent process, meetings with the social workers, surveys, and interviews will take place in a private and closed office at the Addiction Treatment Program to protect the privacy of the participants. Only the participant and staff associated with the study will be present in the office. If there is any concern that this location is not sufficiently protecting the privacy of the participant, then the meeting will end until another location can be found to protect the privacy of the participant.

Participant Discomfort: Participants could feel uncomfortable responding to the surveys and interviews they will be asked to complete. Participants will be informed that they can choose not to answer any question or share any information that makes them feel uncomfortable during the surveys and interviews.

ID: VIEW4E1B62509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
Many individuals receiving methadone for opioid use disorder are homeless and lack the resources to obtain housing, a predicament that negatively impacts their medical and opioid use disorder care. By obtaining the housing vouchers for temporary housing and social work assistance, these individuals could experience improvements in their opioid use disorder and methadone treatment, quality of life, and housing.

2 * Describe the importance of the knowledge expected to result from the study:
While previous studies have shown the benefits of providing permanent housing to individuals receiving methadone for opioid use disorder, none have investigated the benefits of providing temporary housing and social work assistance to these individuals. The potential benefits of these interventions could include improvements in their opioid use disorder and methadone treatment, quality of life, and housing. The data from this study would be written in a manuscript and used as pilot data to apply for a larger grant.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
The greatest risk to participants in this study is a breach in confidentiality, which would cause minimal harm if this did occur because the data collected in this study would not risk the legal or health status of the study participants. The potential benefits of the study are improvements in opioid use disorder and methadone treatment, quality of life, and housing. These potential benefits greatly outweigh the study's low potential risk of harm.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
Participation in this study is voluntary, so the alternative is not to participate in the study.

ID: VIEW4E1852618040O
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
Participants could be withdrawn if the study investigators do not believe that continuing in the study is in the participant's best interest, if they miss more than 50 percent of the monthly meetings with members of the clinic social work team, enter substance use treatment that is associated with housing, or discontinue their methadone treatment at the Addiction Treatment Program.

2 * Describe procedures for orderly termination:
Study investigators would try to engage participants who do not attend meetings with members of the clinic social work team. If participants continue to miss meetings or if continuing in the study would not be in the best interest of the participant, then study investigators would contact the participant to explain the reason for their termination from the study. The study investigators would explain to the participant that their removal from the study would not affect the care they receive at the Addiction Treatment Program (ATP), and the participant would be given the opportunity to ask questions about their removal from the study. If the participant is in temporary housing paid for by the housing vouchers, or if the study had been helping the participant apply for government benefits, gain employment, or apply for permanent-housing vouchers, then staff from the study would update the social workers at the ATP and help transition the participant to the social work assistance available to all patients at the ATP. The goal of doing this would be to give the participant the best opportunity to remain housed and continue the work started during the study.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
Data from the participants removed from the study would be included in the data analysis. Any termination or withdrawal from the study would be noted in the manuscript documenting the results of the study. The care participants receive for their opioid use disorder would not be affected by their withdrawal from the study.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
All meetings with the participants will be held in a private office located at the Addiction Treatment Program. Information gathered from these meetings will only be disclosed to staff involved in the study. Electronic data from the study would be stored in a password-protected database to protect the participant's information. Any physical data would be stored in a locked cabinet in a secure location that could only be access to by study staff.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:
All study interactions with participants will take place in a private office located at the Addiction Treatment Program. The office will be closed, with only staff and the participant present in the room.

3 * Describe potential environmental stressors that may be associated with the research:
There are no potential environmental stressors associated with this research.

4 * Will this study have a site based in the European Union?
○ Yes ● No

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?
○ Yes ● No

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B526B67C00
Name: v2_Privacy of Participants

HP-00100771 Confidentiality of Data_V2

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) Yes
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

Electronic data will be stored and secured in a password-protected database. Any physical data will be stored in a locked cabinet in a locked room at the Addiction Treatment Program. This cabinet will be accessible only to study staff.

3 * How will such data be secured?

Electronic data will be stored in a password-protected database accessible only to staff associated with the study. Physical data will be stored in a locked cabinet in a locked room at the Addiction Treatment Program.

4 * Who will have access to research data?

Only staff participating in the study will have access to the data.

5 * Will study data or test results be recorded in the participant's medical records?

( ) Yes (●) No

6 * Will any data be destroyed? **(Please note that data for FDA regulated research cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)**

( ) Yes (●) No

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?

( ) Yes (●) No

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:

There is a small chance of a breach in confidentiality or loss of privacy. Meeting with participants in private locations, having data accessible only to staff associated with the study, storing electronic data in a password-protected database, and storing physical data in a locked cabinet located in a secure location would mitigate the risk of participants' experiencing a breach of confidentiality.

ID: VIEW4E1B5265E0400
Name: V2_Confidentiality of Data

HP-00100771 Monitoring Plan Selection_V2

Monitoring Plan Selection

1 *Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ○ Data Safety Monitoring by a Committee
- ○ Data Safety Monitoring by an Individual
- ● **There is no data safety monitoring plan in place**

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

No Monitoring Plan

You indicated that there is no data safety monitoring plan in place for the study.

1 * Provide the rationale for why a data safety monitoring plan is not necessary for this study:
Any breach in confidentiality or loss of privacy would pose minimal harm to study participants, as the data collected in this study would not risk the health or legal status of the study participants.

ID: VIEW-iE1B07B5A2400
Name: v2_No Monitoring Plan

HP-00100771 Research Related Costs_V2

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- ☑ **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- ☐ Investigational or Study Device
- ☐ Investigational or Study Drug
- ☐ Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- ☐ Participant
- ☐ Sponsor
- ☐ UM
- ☐ Other
- ☑ **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

○ Yes ● No

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

○ Yes ● No

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

HP-00100771 Payment to Participants_V2

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

● Yes ○ No

ID: VIEW4E1C52A6D7800
Name: v2_Payment to Participants

Payment/Reimbursement Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research.

1 * Payment/reimbursement to participants will be for: (check all that apply)

- [ ] Travel
- [ ] Parking
- [ ] Meals
- [ ] Lodging
- [x] **Time and effort**
- [ ] Other

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more in a calendar year is required to be reported on an IRS Form 1099.***
$80

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?
The participants will receive $40 in either cash or check each time they complete the surveys and qualitative interview at Month 6 and 12 of the study. The maximum direct compensation each participant can receive during the study is $80.

4 * Method(s) of payment/reimbursement to be Used:

- [x] **Cash**
- [x] **Check**
- [ ] Money Order
- [ ] Gift Certificate/Gift Card
- [ ] Other

4.1 If Other, specify:

ID: VIEW4E1C54A6A0000
Name: v2_Payment Detail

HP-00100771 HIPAA_V2

HIPAA (Health Insurance Portability and Accountability Act)

1 *Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*

● Yes ○ No

2 *If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?

● Yes ○ No

ID: VIEWME1B0A2114400
Name: v2_HIPAA

HP-00100771 Protected Health Information_V2

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [x] **Address (if more specific than Zip Code)**
- [ ] Dates
- [ ] Ages over age 89
- [x] **Telephone numbers**
- [ ] Fax numbers
- [x] **Email addresses**
- [x] **Social Security numbers**
- [x] **Medical record numbers**
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [ ] Full-face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- [ ] None

2 * Why is the PHI necessary for this research?
If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).
The PHI in this study will be used to obtain information about methadone dosing, results from the urine toxicology tests, and how to contact participants. Addresses will be collected when participants obtain housing so that staff can contact participants if necessary. Email addresses will be collected from participants who have these as a means of contacting them during the study. Social Security Numbers would be obtained so members of the clinic social work team can help the participants apply for government benefits or permanent-housing vouchers.

3 * What is the source(s) of the PHI?
The sources of the PHI will be from the participants; Methasoft, the software the Addiction Treatment Program uses to document methadone doses for its patients; and Epic, the electronic medical record the Addiction Treatment Program uses to store contact information and results of the urine toxicology tests.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
Protected Health Information will not be reused for purposes outside the scope of this study.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [x] **Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")***
- [ ] Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- ☐ Not applicable (study may qualify as exempt)
- ☐ Request to Waive Consent/Parental Permission (Consent is not being obtained)
- ☐ Request to Alter Consent (Some Elements of Consent Waived)
- ☐ Request to Waive Documentation of Consent (Verbal/Oral Consent)
- ☑ **Written Consent Form**
- ☐ Electronic Consent

2 * Describe the Informed Consent process in detail:
The participants will be brought to a private office at the Addiction Treatment Program (ATP). A designated study member will discuss the purpose and brief synopsis of the study to the participants as well as a discussion of the potential risks and benefits of participant in the study. The approved study member would conduct the Informed Consent with the participant and will allow the participant to ask questions to ensure they understand the information explained to them. After the Informed Consent has been discussed and the participant has asked their questions about the study, the participant will sign the Informed Consent Form.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

● Yes ○ No

4 * Describe who will obtain Informed Consent:
An approved study team member would obtain Informed Consent.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*
N/A

6 * Describe the setting for consent:
The consent process will take place in a private office located at the ATP.

7 * Describe the provisions for assessing participant understanding:
The designated study member conducting the Informed Consent will ask questions to ensure the participant understands the information explained to them. The participant will be provided an opportunity to ask any questions during the process.

8 * Describe the consideration for ongoing consent:
Participants can withdraw their consent to participate in the study at any time. Participants will be informed if there any changes in the risks of participating during the study. If participants decide to withdraw their consent, they will be informed that the treatment they receive at the Addiction Treatment Program will not be affected.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
SASH Informed Consent Form(0.01)	6/26/2023 8:28 AM	6/26/2023 8:28 AM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
SASH Informed Consent 06142023.docx(0.01)	6/14/2023 10:34 AM	6/14/2023 10:34 AM
Informed Consent Form(0.02)	7/7/2022 9:34 PM	7/11/2022 8:21 AM

2 Upload any HIPAA authorization forms here:
There are no items to display

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates: http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEWIE1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Psychiatry

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● No

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● No
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● No

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● No

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ○ Yes ● No

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ○ Yes ● No

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ○ Yes ● No

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Psych Adult	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

HP-00100771

Additional Documents_V2

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
citiCompletionCertificate_Clayton.pdf(0.01)	11/18/2022 10:41 AM	11/18/2022 10:41 AM
Certificate_ HIPAA 201 - Clayton.pdf(0.01)	11/18/2022 10:41 AM	11/18/2022 10:41 AM
Certificate_ HIPAA 125 - Clayton.pdf(0.01)	11/18/2022 10:41 AM	11/18/2022 10:41 AM
SASH_Intake Form.pdf(0.01)	10/25/2022 1:49 PM	10/25/2022 1:49 PM
Smith HIPAA 201.pdf(0.01)	10/18/2022 3:52 PM	10/18/2022 3:52 PM
Smith HIPAA 125.pdf(0.01)	10/18/2022 3:52 PM	10/18/2022 3:52 PM
Smith CITI.pdf(0.01)	10/18/2022 3:52 PM	10/18/2022 3:52 PM
Krebs_HIPAA.pdf(0.01)	10/18/2022 3:50 PM	10/18/2022 3:50 PM
Krebs_CITI.pdf(0.01)	10/18/2022 3:50 PM	10/18/2022 3:50 PM
Bradley_ HIPAA.pdf(0.01)	10/18/2022 3:49 PM	10/18/2022 3:49 PM
Bradley CITI.pdf(0.01)	10/18/2022 3:49 PM	10/18/2022 3:49 PM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
Psych Adult	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1810C500000
Name: v2_Final Page of Application

Add a Team Member

1 * Select Team Member:
Jewell Benford

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Mr. Benford, LCSW-C, is the Compliance Officer for the UM Addiction Treatment Programs. He will help supervise social work activities in the clinic and implementation of social work intervention.

Add a Team Member

1 * Select Team Member:
Aaron Greenblatt

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● Yes ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● Yes ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Greenblatt is the Medical Director at the site where the research will take place. He has extensive experience working with patients receiving methadone for opioid use disorder treatment. He will lead patient recruitment for the study.

Add a Team Member

1 *Select Team Member:
Hannah Smith

2 Research Role:
Research Team Member

3 *Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● No

4 *CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● No

5 *Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 *Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
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