ED-HOME: A PILOT FEASIBILITY STUDY OF A HOMELESSNESS PREVENTION INTERVENTION FOR SUBSTANCE USING EMERGENCY DEPARTMENT PATIENTS

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Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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List of Abbreviations

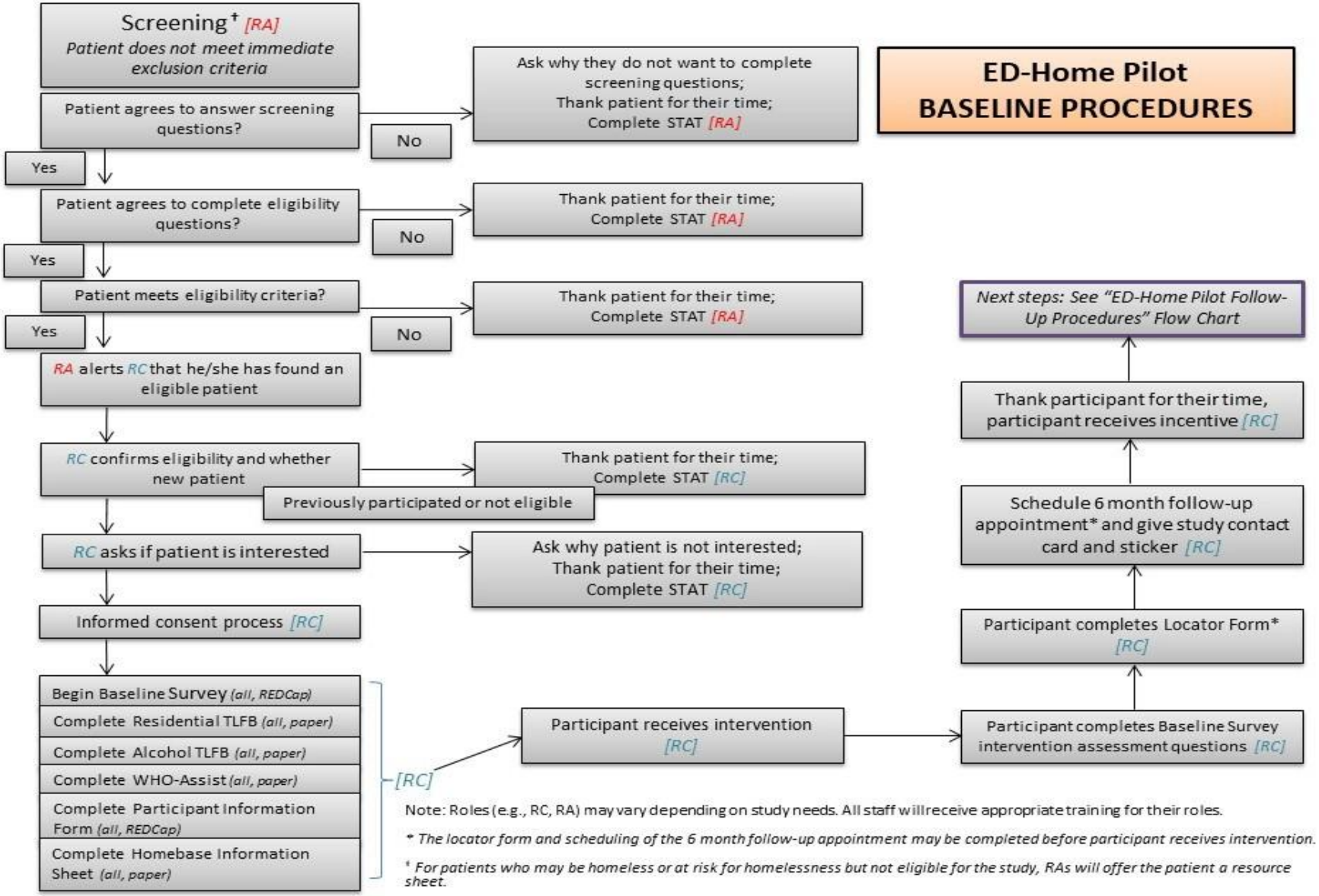
AE	Adverse Event/Adverse Experience
AES	Adult Emergency Services (Bellevue Hospital)
DSMB	Data and Safety Monitoring Board
ED	Emergency Department
FFR	Federal Financial Report
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HRST	Homelessness Risk Screening Tool
ICF	Informed Consent Form
IRB	Institutional Review Board
N	Number (typically refers to participants)
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PES	Pediatric Emergency Services (Bellevue Hospital)
PI	Principal Investigator
RA	Research Assistant
RC	Research Coordinator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UC	Urgent Care (Bellevue Hospital)

Throughout this document, attachments (e.g., study surveys and other instruments) are designated using *underlined italic* font.

Protocol Summary

Title	ED-Home: A pilot feasibility study of a homelessness prevention intervention for substance using emergency department patients
Short Title	ED-Home
Brief Summary	This is a single-arm pilot study to test the feasibility of homelessness prevention and substance use interventions to be delivered to at-risk patients in the Bellevue Hospital emergency department (ED). ED patients (n=40) found eligible for the study will complete a baseline survey and receive referrals to appropriate services, with a final six-month follow-up survey. Interim contacts at 7-10 days, 3 months, and 5 months will be used to assure intervention components were received and to confirm participant contact information. A chart review of participant Bellevue Hospital Center visits will also be performed at the time of the six-month follow-up visit.
Phase	N/A
Objectives	The primary objective is to test the feasibility and acceptability of implementing a homelessness prevention intervention for ED patients with unhealthy alcohol or drug use who are at risk for homelessness.
Methodology	Single-arm pilot feasibility study with pre-post outcome measurement.
Endpoint	Primary endpoints are feasibility of the study and intervention (e.g., participant satisfaction, ability to enroll participants, ability to contact participants at follow-up time points). Exploratory outcomes include 6-month housing and substance use measures.
Study Duration	Approximately 1.5 years.
Participant Duration	Participants will complete a final follow-up survey 6 months after enrollment/baseline visit.
Duration of behavioral intervention	The intervention delivered by investigators will consist of one-time, in-person referrals (at the time of the baseline/enrollment ED visit) and up to 3 follow-up trouble shooting phone calls to occur within 3 months of the initial visit.
Population	Adult (≥18 years old), ED patients with unhealthy alcohol or drug use who are not currently homeless but who are predicted to have a high risk of future homelessness. Patients must speak English, reside in NYC, not be critically ill, and not currently be incarcerated. Patients will not be excluded based on race or gender. Projected sample size: approximately n=40.
Study Sites	NYULH and Bellevue Hospital Center Emergency Department
Number of participants	Approximately 40 participants are expected to be enrolled.
Description of Study Intervention/Procedure	The intervention will consist of: 1) Referral to Homebase homelessness prevention services offered by community-based organizations in NYC; 2) Referral to substance use services (SBIRT and Addiction Leads) available at Bellevue Hospital; 3) Follow-up to ensure participants receive needed services.
Reference Therapy	Standard ED care, which includes referral to the ED social worker and existing substance use treatment services at provider discretion.
Key Procedures	No invasive procedures will be conducted.
Statistical Analysis	Primary feasibility endpoints will be analyzed using descriptive statistics (proportions, means, etc.). Secondary/exploratory end-points will use appropriate comparisons of baseline and 6-month follow-up data.

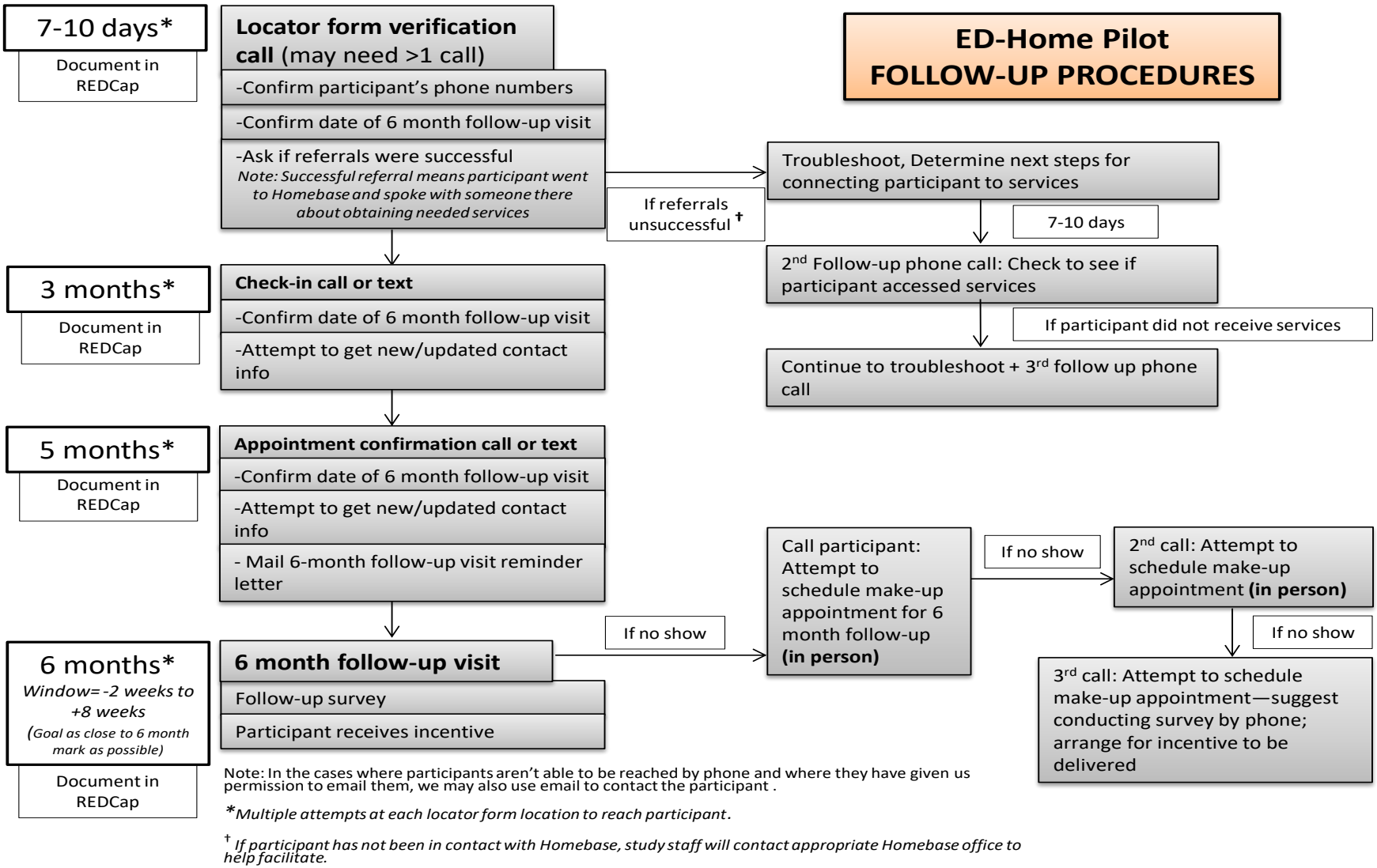
Schematic of Study Design



Note: Roles (e.g., RC, RA) may vary depending on study needs. All staff will receive appropriate training for their roles.

** The locator form and scheduling of the 6 month follow-up appointment may be completed before participant receives intervention.*

† For patients who may be homeless or at risk for homelessness but not eligible for the study, RAs will offer the patient a resource sheet.



Note: In the cases where participants aren't able to be reached by phone and where they have given us permission to email them, we may also use email to contact the participant .

**Multiple attempts at each locator form location to reach participant.*

† *If participant has not been in contact with Homebase, study staff will contact appropriate Homebase office to help facilitate.*

1 Key Roles

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2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Homelessness prevention: promise and challenges. Evidence is mounting that timely yet relatively brief interventions can prevent people from having to enter a homeless shelter.[1,2] Homelessness prevention is of increasing interest to policy-makers and has been expanded in the U.S. over the last several years.[2-5] So far prevention interventions have been implemented in populations including families, veterans, and people with mental illness leaving treatment.[2,5-10] Specific interventions have included time-limited rental subsidies or back-rent payments, landlord mediation, improved institutional discharge planning, and other short-term crisis interventions.[2,5-10] Such interventions have been successful in averting homelessness even in environments marked by structural issues like tight housing markets and low affordable housing availability.[11] One challenge with prevention efforts, however, has been efficiently targeting services to people who are likely to become homeless in the absence of an intervention.[4-6,9,10,12,13] In addition, prevention services are usually only provided to those people who seek them, missing people who are unaware of or unable to access such services.[9]

Emergency departments as sites for homelessness risk screening and prevention. The emergency department (ED) may be an ideal location for homelessness risk screening and prevention, reaching people who are at high risk for homelessness and who might not otherwise access specialized prevention services. The Veterans Health Affairs system has implemented universal homelessness screening and referral in its clinics,[7] yet no research has explored homelessness prevention among ED patients. More than 130 million visits are made to U.S. EDs each year.[14] As the health care "safety net," EDs care for the most vulnerable populations in our society.[15-18] EDs are mandated to care for anyone who walks through their doors for any reason,[19] making them uniquely accessible among health and social service sites. People turn to EDs not just during health crises, but also during life crises. A VA study found a statistically significant increase in the number of ED visits veterans make in the 30 days prior to becoming homeless.[20] A study of new homeless shelter entrants in New York found that 34% had used an ED in the past year.[21] A disproportionate share of ED patients are homeless[22-24] or at risk for homelessness. For example, a survey of all patients presenting over 24 hours in three Michigan EDs found that 3.5% had been evicted in the past year and 16% lived in crowded housing.[16] A survey of 1,500 Philadelphia ED patients found that 18.1% reported housing instability.[25] Other surveys of ED patients have found high levels of food insecurity, low income, and other risk factors for homelessness.[16,25-28] In a preliminary study of 625 randomly selected Bellevue Hospital ED patients surveyed over the course of 3 months, 30.5% had a history of homelessness in their lifetimes and 19.8% had been homeless in the past year. Among those not currently homeless, 18% were worried about having stable housing in the next 2 months. Further, 9.1% had been evicted at least once in the past year.

ED patients with unhealthy alcohol or drug use may be at even higher risk of homelessness than other ED patients given the strong associations between homelessness and substance use. One study of 19,055 ED patients found that those who screened positive for substance use had very high rates of homelessness or unstable housing: 22.8% were currently living in a shelter or on the streets and an additional 36.1% were "doubled up" with family or friends.[29] With more than 5.1 million visits for substance use-related problems annually[30] and nearly one-third of ED patients screening positive for unhealthy alcohol or drug use,[31] EDs may be important sites for interventions to prevent homelessness among substance users. Given that only a small subset of substance users and people who are homeless access specialty substance treatment programs, and that both populations face barriers to accessing primary care,[32-39] ED-based prevention programs have the potential to reach more people—and potentially more vulnerable people[40]—than interventions at other sites.

Summary. EDs have potential as important health care delivery settings for homelessness prevention efforts among all patients, and particularly among patients with unhealthy alcohol or drug use. In earlier research, we developed an empirically-based homelessness risk screening tool (HRST) to identify ED patients at high risk for future shelter entry. We also conducted qualitative interviews with ED patients to learn about their pathways to homelessness and thoughts about future homelessness prevention

interventions. *In the current study, we will build upon this past work to conduct a pilot study to test the feasibility of an intervention designed to prevent homelessness among ED patients with unhealthy alcohol or drug use.*

2.2 Rationale

The goal of this study is to test the feasibility and acceptability of implementing a homelessness prevention intervention for ED patients with unhealthy alcohol or drug use who are at risk for homelessness. It is important to conduct this pilot feasibility study because there have been no prior studies of ED-based homelessness prevention interventions, and therefore a pilot study is an appropriate first step in expanding our knowledge and determining whether and how future interventions and studies will be possible. Given that this is a feasibility study, the choice of a single-arm study (intervention arm only) is appropriate. This feasibility study will inform a larger future trial of homelessness prevention interventions for substance using ED patients. Attempting to prevent homelessness among ED patients is important for the reasons stated in section 2.1.

2.3 Potential Risks & Benefits

2.3.1 Known Potential Risks

There is no known risk from the intervention itself. The study presents minimal risks. Study subjects are not expected to face any physical or financial risks as a result of participating in the study. Legal risks to study subjects are minimal despite the sensitive nature of some study questions, given that all study subject information will be treated as confidential and securely protected, and a NIH Certificate of Confidentiality has been obtained for this study. There are small risks of psychological discomfort, fear that refusal to participate will affect health care services, and potential breach of confidentiality.

1. Discomfort associated with answering personal questions during study surveys/assessments (immediate risk): Participants will complete surveys that include questions on health status, mental health, substance abuse, socioeconomic status, homelessness and housing, and other topics that may cause personal discomfort or anxiety. In the informed consent process, participants will be instructed that they can divulge as little or as much as they choose and are free to withdraw from the study at any time and for any reason.

2. Fear that refusal to participate will affect care or services (immediate risk): Given that participants will be recruited while they are patients in the Bellevue Hospital ED, they may fear that refusal to participate in the study will adversely affect the care they receive. This risk is minimal because research staff who will be enrolling patients into the study are not part of the patients' treatment teams, and it will be clearly explained to potential participants that refusal to participate will in no way affect their care in the Bellevue Hospital ED.

3. Potential breaches of confidentiality (immediate and long-term risk): There is a small risk of breach of confidentiality. A breach of confidentiality could potentially be damaging to study subjects if personally identifying information was released along with their answers to the baseline surveys. Such a breach is improbable, however, because of the safeguards that will be taken around the storage of personally identifying information.

Given the steps that we will take to minimize the chances of breach of confidentiality and other risks, participating in this study presents low risk and thus the risk/benefit ratio is favorable, particularly given the potential benefits to participants described below. Further, the knowledge gained from the proposed research has the potential to benefit future ED patients who are at risk for homelessness.

2.3.2 Known Potential Benefits

All participants in the study will receive an intervention that includes: 1) Referral to Homebase homelessness prevention services offered by community-based organizations in NYC; 2) Referral to substance use services (SBIRT and Addiction Leads / peer counselor) available at Bellevue Hospital; 3)

Follow-up to ensure patients receive needed services. A prior randomized controlled trial showed that people receiving Homebase services in NYC had lower risk of entering a homeless shelter in the future.[11] Therefore, one potential benefit to pilot study participants is that they will be referred to—and if they go and are found eligible will receive—services that may reduce their risk for future homelessness. Participants will also receive referrals to appropriate substance use services that are already offered at the study hospital, including SBIRT (screening, brief intervention, and referral to treatment) and peer navigator/social work services (Addiction Leads). Prior research has suggested that receipt of such services in the ED may improve substance use related outcomes for some patients, particularly those with unhealthy alcohol use.[31,41,42]

3 Objectives and Purpose

The primary objective of this study is to test the feasibility and acceptability of implementing a homelessness prevention intervention for ED patients with unhealthy alcohol or drug use who are at risk for homelessness. Accomplishing this objective will allow us to modify the intervention and study designs to be proposed for a future larger, multisite study that will include testing for outcomes/efficacy.

3.1 Primary Objective

The primary objective of this study is to test the feasibility and acceptability of implementing a homelessness prevention intervention for ED patients with unhealthy alcohol or drug use who are at risk for homelessness.

3.2 Secondary Objectives (if applicable)

Not applicable.

4 Study Design and Endpoints

4.1 Description of Study Design

We will conduct a single-arm (intervention only) pilot feasibility study of a homelessness prevention and substance use intervention for Bellevue Hospital ED patients with unhealthy alcohol or drug use who are at risk for future homelessness, with longitudinal follow-up to 6 months after the baseline visit.

4.2 Study Endpoints

4.2.1 Primary Study Endpoints

Given the primary study objective around feasibility and acceptability, the primary study endpoints represent a constellation of feasibility and acceptability measures that will be informative in modifying/developing a future larger intervention study. We will track the number of patients approached, the number screening positive for unhealthy alcohol or drug use, the number screening positive for homelessness risk, and the number of those eligible for the intervention who agree to participate. We will track reasons for study ineligibility and refusal, and will compare basic characteristics (e.g., gender, age, race, drug and alcohol use) of those who agreed and did not agree to participate. We will also track the number and location of referrals made for homelessness prevention and/or substance use services, the number of appointments kept, the number and types of homelessness prevention and other services actually received, and the length of time between the ED intervention and receipt of services. We will track the ability to contact patients for the 6-month follow-up interview (e.g., number of calls needed). Data sources for these feasibility endpoints include the *ED-Home Baseline Screening and Survey* (see attachment) and the participant tracking and follow-up information that will be documented on REDCap (*ED-Home Follow-up Procedures Form* and *ED-Home Tracking Form)* and using a tracking log in Excel that will be used internally to manage participant status, attempts of contact with participants, attempts of contact with providers, and necessary follow-up steps; no protected health information will be recorded on the Excel tracking log. In addition, we will gather information on acceptability of and satisfaction with both the overall intervention and its individual components from patients both immediately after the intervention is provided (while they are in the ED) and at the 6-month follow-up interview using a series of intervention assessment questions contained in the

baseline and follow-up surveys (see *ED-Home Baseline Screening and Survey* and *ED-Home 6-Month Follow-up Survey*). At the 6 month follow-up interview, as part of the *ED-Home 6-Month Follow-up Survey*, we will use the *Housing Risk Flyer* as well as a NYC HRA YouTube video. We will also speak with stakeholders (e.g., ED providers, homelessness prevention service providers) to obtain feedback on the intervention and factors to enhance its future implementation and sustainability.

4.2.2 Secondary Study Endpoints

Not applicable.

4.2.3 Exploratory Endpoints

Exploratory outcomes will include new onset homelessness as measured by entry into a homeless shelter within 6 months of the ED intervention (determined using the Department of Social Services CARES database), multiple self-reported housing status and substance use measures at the 6-month follow-up interview (see *ED-Home 6 Month Follow-Up Survey* and *Additional Baseline and Follow-up Questionnaires* attachments), and measures of health services use (see *ED-Home EMR Data Abstraction Tool*). Although we are not powering the study to show statistically significant effects on these outcomes, we will be able to determine feasibility of outcome measurement and gain a preliminary sense of potential intervention effects.

5 Study Enrollment and Withdrawal

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Be a patient in the Bellevue Hospital Center ED (including the Adult Emergency Services, Pediatric Emergency Services if ≥18 years old, and Urgent Care).
2. Be ≥18 years old.
3. Screen positive for homelessness risk using the homelessness risk screening tool (HRST).
4. Screen positive for unhealthy alcohol or drug use.
5. Able and willing to provide consent.

All participants must be able to and agree to provide informed consent to study participation.

5.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Medically (e.g., critically ill) or psychiatrically unstable.
2. Unable to provide informed consent for other reason (e.g., dementia or other cognitive deficit, profound intoxication).
3. Incarcerated or in police custody.
4. Unable to understand and speak English.
5. Lives outside NYC and/or cannot give a NYC ZIP code.
6. Already homeless (residing in a shelter or on the streets).
7. Does not have a telephone where can be reached for follow-up.
8. Has already received specialized peer navigator/addiction social worker services (Addiction LEADs) during current ED visit.
9. Has already participated in the study.

Non-English speaking patients are being excluded because English-speakers are at highest risk for shelter entry in New York City, and our primary patients of interest for this intervention are those at risk for shelter entry. Limited resources for this small pilot feasibility study preclude us from providing the translation and staffing necessary to enroll lower risk language groups.

5.3 Vulnerable Subjects

Children under the age of 18 will be excluded from the study. Pregnant women will not be excluded because pregnancy is a known risk factor for future homelessness. This research does not pose any risk to the fetus.

Patients who are not currently incarcerated, under arrest, or otherwise detained but who may be on probation or parole will not be excluded from the study as these patients are not considered prisoners for research and may be at particularly high risk for future homelessness and could benefit from homelessness prevention interventions. It is expected that most participants found to be eligible for the study will be from socioeconomically disadvantaged groups, as the study is targeted to patients who are at risk for future homelessness. Further information on potential risks and benefits appears in section 2.3.

5.4 Strategies for Recruitment and Retention

Study participants will be recruited exclusively in the Bellevue Hospital ED (including AES, PES, and UC). ED patients will be approached by trained study RAs to screen for study eligibility (see ED-Home Baseline Procedures flow chart in Schematic of Study Design section). Patients will only be approached during periods when they are not receiving active clinical care (e.g., RAs will not interrupt if a doctor or nurse is talking with the patient). Patients who are medically or psychiatrically unstable will also not be approached.

We will use a random sampling scheme of adult ED patients. Trained Research Assistants (RAs) will begin each shift in a randomly assigned section of the ED to start patient recruitment for the shift (these sections include the "sides" of the AES, the UC, and the PES). The RA will then approach patients sequentially beginning with a random first patient in the randomly assigned patient area and moving systematically through sequential areas of the ED once covering the initial area. RAs may use the publically displayed "white boards" located in all sections of the ED to assist in identifying appropriate patients for screening; for example, the "white boards" display patient age and location, which will assist RAs in identifying patients who are ≥18 years old. In addition to the random sampling scheme as described above, it is possible that ED care providers may identify specific patients who they feel would benefit from the study and may ask RAs to screen those patients for eligibility. In those cases, the RA/RC can break the random sampling scheme but will make a note in REDCap that this was done so that we can track recruitment processes for our feasibility study outcomes.

Study procedures including screening and informed consent will occur in the Bellevue Hospital ED. Multiple steps will be taken to maximize patient privacy, including: asking any visitors to leave the room/area; moving patients to private or semi-private areas of the ED when feasible; speaking in a low voice near patients' heads.

Upon approaching patients, RAs will explain that they are conducting a research study and obtain patient verbal assent to complete screening questions for study eligibility. A standard screening tool will be used, with RAs guided through the screening and entering question responses in real-time using REDCap (see *ED-Home Baseline Screening and Survey* attachment). Patients who are found eligible for the study will be invited to participate. The informed consent process will be conducted by the study RC and will include explaining to patients what will occur in the study, what information they will be asked to give, and who receives and can use this information (see *ED-Home Informed Consent* and *ED-Home Key Information Sheet* attachment). Written informed consent is required for study participation. Participants will sign two consent forms; one copy to retain themselves and the other for study records. For participants in whom capacity to complete informed consent is questionable, a validated consent capacity quiz will be completed (see *ED-Home UBACC* attachment) and/or research staff will discuss with the patient's treating provider prior to obtaining written informed consent.

Participant retention will be enhanced in the following ways:

- Detailed locator information will be collected from each participant. This information will include multiple contact phone numbers and other information that will enhance our ability to contact participants for follow-up procedures. See *ED-Home Locator Form* attachment for full details.
- Participants will be given a study contact card and sticker to allow them to contact study staff proactively as needed, for example, if their contact information has changed. See *ED-Home Study Contact Card and Sticker* attachment.
- Follow-up participant contact including follow-up visit reminders will occur in the manner and schedule outlined in the ED-Home Baseline Procedures flow chart in the Schematic of Study Design section.

5.4.1 Use of DataCore/Epic Information for Recruitment Purposes

Not applicable.

5.5 Duration of Study Participation

The duration of active study participation is approximately 6 months, with the final follow-up survey with patients occurring 6 months after baseline/enrollment. In cases in which it is difficult to contact or find participants for the follow-up survey, the follow-up visit may be conducted up to 2 months after the 6 month follow-up time period (i.e., up to 8 months after study enrollment). See the *ED-Home Pilot Follow-Up Procedures flow chart* in the Study Schema section for details.

5.6 Total Number of Participants and Sites

We plan to enroll approximately 40 participants at a single site (Bellevue Hospital Center ED). If there are multiple participants who drop out of the study after being consented and/or who cannot be reached for follow-up procedures, we may recruit additional participants as needed to achieve the primary study endpoints.

5.7 Participant Withdrawal or Termination

5.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request, which can be made in writing or verbally to the study PI.

Investigators may terminate participation in the study if:

- Any clinical adverse event (AE) or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- It is discovered that participant lacks cognitive or mental capacity to understand the study, whether lacking such capacity at the time of initial consent (unidentified at the time) or during follow-up procedures.

In the case of participant withdrawal or termination, information already collected from the participant will still be used for the purposes of the study unless:

- The study participant explicitly revokes consent to use his/her information for the study, either in writing or verbally to the study PI; or,
- It is determined that the original study consent was not valid (for example, in a case where it is determined that the study participant likely did not have capacity to provide informed consent at the time it was initially conducted).

5.7.2 Handling of Participant Withdrawals or Termination

There are no risks to participants from withdrawing from the study or termination of participation. As noted above, participants will be asked if investigators can continue to use information already collected from them for the purposes of the study, including use of their personally identifying information to examine outcomes in data sources specified in the informed consent form (including Department of Homeless Services data and Bellevue Hospital electronic medical record data). No additional information will be collected from participants themselves after withdrawal or termination from the study.

As this is a feasibility study, if fewer than five participants withdraw or are terminated from the study they will not be replaced. If five or more participants withdraw or are terminated from the study, study enrollment may be increased to replace them in order to achieve adequate ability to examine the primary feasibility outcomes.

5.7.3 Premature Termination or Suspension of Study

Premature termination or suspension of the study is not expected.

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and the study sponsor, and will provide the reason(s) for the termination or suspension.
Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Lack of adequate funding to complete the study

None of the above are expected to occur for this small feasibility pilot study.

The study may resume once concerns about safety, protocol compliance, and/or data quality are addressed and satisfy the sponsor and/or IRB.

6 Behavioral/Social Intervention

6.1 Study Behavioral or Social Intervention(s) Description

The intervention will consist of:

1) Referral to Homebase homelessness prevention services offered by community-based organizations in NYC;
2) Referral to substance use services (SBIRT and Addiction Leads) available at Bellevue Hospital;
3) Follow-up to ensure participants receive needed services.

Each of these components is described in more detail below.

Referral to Homebase homelessness prevention services
Homebase is the homelessness prevention program offered by the NYC Department of Social Services. It has been found in prior research to be effective in reducing future shelter entries among New Yorkers at risk for homelessness. Homebase services are tailored to individual needs and may include assistance with landlord-tenant mediation, assistance in paying rental arrears, other financial assistance, assistance with benefits applications (e.g., SNAP), family mediation, and other services. Upon initial arrival to a Homebase office, clients are assessed for Homebase service eligibility by a case worker. Eligible clients are assigned to a case worker and receive services. Homebase services are currently provided by seven different community based organizations in NYC, at more than fifteen different locations spread throughout the city; the specific location at which clients will be served depends on their zip code.

Study staff will determine to which Homebase office to refer study participants based on their zip code. Study staff will write down the name, location, hours, and contact information for the appropriate Homebase office and give this information to participants. Study staff will also provide study participants with an informational handout on Homebase (see *ED-Home Homebase Information Sheet* attachment). Study staff will make the referral to Homebase using an *ED-Home Homebase Referral Form for Bellevue Pilot* which will be e-mailed to the appropriate Homebase office as well as to related staff from the NYC Department of Social Services (see *ED-Home Email Template for Homebase*). This referral form was developed in conjunction with a pilot program of the Department of Health and Mental Hygiene of hospital referrals to Homebase in NYC. The Homebase providers are asked to reply to study staff by e-mail within 1 week to confirm that the referral was received and appropriate, contact the participant within 1 week either by phone or NYULH SendSafe email to discuss with the participant how to prepare for visit to Homebase and schedule an appointment, and reply to study staff by e-mail within 6 weeks to confirm whether the client was enrolled, declined to enroll, or was unable to be enrolled in Homebase services. Additionally, study staff may communicate with Homebase staff and/or the NYC Department of Social Services (including Human Resources Administration Prevention & Community Services) by phone and/or NYULH SendSafe email to facilitate if the participant has not been in contact with Homebase since baseline or to ensure referrals are successful. A successful referral would mean that the participant went to Homebase and spoke with someone there about obtaining needed services.

Referral to substance use services
Bellevue Hospital Center already offers SBIRT (Screening, Brief Intervention, and Referral to Treatment) services for emergency department patients. These services are free of charge and are available to all patients during times when SBIRT staff are present. SBIRT services have been described in the prior literature. In brief, they consist of assessing patients' substance use, offering a brief intervention using principles of harm reduction and motivational interviewing, and referring patients to substance use treatment as appropriate. By its nature, these services are tailored based on individual needs. Participants may be provided with brochures or other written material about substance use as appropriate for the individual. All SBIRT providers have been trained in SBIRT procedures. SBIRT is provided as part of routine ED care, separate from this study.

The Bellevue Hospital Center ED also offers new substance use services called Addiction Leads, which consists of a peer counselor/social worker team. These services are also free of charge and are available to patients who need them during the hours in which the peer counselor/social worker are available. This is a new program at Bellevue Hospital. As such, the exact services that will be provided may vary somewhat during the study time period but will consist of assessing patients' substance use, counseling patients about their substance use, connecting patients with medication therapy for substance use as appropriate (including via prescriptions given by ED physicians), and connecting patients with outpatient or inpatient substance use treatment referrals as appropriate. Patients may be provided with brochures or other written material about substance use as appropriate for the individual.

The role of the study staff will be to contact the SBIRT and/or Addiction Leads teams during the participant's baseline ED visit. The SBIRT and/or Addiction Leads teams will then assess and provide services to the participant during the baseline ED visit. The exact services provided will depend on participant needs, as these are designed to be individually tailored services. Of note, both of these programs are considered to be standard of care in the ED; study staff will simply facilitate by making the referral and ensuring participants receive services during their ED visit. Participants will be referred to one or both of these substance use services depending on availability of service staff, participant need, and participant interest.

6.1.1 Administration of Intervention

Referral to Homebase will be provided in-person by study staff as detailed above during the study baseline ED visit. Participants will be encouraged by study staff to visit the appropriate Homebase office within one week from the time of their baseline visit; some Homebase offices may accept appointments and others operate on a walk-in basis. Homebase services are generally provided in-person at the Homebase offices, though some services may also be provided by staff over the phone. The frequency, mode, and duration of contact with Homebase will be determined by the participant and Homebase staff, and is likely to vary depending on individuals' needs.

Referral to substance use services will be provided in-person by study staff as detailed above. The SBIRT and Addiction Leads teams will provide services as detailed above in-person during the baseline ED visit. Follow-up services will depend on the individual needs of the participant and may include follow-up phone calls to check on progress. Participants may also be referred to other services, such as outpatient clinics for substance use or inpatient substance use treatment programs. The exact services, timing, frequency, mode, and duration will depend on individual participant needs.

Follow-up by study staff to ensure that participants receive needed services will occur by phone. Study staff will talk with participants to help facilitate service receipt by phone up to three times, using the schedule as outlined in the Schematic of Study Design Section (Follow-Up Procedures Flow Chart). In the cases where participants aren't able to be reached by phone and where they have given us permission to email them, we may also use a study NYULH SendSafe email to contact the participant. Additionally, if we are unable to reach the participant, and the participant has given us permission to do so, we may contact the participant's place of work, health care providers, case workers/social workers, or substance use treatment programs that they attend. Study staff will also communicate with staff from Homebase and the NYC Department of Social Services as needed to facilitate referrals.

6.1.2 Procedures for Training Interventionalists and Monitoring Intervention Fidelity

ED-Home study staff will be trained in making referrals to Homebase, SBIRT, and Addiction Leads services. Study staff will also be trained in the protocol for making follow-up phone calls to help ensure that participants receive needed services. Details on all referrals at the time of baseline and all follow-up phone calls will be documented in REDCap, which will allow for monitoring of adherence to study procedures.

As this is a real-world intervention utilizing referrals to existing social and substance use services operated by entities separate from the ED-Home study, study staff will not have a role in training, monitoring, or supervising the staff providing Homebase, SBIRT, Addiction Leads, or other interventions. Study staff will be able to obtain limited information from study participants during baseline and six-month follow-up interviews about what services they were able to receive and their satisfaction with those services. As detailed above, study staff will also receive information from Homebase about the status of referrals that have been made. Other information about service receipt will be obtained as part of measuring the feasibility of the study, as outlined in other sections of the protocol.

6.1.3 Assessment of Subject Compliance with Study Intervention

We will ascertain in follow-up phone calls and at the time of the 6 month follow-up survey what services participants have received as a result of study intervention referrals, and the results of those referrals. This information will be based primarily on participant self-report, with additional information obtained from Homebase staff as needed.

7 Study Procedures and Schedule

7.1 Study Procedures/Evaluations

7.1.1 Study Specific Procedures

Study procedures are outlined in the two flow charts in the Schematic of Study Design section. These procedures include:

- Screening for study eligibility, informed consent process for eligible and interested patients (baseline).
    - For patients who may be homeless or at risk for homelessness but not eligible for the study, RAs will offer the patient a resource sheet (see *Housing Resource Sheet*).
- Survey (to be administered at baseline and 6 month follow-up visits): verbally administered survey to collect participant satisfaction information on intervention components and participant information including sociodemographics, physical and mental health, housing history, substance use history, criminal justice history, social support and social determinants of health. See specific instruments (attachments) for details:
    - *ED-Home Baseline Screening and Survey* (to be administered on REDCap)
    - *ED-Home 6 Month Follow-Up Survey* (to be administered on REDCap)
        - As part of the *ED-Home 6 Month Follow-Up Survey*, we will show participants the *Housing Risk Flyer* (administered on paper) which highlights certain risk factors for losing housing. We will then ask participants a series of questions about what they thought of the flyer.
        - As part of the *ED-Home 6 Month Follow-Up Survey*, we will show participants a NYC HRA YouTube video (administered on YouTube on study iPad) about a woman who successfully connected to Homebase. We will then ask participants a series of questions about what they thought of the video.
    - *Additional Baseline and Follow-up Questionnaires* administered on paper: alcohol timeline follow-back; residential timeline follow-back; WHO-ASSIST.
- Participant information form (baseline only): collects name, date of birth, SSN (if applicable) to allow future linkage with NYC DSS CARES database and Bellevue Hospital medical records (*ED-Home Participant Information Form*).
- Intervention (begins at baseline): detailed in Section 6.1. Includes:
    - Homebase referral (baseline only): contains participant basic information and is e-mailed

to the appropriate Homebase office *(ED-Home Homebase Referral Form for Bellevue Pilot)*
  - Homebase information sheet (baseline only): contains name, location, hours, and contact information for the appropriate Homebase office as well as information about Homebase. This referral information will be given to the participants (*ED-Home Homebase Information Sheet).*
  - SBIRT (Screening, Brief Intervention, and Referral to Treatment) and/or Addiction Leads services for substance use in ED (as detailed in Section 6)

- Locator form (baseline only): collects detailed contact information from participants to allow for future follow-up (*ED-Home Locator Form*).
- Study contact card and sticker (baseline only): serves as a reminder for the participant's 6 month follow-up visit and contains study staff information to allow participants to contact study staff proactively as needed *(ED-Home Study Contact Card and Sticker).*
- Follow-up phone calls to confirm participant contact information, confirm follow-up appointment, and reschedule missed visits (see ED-Home Follow-Up Procedures Flow Chart in Schematic of Study Design section), documented in REDCap (*ED-Home Tracking Form* and *ED-Home Follow-up Procedures Form)* and tracked using an Excel tracking log for internal study management purposes.
- Follow-up phone calls and/or NYULH SendSafe emails with participants and service providers (e.g., Homebase) to confirm referrals successful and troubleshoot as needed (see ED-Home Follow-Up Procedures Flow Chart in Schematic of Study Design section), documented in REDCap (*ED- Home Tracking Form* and *ED-Home Follow-up Procedures Form)* and tracked using an Excel tracking log for internal study management purposes.
- Mailing a follow-up visit reminder letter containing details of the participant's appointment, documented in REDCap (*ED-Home Follow-up Visit Reminder Letter* and *ED-Home Follow-up Procedures Form).*
- Electronic medical record review for Bellevue Hospital to ascertain information on ED visits, inpatient hospitalizations, outpatient visits, and substance use service visits at Bellevue Hospital (*ED-Home EMR Data Abstraction Tool*).
- Via NYC governmental agencies (NYC Department of Social Services and/or NYC CIDI), review of CARES database (with consent of participants) for data on participants' homeless shelter use, including dates and types of shelter use prior and subsequent to study enrollment. NYC DSS—which administers the Homebase program to which we are referring participants as part of the intervention—has agreed to inform us of the outcomes of our referrals (either directly or via their contracted agencies), including whether the participants enter a homeless shelter, for participants who have provided consent. NYULH researchers will not be directly accessing outside databases.

7.1.2 Standard of Care Study Procedures

The study will not interfere with the standard clinical care that patients receive while in the ED. The referral to substance use services (SBIRT and Addiction Leads) are part of standard care offered in the ED during times in which these programs operate. In general, SBIRT and Addiction Leads staff actively screen patients in the ED to identify patients in need of their services. In addition, clinical staff (e.g., nurses, physicians) can refer patients to SBIRT and Addiction Leads programs based on their clinical judgment of need. The SBIRT and Addiction Leads services that will be offered to study participants are the same as those offered as part of routine clinical care; the only difference is that for the study our study staff will facilitate real-time referrals for participants to ensure that participants receive these ED-based services. Therefore, any referrals, treatments (including assistance in obtaining medication treatment), or other services provided as part of SBIRT or Addiction Leads referrals will be considered to be part of standard of care in the ED, not unique services offered through the study.

Other referrals as part of the study (e.g., to Homebase) are not currently part of routine/standard of care in the ED, though currently ED care providers refer patients to social workers on an *ad hoc* basis as needed to assist with housing and homelessness concerns. Our study referral to Homebase represents an enhancement in the standard of care since currently social work services in the ED for housing/homelessness are quite limited in scope.

7.2 Laboratory Procedures/Evaluations

Not applicable.

7.3 Study Schedule

Full details on the study schedule, including all baseline and follow-up procedures, are provided in the Schematic of Study Design figures presented near the beginning of this protocol.

7.3.1 Screening

Screening for study eligibility will occur during a patient's Bellevue Hospital ED visit. The process for screening is provided in the *ED-Home Pilot Baseline Procedures* flow chart in the Study Schema section of this protocol. The process for screening is fully described in protocol Section 5.4 and the attachment *ED-Home Baseline Screening and Survey*.

7.3.2 Enrollment/Baseline

The baseline/enrollment visit will occur during the same ED visit as screening. All baseline procedures will occur during this visit. Research staff will confirm eligibility for the study by reviewing the screening information collected by RAs and affirming accuracy with participants. The sequence of baseline visit events is outlined in the ED-Home Pilot Baseline Flow Chart in the Study Schema section.

Enrollment/Baseline Visit (Visit 1, Day 0)

- Verify inclusion/exclusion criteria.
    - If patient may be homeless or at risk for homelessness but not eligible for the study, give homelessness resource sheet.
- Verify patient has not already participated in the study.
- Explain the study. Obtain informed consent of potential participant verified by signature on study informed consent form. One copy of completed informed consent form will be given to participant and the other copy retained for study records.
- Complete baseline survey and supplemental questionnaires (see instruments as listed in Section 7.1.1).
- Complete participant information form (see Section 7.1.1).
- Real-time referral to substance use services to be provided during baseline visit (SBIRT and/or Addiction Leads).
- Referral for Homebase homelessness prevention services.
- Complete Participant Locator Form (see Section 7.1.1).
- Schedule follow-up appointment and give appointment using study contact card and sticker.
- Participant given $30 baseline reimbursement and one round-trip regular MetroCard.

7.3.3 Intermediate Visits

Intermediate "visits" will occur via phone as outlined in the ED-Home Follow-Up Procedures Flow Chart in the Study Schema section. In the cases where participants aren't able to be reached by phone and where they have given us permission to email them, we may also use a study NYULH SendSafe email to contact the participant. Additionally, only if we are unable to reach the participant directly and if the participant has given us permission to do so, we may contact the participant's place of work, health care providers, case workers/social workers, or substance use treatment programs that they attend by phone. The purpose of these contacts is solely to assist us in getting in contact with the participant to minimize loss from the study (e.g., obtaining from these secondary contacts any new phone number information the participant may have); we will not be sharing any information about the study or the participants with these contacts. The timeline provided is suggested, but exact dates may deviate depending on circumstances such as how difficult it is to contact the participant. Strict time windows will not be mandated for intermediate contacts, though all attempts will be made for these contacts to occur with timing as close to that outlined in the flow chart as possible. This is appropriate for a feasibility study and dates of all follow-up contacts and attempts at contacts will be recorded on REDCap (see *ED-Home Tracking Form*) and a summary Excel tracking

spreadsheet that will be used internally to manage participant status, attempts of contact with participants, attempts of contact with providers, and necessary follow-up steps; no protected health information will be recorded on the Excel tracking log.

Intermediate Contact 1 (Day 7–10)
- Confirm participant contact information.
- Confirm 6 month follow-up visit date.
- Ascertain whether referrals successful. If unsuccessful troubleshoot and decide next steps.

Intermediate Contact 1.2 (as needed, 7–10 days after Intermediate Contact 1)
- Only for participants in whom referrals were unsuccessful.
- Ascertain whether participant received services to which referred. If unsuccessful troubleshoot and decide next steps.

Intermediate Contact 1.3 (as needed, 7–10 days after Intermediate Contact 1.2)
- Only for participants in whom referrals were unsuccessful.
- Ascertain whether participant received services to which referred. If unsuccessful troubleshoot and decide next steps.

Intermediate Contact 2 (3 months after baseline)
- Confirm participant contact information.
- Confirm 6 month follow-up visit date.

Intermediate Contact 3 (5 months after baseline)
- Confirm participant contact information.
- Confirm 6 month follow-up visit date.
- Mail participant 6-month follow-up visit reminder letter.

7.3.4 Final Study Visit

The final study visit will be the 6 month follow-up visit. The procedure for participants who do not come to the follow-up visit is documented in the ED-Home Follow-Up Procedures Flow Chart in the Study Schematic Section.

Final Study Visit (6 months, window -2 weeks to +8 weeks)
- Complete 6 month follow-up survey (see instruments as listed in Section 7.1.1).
- Participant is reminded that this is the final study visit. Participant is thanked for his/her time and has the opportunity to ask any questions about the study.
- Participant given $50 (cash or gift-card) follow-up reimbursement.

7.3.5 Withdrawal Visit

Participants may choose to withdraw from the study by informing the PI in writing or by phone. There will not be a separate withdrawal visit. See Section 5.7 for additional details.

7.3.6 Unscheduled Visit

Unscheduled visits are not anticipated. Participants will be given contact information for the study to inform us of any change in their contact information. If the participant makes such contact it will be documented in the follow-up log in REDCap.

7.4 Concomitant Medications, Treatments, and Procedures

Not applicable.

7.5 Justification for Sensitive Procedures

Not applicable.

7.5.1 Precautionary Medications, Treatments, and Procedures

Not applicable.

7.6 Prohibited Medications, Treatments, and Procedures

Not applicable.

7.7 Prophylactic Medications, Treatments, and Procedures

Not applicable.

7.8 Participant Access to Study Intervention at Study Closure

Participants will still be able to access all existing community/social services for which they are eligible and ED/health care at the end of the study as they would if they had not participated in the study.

8 Assessment of Safety

8.1 Specification of Safety Parameters

This is an extremely low-risk study given the nature of the intervention (referrals to established social services). As such, study endpoints do not include safety parameters. Since the study includes participants with social and medical risks including housing instability and homelessness, we expect that some participants will worsen in status during the course of the study unrelated to the study. Though we will document and respond to any adverse events that we become aware of during the study as described below, we are not performing explicit investigations to attempt to discover adverse events since such events are not expected related to the study. For example, we are not tracking diagnostic test results. We are not tracking hospital stays in real-time. Information about hospitalizations will be recorded retrospectively as an exploratory study outcome as previously described, but such stays will not be considered adverse events.

8.1.1 Definition of Adverse Events (AE)

Required text: An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal.
- is associated with a serious adverse event.
- is associated with clinical signs or symptoms.
- leads to additional treatment or to further diagnostic tests.
- is considered by the investigator to be of clinical significance.

Study specific text: For the purpose of this study, the following events will not be reported as AEs:

- Mild unrelated event.
- Moderate unrelated event. This would typically include physical events such as headache, cold, etc. that were considered unrelated to study participation.
- Substance use events, including:
    - Worsening of substance use
    - Need for higher level of care
    - Signs and symptoms of substance use withdrawal
    - Drug or alcohol craving
    - Medical events that are directly related to substance use

8.1.2 Definition of Serious Adverse Events (SAE)

Serious Adverse Event

Required text: Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening

- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

Study specific text: Given the population being enrolled in the study, it is expected that most participants will continue to have substance use (drug and alcohol), several may have overdose, and many may have hospitalizations or other treatments related to their substance use. These outcomes are being included in the 6 month follow-up assessment for exploratory analyses. When we learn about these outcomes at the time of follow-up assessments they will not be considered AEs/SAEs, but rather will be analyzed as for other exploratory study outcomes. We do not expect to learn about these outcomes in the interim (during the study before the 6 month follow-up visit) because we are not actively tracking participants' clinical status or health care use.

8.1.3 Definition of Unanticipated Problems (UP)

Unanticipated Problems Involving Risk to Subjects or Others
Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e., not described in study-related documents such as the IRB-approved protocol or consent form, not expected events given the eligible study population, etc.).
- Related or possibly related to participation in the research (i.e., possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the unique procedures involved in the research).
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

8.2 Classification of an Adverse Event

8.2.1 Severity of Event

The following guidelines will be used to describe adverse event severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

8.2.2 Relationship to Study Intervention

All events considered to be AEs will have their relationship to the study intervention/study participation assessed by the study PI, with consultation from the IRB, study sponsor, and/or study DSMB as appropriate. Determinations will be made based on factors including considerations of causality based on temporal relationships and clinical judgment. The degree of certainty about causality will be graded using the categories below:

- **Definitely Related** – There is clear evidence to suggest a causal relationship between study participation and the AE, which would not have occurred in absence of study participation.
- **Probably Related** – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely.
- **Possibly Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial intervention). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related," as appropriate.
- **Unlikely to be Related** – A clinical event unlikely based on temporality or clinical judgment to be related to the study. A temporal relationship to intervention administration may make a causal relationship improbable and/or there are other probable causes of the event (e.g., the participant's clinical condition, other concomitant treatments).
- **Not Related** – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology.

8.2.3 Expectedness

The study PI will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.3 Time Period and Frequency for Event Assessment and Follow-Up

The occurrence of an AE or SAE may come to the attention of study personnel during study visits during study procedures as specified including participant surveys. Participants may also provide unsolicited information on AEs or SAEs during study visits. Given the low-risk nature of this study, AEs will not be monitored after the final study visit (6 month follow-up visit).

8.4 Reporting Procedures – Notifying the IRB

The PI will report the following types of events to the IRB and DSMB:

- AE or SAE AND unanticipated AND possibly, probably, or definitely related to the study. Study-specific descriptions of what will and will not be considered AEs or SAEs are provided in Sections 8.1.1 and 8.1.2.
- Anticipated adverse events occurring with greater frequency than expected.
- Knowledge of any death of a study participant, even if determined unrelated to the study.
- Other unanticipated problems involving risks to study participants or others.

These events will be reported according to the NYU Langone Health IRB's reporting guidelines.

8.4.1 Adverse Event Reporting

AEs (see section 8.1.1) that are unanticipated and possibly/probably/definitely related to the study, or are occurring with greater frequency than expected, will be reported to the IRB using the appropriate forms via Research Navigator within 72 business hours of becoming known to the PI. Additionally, such AEs will be recorded on a summary report provided yearly to the IRB at the time of study continuation. The PI will have primary responsibility for reporting AEs, with assistance from the study RC.

8.4.2 Serious Adverse Event Reporting

SAEs (see section 8.1.2) that are unanticipated and possibly/probably/definitely related to the study, or are occurring with greater frequency than expected, or any deaths of study participants will be reported to the IRB as quickly as possible after becoming known to the PI, and within 72 business hours. Reporting will be completed using the appropriate forms via Research Navigator. When appropriate and possible the PI will also attempt to discuss by phone with IRB staff. Additionally, such SAEs will be recorded on a summary report provided yearly to the IRB at the time of study continuation. The PI will have primary responsibility for reporting AEs, with assistance from the study RC.

8.4.3 Unanticipated Problem Reporting

In addition to AE and SAE reporting as specified above, other unanticipated problems (UPs) involving risks to study participants or others will be reported to the IRB within 72 business hours. UP reports will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

8.4.4 Reporting of Pregnancy

Not applicable; we are not testing participants for pregnancy.

8.5 Reporting Procedures – Notifying the Study Sponsor

Adverse Events (AEs) deemed to be possibly, probably, or definitely related to the study will be reported to the NIDA PO at least once per year. At a minimum, this report will describe the event, when it occurred, and the outcome/resolution. If there were no AEs, a statement that no AEs occurred will be included in the yearly progress report or communicated to the PO in writing. Serious Adverse Events (SAEs) are not expected but—if determined to be possibly, probably, or definitely related to the study—would be reported to the NIDA PO within 72 hours of the event by email. At a minimum, this notification would include a brief explanation of the SAE and when it occurred. A written follow up would be sent within 5 business days of the event, after consultation with the site IRB. The written follow up would include information on the date of the event, what occurred, actions taken by project staff, planned follow up, whether participant will continue in the study, and any recommendations from the IRB. In addition, any negative IRB actions relevant to the study will be reported to the NIDA PO within 72 hours of the IRB action.

8.6 Reporting Procedures – Participating Investigators

Not applicable (this is a single-center trial).

8.7 Study Halting Rules

Given the low-risk nature of our intervention and the fact that this is a pilot feasibility study we do not anticipate any circumstances under which the study would need to be halted.

8.8 Safety Oversight

This is an extremely low-risk study. The study has a small DSMB consisting of independent investigators (not otherwise affiliated with the study) who have the appropriate expertise to advise on issues of study safety, ethics, and data management. The DSMB meets once yearly to review study data and draft a report, which is sent to the study sponsor. The study sponsor has previously approved the DSMB process for the parent grant for this study (K23 DA039179). Additionally, any concerns or recommendations for changing or halting the study made by the DSMB will be reported promptly to the IRB.

DSMB members include:

- Dr. Stephen Wall, Associate Professor, Department of Emergency Medicine
- Dr. Babak Tofighi, Assistant Professor, Department of Population Health

It is the responsibility of the Principal Investigator to oversee the safety of the study. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above.

9 Clinical Monitoring

Given that this is an extremely low risk study that does not involve medical procedures or treatments, external clinical monitoring and/or independent audits are not appropriate. The study PI will be responsible

for ensuring internal quality management of study conduct, data collection, documentation, and completion. This monitoring will occur on an ongoing basis in conjunction with other study staff to ensure timely recognition of any potential problems. The study RC will conduct weekly data quality assurance checks using procedures developed in conjunction with the PI, and results of these QA checks will be discussed weekly with the PI or immediately if any significant problems are identified.

10 Statistical Considerations

10.1 Statistical and Analytical Plans

There will not be a formal SAP for this small feasibility pilot study.

10.2 Statistical Hypotheses

As the primary endpoints for this study are measures of feasibility that are descriptive in nature, there are no formal or testable null or alternative hypotheses. For exploratory endpoints of housing and substance use outcomes, we will test the hypothesis that participants will have improved in these outcome measures at the time of the 6-month follow-up survey compared to the baseline survey. However, as noted previously, the study is not being powered to formally test these hypotheses and, therefore, any such analyses will be considered purely exploratory in nature.

10.3 Analysis Datasets

A single analysis dataset will include all participants. The analysis dataset will consist of the following:

- Baseline and follow-up participant surveys and other study instruments.
- Participant locator form information.
- Information collected from follow-up/tracking phone calls and/or NYULH SendSafe emails with participants and/or applicable service providers, as previously described.
- Participant information extracted from approved external sources (with participant consent) including the Bellevue Hospital Center EMR and the NYC DHS CARES dataset.

10.4 Description of Statistical Methods

10.4.1 General Approach

This is a single-arm pilot study to examine feasibility. Methods appropriate for a feasibility study, including descriptive statistics, and simple bivariate and multivariable analyses will be used.

10.4.2 Analysis of the Primary Efficacy Endpoint(s)

There are not primary efficacy endpoints for this study. Rather, the primary endpoints are measures of intervention/study feasibility. The main analyses for feasibility will involve simple descriptive analyses examining endpoints including:

- Number of patients approached, number (percent) screening positive for unhealthy alcohol or drug use, number (percent) screening positive for homelessness risk.
- Number (percent) of those approached who are eligible for the study. Number (percent) reasons for ineligibility.
- Number (percent) of those eligible who agree to participate. Number (percent) reasons for refusal.
- Basic characteristics (e.g., gender, age, race, primary drug vs. alcohol use) of those who were eligible vs. ineligible and agreed and did not agree to participate using descriptive statistics and bivariate analysis.
- Number and location of referrals made for homelessness prevention and/or substance use services. Number and types of homelessness prevention and other services actually received. Length of time between the ED intervention and receipt of services.
- Participant satisfaction and self-efficacy measures as assessed at baseline and 6 month follow-up visits.

- Ability to contact patients at follow-up time points (e.g., number of phone calls required, whether participant appeared for the 6-month follow-up interview).

We may also examine for associations between participant characteristics and certain feasibility outcomes using bivariate and multivariable analyses as appropriate. For example, ability to contact participants and successfully complete the final study follow-up visit may be examined by number of phone numbers provided by the participant at baseline or by participant characteristics (e.g., type of substance use).

10.4.3 Analysis of the Secondary Endpoint(s)

Not applicable (there are not secondary endpoints).

10.4.4 Safety Analyses

Not applicable. AEs and SAEs will be recorded and reported as previously described.

10.4.5 Adherence and Retention Analyses

Adherence and retention are key components of our primary feasibility endpoints. These analyses are described in Section 10.4.2.

10.4.6 Baseline Descriptive Statistics

Simple descriptive statistics will be examined for baseline characteristics of study participants, as collected on the baseline study survey.

10.4.7 Planned Interim Analysis

Not applicable.

10.4.7.1 Safety Review

Not applicable.

10.4.7.2 Efficacy Review

Not applicable.

10.4.8 Additional Sub-Group Analyses

There are no planned sub-group analyses for this feasibility study. Any sub-group analyses conducted on the basis of experience with the trial will be purely exploratory in nature.

10.4.9 Multiple Comparison/Multiplicity

Not applicable.

10.4.10 Tabulation of Individual Response Data

All planned analyses use aggregate data. Individual data will not be published.

10.4.11 Exploratory Analyses

Planned exploratory analyses will include examining new onset homelessness as measured by entry into a homeless shelter within 6 months of the ED intervention (determined using the Department of Social Services CARES database), multiple self-reported housing status and substance use measures at the 6-month follow-up interview compared to baseline, and measures of health services use. Although we are not powering the study to show statistically significant effects on these outcomes, we will be able to determine feasibility of outcome measurement and gain a preliminary sense of potential intervention effects which may help in determining sample size and other design considerations for future larger studies. Additional exploratory analyses may be conducted based on stakeholder interests and feedback, including as determined during yearly stakeholder meetings.

10.5 Sample Size

Our goal is to test the feasibility and acceptability of the intervention and study processes. We expect this goal can be accomplished by enrolling approximately 40 ED patients, which will allow us to try the intervention for a range of different types of patients and to encounter a wide array of issues to be considered for a future large trial. The enrollment goal of approximately 40 patients, which equates to 1–2 patients per week over 6 months, is feasible. As this is a feasibility study only—not a study meant to test outcome effects—further sample size calculations are unnecessary and would be inappropriate.

10.6 Measures to Minimize Bias

10.6.1 Enrollment/Randomization/Masking Procedures

Not applicable. This is a single-arm, non-randomized study; no blinding or masking is appropriate.

10.6.2 Evaluation of Success of Blinding

Not applicable. The study is not blinded.

10.6.3 Breaking the Study Blind/Participant Code

Not applicable. The study is not blinded.

11 Source Documents and Access to Source Data/Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Original paper documents for the current study include: signed study consent forms, study reimbursement receipts, study screening and survey assessments (paper forms include TLFBs and WHO-ASSIST; other baseline and 6-month assessments will be maintained on REDCap), documentation of study contacts including follow-up phone calls.

For paper forms, all entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. Do not erase or white out errors. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it. For study information entered into REDCap, REDCap automatically keeps logs of all changes made in forms.

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB/EC, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

12 Quality Assurance and Quality Control

Multiple steps will be taken toward quality assurance (QA) and quality control (QC).

- All study staff, including RAs and RC, will be thoroughly trained both in overall GCP and human subjects protections and in study-specific procedures.
    - Formal training will occur prior to the study beginning recruitment.
    - Continuous training will occur in weekly staff team meetings.
- RAs will be closely supervised by the RC, with PI oversight. The RC will be supervised by the PI.
- A SOP document will clearly outline all study procedures, including QA/QC procedures.
- Multiple QA/QC protections are built into REDCap data collection software being used for this study, including forced question entry (i.e., specified questions cannot be left blank), automatic logging of all activities in REDCap including any entry changes, and study staff permission rules.

- All paper forms, including consent forms, will be regularly reviewed (both at the time of initial completion and at least weekly) for completeness.
- Weekly QA/QC reviews between the PI/RC will include:
    - Review of numbers of patients approached, eligible/ineligible, refused, participated.
    - Review to ensure that all eligibility classifications were made correctly.
    - Review for missing or out of range data.
    - Review of any potential QA/QC issues identified by any study staff member (which did not warrant more immediate discussion).

The PI and RC will oversee QA and QC efforts.

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

13 Ethics/Protection of Human Subjects

13.1 Ethical Standard

The PI will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

13.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form will be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

13.3 Informed Consent Process

In obtaining and documenting informed consent, the investigators will comply with applicable regulatory requirements in adherence to 45 CFR Part 46.

13.3.1 Consent/Assent and Other Informational Documents Provided to Participants

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention. The written consent form was developed using the IRB-approved template and includes all required components. In addition, participants will be given a Simplified Study Information Handout that explains the key points of the study in simple, easy to understand language. The following consent materials are submitted with this protocol: *ED-Home Informed Consent* and *ED-Home Key Information Sheet.*

13.3.2 Consent Procedures and Documentation

Eligible patients will be invited to complete the written informed consent process in the ED. Multiple steps will be taken to ensure participant privacy during the consent process, including: asking any visitors to leave the area; using a private room or treatment bay when available (many of the treatment areas in the ED are private rooms with doors that close or single-patient bays with curtains that close, but if the patient is not already in one of these locations patients can be moved to a more private area of the ED); research staff speaking in a quiet voice to avoid others overhearing the conversation. Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to potential participants. An IRB-approved key information form and informed consent document will be provided to patients and will also be verbally explained by trained study staff (generally RC, though may include the PI) and will detail, in simple and plain language, all study procedures and potential risks of participating in the study. As part of the consent process, study staff will explain the purpose of the study,

all study processes, risks and benefits of being in the study, alternatives to being in the study, what information will be collected from participants, and how that information will be used. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

Privacy will be assured by asking any visitors to leave the area (though visitors will be allowed to stay for the consent process if preferred by participants). When feasible, research staff will also offer to move participants to a more private/quiet location of the ED.

Participants will be invited to carefully review the full study informed consent document, and to ask any questions they might have. Potential participants will have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The participant and the person obtaining informed consent will sign and date two copies of the informed consent document prior to any procedures being done specifically for the study. One copy of the signed informed consent document will be given to the participant for his/her records and the other signed copy will be stored with study research records in a locked file cabinet in a locked office. Any alteration to the standard consent process and the justification for such alteration will be documented.

Regular audits will be performed by the RC to ensure that consent forms are fully and properly completed and stored for all study participants.

Participant capacity and comprehension: Potential participants will be required to demonstrate adequate comprehension of the study and decision-making capacity to participate in the study. Only patients who have the capacity to give informed consent will be included in the study. Patients will not be included if they are too acutely intoxicated to give informed consent or otherwise medically unfit to participate, as determined by trained study staff or the ED care team. If there is any question about the patient's capacity to provide informed consent, study staff will: a) ask ED care providers (e.g., physician, nurse) for advice about whether the participant has capacity to provide consent, and/or b) complete formal assessment of decisional capacity for participation in research using the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC). The UBACC has been previously validated and used for studies at Bellevue Hospital, and generally takes less than 5 minutes to administer.

13.4 Posting of Clinical Trial Consent Form

The informed consent form will be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

13.5 Participant and Data Confidentiality

Files containing the collected survey data will be stored in a secure NYULH IT-managed network drive behind appropriate firewalls and meeting all requirements for protection of sensitive patient information, and will be accessed only from password protected and NYULH IT-managed security-compliant computers. Only the PI and other necessary study team members will have access to study data. The only paper documents containing identifying information that will be maintained are participant signed consent forms, Homebase referral form, and 6-month reminder letter. These forms will be stored in a locked file cabinet in the PI's locked office. Other documents including any paper survey instruments (such as TLFBs and WHO-ASSIST) will not contain participant signatures or other participant identifying information aside from unique non-identifying participant ID numbers. Participants will be informed of the procedures that will be used to protect their confidentiality during the informed consent process, and questions will be answered to ensure they are comfortable sharing personally identifying information and answering potentially sensitive questions. The collection and use of patient identifying data will be minimized, and the study will use unique participant ID numbers that are assigned by REDCap and are not identifying. Identifying data will be destroyed as soon as feasible, and de-identified data will be used whenever possible for data analysis. Any downloaded participant identifying information will be stored in a separate file from participant survey results to minimize risks of associating identifying information with survey responses.

All research assistants and others involved in the study will be required to complete appropriate IRB Human Subjects and HIPAA trainings. The PI will be responsible for ensuring that all staff involved in the study understand and follow all human subjects' confidentiality protection measures. Any potential breaches of confidentiality will be reported to the study PI, who will report such breaches to the IRB and any appropriate regulatory and funding agencies, and take any further corrective measures as appropriate. Study findings will be presented using only aggregate data; no publication or presentation will involve use of any individually identifying information.

Participants will provide informed consent to evaluate the exploratory outcome of homeless shelter entry using the NYC Department of Social Services (DSS) CARES database. The minimum possible participant identifying information will be provided to allow the appropriate NYC agency to share participant shelter use outcomes with the study team, only for participants who have been referred to their Homebase program and who have provided informed consent. For any other data linkage with CARES procedures will be outlined in a formal Memorandum of Understanding signed by all parties and approved by NYULH.

Upon request only, the PI will allow access to study data by the study sponsor and/or IRB for purposes of study monitoring and assurance with applicable regulations.

Information about study participants will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed participant authorization informing the participant of the following:

- What protected health information (PHI) will be collected from participants in this study.
- Who will have access to that information and why.
- Who will use or disclose that information.
- The rights of a research participant to revoke their authorization for use of their PHI.

In the event that a participant revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For participants that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor. The study monitor, other authorized representatives of the sponsor, or representatives of the IRB may inspect all documents and records required to be maintained by the investigator. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

To further protect the privacy of study participants, a Certificate of Confidentiality has been obtained from the NIH. This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants. There are limitations to Certificate of Confidentiality protections which are clearly outlined on study consent forms.

13.5.1 Research Use of Stored Human Samples, Specimens, or Data

No human samples or specimens are being collected or stored for this study. Survey and other data being collected for this study will be handled as documented in Section 14 below.

13.6 Future Use of Stored Specimens

Not applicable. No biological specimens will be collected from subjects.

14 Data Handling and Record Keeping

14.1 Data Collection and Management Responsibilities

Data collection will occur by approved, trained study RAs, the study RC, and the study PI. The study PI will have ultimate responsibility for overseeing data collection and management. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

The majority of data collection will occur using REDCap on NYULH IT-managed tablet computers (iPads), which will be password protected. Access to REDCap will only be granted to approved study personnel, each of whom will have a unique user ID and password to be used when collecting data. RAs will each be assigned a unique "data access group" in REDCap, meaning that each RA will only be allowed to see and edit the records that he/she initiates. Further, REDCap permissions and functionality will be restricted for RAs so that they do not have the ability to see other RAs' records, delete records, or change forms. In addition to these protections, REDCap has other functionality that will ensure data collected are complete and reliable, including data entry field limitations and forced responses to indicated questions. REDCap also automatically maintains an audit log of all REDCap activity, including any changes made to records and who has made them. All information entered into REDCap is automatically saved in the NYULH internal REDCap project, accessible only to approved study personnel. For QA monitoring and data analysis, REDCap data will be downloaded in the form of Excel and/or statistical programming software files. These files will be password protected and saved in secure NYULH IT-managed network drive accessible only to the PI, RC, and any other approved personnel.

For data collected on paper forms (*Additional Baseline and Follow-up Questionnaires* and *ED-Home Homebase Referral Form for Bellevue Pilot*) as well as for paper consent forms and reimbursement receipts, documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink only will be used to ensure clarity of reproduced copies. When making changes or corrections, research staff will cross out the original entry with a single line, and initial and date the change. All completed paper forms will be stored in a locked file cabinet in the PI's locked office. Data collection paper forms will additionally be scanned and saved electronically in secure NYULH network drive folders accessible only to the PI, RC, and any other approved study personnel.

The PI and RC will monitor data collection regularly via the QA/QC procedures outlined in Section 12. Further, all RAs will receive standard training in study procedures and will complete supervised shifts until they are fully competent in all study data collection. The RC and PI will be available in real-time to answer any RA's questions about data collection. Further, weekly study team meetings will be used to continually reinforce standards of good data collection and management.

14.2 Study Records Retention

Study documents and data will be retained for the longer of 3 years after close out or 5 years after final reporting/publication. These documents and data will be retained for a longer period, however, if required by local regulations. Personally identifying information will be destroyed as soon as possible and within three years from final study reporting/publication. It is the responsibility of the sponsor to inform the investigator when data and documents no longer need to be retained.

14.3 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or SOP requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH E6:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3.
- 5.1 Quality Assurance and Quality Control, section 5.1.1.
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

It is the responsibility of the site to use continuous vigilance to identify and report deviations within five working days of identification of the protocol deviation. All deviations will be reported to the NIDA Program Official, within five business days if deemed serious or during regular yearly reports if minor. Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements.

14.4 Publication and Data Sharing Policy

A publication plan will be made by the PI and other applicable co-investigators. The PI will have ultimate responsibility and decision-making authority regarding the publication plan. The International Committee of Medical Journal Editors (ICMJE) guidelines for authorship will be followed. This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

15 Study Finances

15.1 Funding Source

The study is funded by the NIH/NIDA (K23 DA039179). The Principal Investigator, Dr. Kelly Doran, is the NIH/NIDA grant holder.

15.2 Costs to the Participant

There are no anticipated costs to participants.

15.3 Participant Reimbursements or Payments

Participant reimbursement will be made in accordance with the NYULH Policy on Human Subject payment.

Participants will be given $30 after the baseline visit, at the completion of all baseline visit study procedures as described, to compensate them for their time and effort. Participants will also be given a round-trip MetroCard at the completion of the baseline visit to facilitate their ability to participate in the follow-up visit. Participants will be given $50 after completion of the 6-month follow-up visit, including completion of the 6-month follow-up survey. For follow-up visits conducted in person, participants will receive $50 cash. For follow-up visits conducted over the phone, participants will receive a $50 gift card via certified mail. No additional payments or gifts will be given.

These participant reimbursement amounts are in line with reimbursement amounts that have been used in other studies with similar patient populations—including other studies at Bellevue Hospital Center—and for similar amounts of participant time. They are not expected to constitute undue inducement of patients to participate in the research or to continue beyond a point that they would have otherwise withdrawn. Participants have the right to withdraw from the study without financial penalty. In other words, any reimbursement already distributed to the participant will not be revoked.

Participant reimbursement receipts will document the provision of the reimbursements made in cash. All payments made to participants using gift-cards will be tracked and reconciled on a monthly basis using a

disbursement payment tracker. Further, a disbursement log in accordance with the NYULH Policy on Human Subject Payments will be used to document distribution of payments with all study participants which includes the following information: the Human Subject identifier, IRB approved protocol, amount disbursed, date of the disbursement, acknowledgment by participant of participation and/or receipt of funds (e.g. signature of the participant), acknowledgement of distribution (i.e. signature from the principal investigator or responsible administrator), and whether or not the human subject is an employee of NYULH.

14 Study Administration

14.1 Study Leadership

The study is being led by the Principal Investigator, Dr. Kelly Doran. The PI is responsible for overall decisions and oversight of the study. Day to day conduct of the research is being overseen by the study Research Coordinator, Daniela Fazio. A team of research assistants—who are part of the Department of Emergency Medicine's Research Associate Program—will be supervised directly by the Research Coordinator (Daniela Fazio), with oversight by the PI (Kelly Doran). There is also a DSMB for this study, as described in Section 8.8. A stakeholder group consisting of leaders from relevant community service organizations, governmental/policy organizations, and the research team meets once yearly. At this meeting, the PI provides the stakeholder group with updates on the study to date and solicits input and advice.

15 Conflict of Interest Policy

Any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULH investigators will follow the applicable conflict of interest policies.

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17 Attachments

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

The following attachments are included:

Attachment A.	Schedule of Events
Attachment B.	ED-Home Baseline Screening and Survey
Attachment C.	ED-Home 6 Month Follow-up Survey
Attachment E.	ED-Home Key Information Sheet
Attachment F.	ED-Home UBACC
Attachment G.	ED-Home Participant Information Form
Attachment H.	ED-Home Locator Form
Attachment I.	Additional Baseline and Follow-up Questionnaires
Attachment J.	ED-Home Homebase Information Sheet
Attachment K.	ED-Home Homebase Referral Form for Bellevue Pilot
Attachment L.	ED-Home Study Contact Card and Sticker
Attachment M.	Housing Resource Sheet
Attachment N.	Housing Risk Flyer
Attachment O.	ED-Home Tracking Form
Attachment P.	ED-Home Follow-up Procedures Form
Attachment Q.	ED-Home Follow-up Visit Reminder Letter
Attachment R.	ED-Home Email Template for Homebase
Attachment S.	ED-Home EMR Data Abstraction Tool

Attachment A
Schedule of Events

Activity	**Baseline** [Day 0]	**Intermediate Contact 1** [Day 7-10]	**Intermediate Contact 1.2** [7-10 days after Intermediate Contact 1, if needed]	**Intermediate Contact 1.3** [7-10 days after Intermediate Contact 1.2, if needed]	**Intermediate Contact 2** [3 months after Baseline]	**Intermediate Contact 3** [5 months after Baseline]	**Final Study Visit and Exploratory Outcomes** [6 months after Baseline, window -2 to +8 weeks]
Screening							
Screening questions	X						
Eligibility questions	X						
Verify inclusion/exclusion criteria	X						
Verify patient not already in study	X						
Informed consent process	X						
Survey							
ED-Home Survey (REDCap)	X						X
Housing Risk Flyer							X
NYC HRA YouTube video							X
Additional baseline and follow-up questionnaires	X						X
Participant information form	X						
Locator form	X						
Intervention							
Referral to and delivery of Bellevue substance use services	X						
Referral to Homebase services	X						
Troubleshoot unsuccessful Homebase referrals		X	X	X			
Follow-up Phone Calls							
Confirm participant contact information		X			X	X	
Confirm 6-month follow-up visit date		X			X	X	
Document successful Homebase referrals		X	X	X			
Additional Procedures							
Housing resource sheet (ineligible patients only)	X						
Homebase information sheet	X						
Schedule follow-up appointment	X						
Give study contact card and sticker	X						
Reimbursement	X						X
Send 6-month follow-up visit reminder letter						X	
Electronic Medical Record Review							X