Research Participant
Key Study Information Form

Title of Study: ED-Home
s18-02040

Principal Investigator: Kelly Doran, MD, MHS
Departments of Emergency Medicine & Population Health
NYU Langone Health
462 1st Avenue, Room A-345; NY, NY 10016
(212) 263-5850

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

Purpose of the Research Study
The purpose of this research study is to determine the feasibility of creating a program in the emergency department that helps people with their housing and alcohol or drug use. We are asking you to take part in this research study because you are a patient in the emergency department and meet the eligibility criteria for being a part of this study.

Other Key Information
Today, you will be asked to complete a survey and you will receive referrals to services that might help you with your housing and your alcohol or drug use. These services will be tailored towards your needs. You will be asked to meet with a substance use counselor in the emergency department, and we will give you referral information for housing services in NYC called Homebase. In order to make effective referrals for you, we will email Homebase and related staff from NYC Department of Social Services a referral form containing your basic information. Later today, we will ask you questions about the services provided to you today and we will obtain your contact information.

After today, we will contact you at least three times in order to verify your contact information, see if you need help accessing services, and confirm your follow-up appointment in 6 months, which will be the last part of the study and will involve completing another survey.

We will also ask you for personal information such as your name and birthdate in order for researchers to look at records and databases to see whether you use health care services or a shelter in the future.

Foreseeable Risk and Benefits
A comprehensive list of all possible risks and discomforts related to this research is included in the full consent form. Overall, this study is considered to have “minimal risk.” Some survey questions may be sensitive in nature and may, therefore, frustrate or upset you. Additionally, your privacy could be lost by mistake. Multiple steps will be taken to protect against any risk. All study information will be kept confidential and securely protected. Only study researchers are able to access your sensitive information.

We expect that you may benefit personally from being in this study by receiving advice and referrals to services you may need that will help you with housing and alcohol or drug use. You will also be paid $30 for completing the survey today, $50 for completing the survey in 6 months, and you will receive a round-trip MetroCard today. By participating in this study, you will also help us learn how to best help future emergency department patients.

Alternatives to Participation
Participating in this study is optional and you may choose not to participate. No one can force you to be in this study. If you choose not to participate, you will still receive the care you regularly would in the emergency department.

For in-depth details regarding this study, please refer to the full informed consent document. For questions and concerns regarding any of this information, contact the study principal investigator Kelly Doran at (212) 263-5850.

NYU Langone Health

Research Participant Informed Consent Form

Title of Study:	ED-Home s18-02040
Principal Investigator:	Kelly Doran, MD, MHS Departments of Emergency Medicine & Population Health NYU Langone Health 462 1st Avenue, Room A-345; NY, NY 10016 (212) 263-5850
Emergency Contact:	Kelly Doran (212) 263-5850

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “participants” or “research participants.” These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family or friends. If you have questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to learn more about how we can best provide services to emergency department patients to help them with their housing and alcohol or drug use. We are asking you to participate because you are a patient in the emergency department and meet the study eligibility criteria.

3. How long will I be in the study? How many other people will be in the study?

You will be in the study for approximately 6 months. About 40 people aged 18 and older will be in this study.

4. What will I be asked to do in the study?

In this study, you will be asked to complete surveys, receive information about and referrals to services that might help you, and speak with study staff over the phone. Your participation in this study will last for 6 months and will involve two in-person visits (one today and one 6 months from today), and at least three follow-up phone calls. We will schedule the follow-up visit at a time that is convenient for you.

All of the questions you answer and other information you provide to us will be kept confidential—that means that we will not be sharing your answers with your doctors, family members, or anyone else who is not part of the research team. You are free to skip any questions that you prefer not to answer. At any time in the study, you may decide to withdraw from the study. If you withdraw, no more information will be collected from you. If you decide to withdraw from the study after today, you can call or write to the Principal Investigator using the contact information listed on page 1 of this form. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can be used.

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study. Below is a list of each study visit that is part of the study. This list includes about how long each visit should take and a list of the research procedures to be done at each visit. This section will help you understand what is expected of you at each visit.

Visit 1: Your Initial Visit

This visit will occur today during your emergency department stay; the research activities will take approximately one hour to complete. During this visit, you will be asked to complete a confidential survey. After this survey, we will be providing you with referrals to services that might help you with your housing situation and your alcohol or drug use; these services will be tailored based on your needs. The survey and other activities we do as part of the study today will occur during your emergency department visit, during periods when you would otherwise be waiting. If a doctor or nurse comes to provide you with care while we are talking, we would pause the study so that we do not slow down your medical treatment.

At this visit, we will:

- Ask you questions about your basic characteristics (like your age), personal information (like your name and birthdate), health, living situation, past experiences with homelessness, drug and alcohol use, and other past experiences in your life.
- Ask for you to meet with one or more of the substance use counselors in the emergency department.
- Give you referral information for homelessness prevention services in NYC called Homebase which can help you with things such as paying rent, helping with landlord problems, and helping to get other services or benefits. We will e-mail a referral form to Homebase and the NYC Department of Social Services staff that will contain basic information about you such as your name and address. We may also continue to communicate back and forth with these staff by phone or e-mail to find out about the services you were able to receive and help make sure you receive services you need. We

will not be sharing your answers to the survey with anyone outside the research team and nobody else will be given access to your medical records.
- Ask you some questions about what you thought of the services provided to you today.
- Collect your contact information and information on other ways to reach you.
- Collect the names and contact information for people who might help us reach you if we lose touch with you.
    - We will not share any information about you or details about the study with these people.

Intermediate Contact: Follow-up Phone Calls
After today, we will call you in 7–10 days to verify your contact information and see if you need help accessing services. Over the next six months, we will contact you at least two other times by phone to confirm your contact information and follow-up appointment. We will also send you a letter to remind you about your follow-up appointment.

Visit 2: Your Final Study Visit
The final study visit will be 6 months from now and will occur at Bellevue Hospital Center. This visit will take approximately one hour to complete. During this six month follow-up visit, you will complete another confidential survey.

At this visit, we will:
- Ask you questions about your basic characteristics (like your age), health, living situation, past experiences with homelessness, drug and alcohol use, and other past experiences in your life.
- Ask you some questions about what you thought of the services provided to you today as well as your experiences with Homebase.

We will use your personal information (such as your name and birthdate) to look at your visit records at Bellevue Hospital, for example, to see how often you have emergency department and clinic visits in the future or to help us find you for the six month follow-up visit. The NYC Department of Social Services or an organization called the NYC Center for Innovation through Data Intelligence (CIDI) may also assist us by using the personal information you give us to find your data in the CARES database, which contains information on shelter stays and certain other homeless services in New York City, to see if you use a homeless shelter after your visit today. These organizations have expertise in keeping your personal information private and secure. When using such databases, researchers will strictly protect and keep confidential your identity; your data will not be released to anyone or published. All of your personal information will be protected and remain confidential. Also, your personal information will not be linked to your answers to the survey questions. Any identifiable personal information collected and/or used for the purposes of this research will not be used for future research studies.

5. What are the possible risks or discomforts?

Overall, this study is considered to have “minimal risk.” Some survey questions may be of a sensitive nature, and you may therefore become frustrated or upset as a result. If you become upset by questions, you may stop at any time or choose not to answer a question. If you would like to talk to someone about your feelings, please let the researcher administering the survey

know. The most significant risk related to the study is a breach of participant confidentiality. Though this is a real risk with any research study—or anytime you give your personal information to anyone—multiple steps will be taken to protect against this risk. All study participant information will be treated as confidential and securely protected, and additionally, a NIH Certificate of Confidentiality was obtained for this study to further protect your information. We will store your information in special high security computer files. Only the study researchers will be able to access your information. The police, social workers, your doctors, and other people will not be allowed to access the data we collect about you.

6. What if new information becomes available?

We do not expect to find more information during the course of this study that would be important for you or would cause you to change your mind about being in the study.

7. What are the possible benefits of the study?

We expect that you may benefit from being in this study by receiving advice and referrals to programs to help you with your housing situation and any problems with alcohol or drug use that you identify. We will also try to help to make sure you are able to get services that you need; this may include us calling other organizations to help you get services. We hope that this study will help us learn how to design programs to help future emergency department patients who may have problems related to housing and alcohol or drug use. By participating in the study, you will help us learn how to better serve emergency department patients in the future.

8. What other choices do I have if I do not participate?

You may choose to not participate in this research study. In other words, participating in the study is optional. If you do not participate in this study, you will still receive care as you regularly would in the emergency department.

9. Will I be paid for being in this study?

You will be paid $30 for completing the study today and $50 for completing the survey during the 6 month follow-up. You will also receive a round-trip MetroCard today. You will receive these payments once you finish the study procedures, even if you decide not to answer certain questions that you find to be too sensitive to answer on the surveys, as long as you have answered most of the questions and have provided your name, birthdate, and contact information.

10. Will I have to pay for anything?

You do not need to pay for anything to be in this study. Services that you receive as part of your regular care in the emergency department today will be billed to you or your insurance as they normally would.

11. What happens if I am injured from being in the study?

There is no risk of being injured from this study.

12. When is the study over? Can I leave the study before it ends?

We will schedule a follow-up appointment 6 months from today when you will complete another survey; this will be our last contact with you as part of the study.

The study doctor, the sponsor of the study or government monitors, or the NYU School of Medicine IRB can take you out of the study without your permission at any time for the following reasons:

- The study staff finds out you do not meet the eligibility requirements of the study.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop or change the study.

It is your choice to be in this study. No one can force you to be in the study. No one can force you to stay in the study. You can leave the study at any time. Leaving the study will not affect the care you receive. You will still receive the same high level of expert care you were receiving at NYU School of Medicine and/or Bellevue Hospital before you became part of the study.

13. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information. We are not providing medical services as part of this study and we will not be putting any new information into your medical record. The study records are being kept separately from your medical records.

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This adds special protection for the research information that may identify you. Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. Your information cannot be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases). The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight. The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information

that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with researchers connected with this study—in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
The following information may be used in connection with this research:

- Information you provide to researchers today and in the future, including your answers to survey questions, and your personal and contact information. This information will only be used for the research purposes described on this consent form.
- The referral form to Homebase services and the NYC Department of Social Services.
- The study consent form.

Your information will not be shared with others unless they are part of the study research or oversight teams.

Who may use and share information in connection with this study?
The following individuals may potentially use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, research assistants, and personnel responsible for the support or oversight of the study.
- The study sponsor: the National Institutes of Health.
- Organizations contracted by the researchers to complete this study, which may include the NYC Department of Social Services, the NYC Center for Innovation through Data Intelligence, and DSS/HRA Homebase.
- The Data & Safety Monitoring Board for the study and the Institutional Review Board.
- Limited information may be shared with social services providers including Homebase staff, only in facilitating and following up on service referrals.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow at NYU School of Medicine. We share your health information only when we have to. We ask anyone who receives this information from us to protect your privacy. Once your information is shared outside NYU School of Medicine, we cannot promise that it will remain private, though all entities that receive your information as part of this study will follow protocols to keep your information confidential and private.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your information at any time. If you withdraw your permission, we will not be able to take back information that has already

been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in the study.

How long may my information be used or shared?
Your research records will be kept for at least five years after the study is over or as long as the sponsor requires them to be kept. They will be stored in a place that will not allow anyone to see them without permission. Because research is an ongoing process, we cannot give you an exact date when we will destroy your research records. Personally identifying information, however, will be destroyed as soon as possible and within three years from final study completion.

15. Optional permission for future use

NYULH would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULH or its research partners. Such health information may include biological samples from the study.

To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULH will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULH or its research partners. _____ Subject Initials

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies—including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research participant?

If you have questions, concerns, or complaints regarding your participation in this research study, or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on the top of page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Participant (Print)	Signature of Participant	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Version date (IRB Use only): 2019.01.14