Informed Consent to Participate in a Randomized Controlled Trial

An Enhanced Housing Placement Assistance (EHPA) Program for Homeless Persons Living With HIV/AIDS in New York City

NCT03334825

Informed consent form

April 5, 2012

Title: The Enhanced Housing Placement Assistance Program Implementation and Evaluation

Study Sponsor:

- Care, Treatment and Housing Program, Bureau of HIV/AIDS Control and Prevention, New York City Department of Health and Mental Hygiene

Study Investigator:

- John Rojas, New York City Department of Health and Mental Hygiene, Gotham Center, 42-09 28th Street, 22nd Floor, Long Island City, NY 11101-4132, Tel: (347) 396-7428

IRB Information:

- Institutional Review Board**,** New York City Department of Health and Mental Hygiene, Gotham Center, 42-09 28th Street, 14th Floor, Long Island City, NY 11101-4132,Tel: (347) 396-6052

Client Name: _____

Your participation in this study is voluntary. Please take your time and read this Informed Consent Form carefully before you decide whether or not to take part in this research study. The reason for this study, the benefits, risks, and other information will be explained below. A member of our team will talk to you about taking part in this study. People who agree to take part in this study are called 'participants.' If you have any questions about this project, the consent form, or words that you do not understand, please ask.

Why am I being invited to take part in this research study?

You are invited to take part in this research project because you are HIV-positive and are living in HIV emergency housing in the form of a single room occupancy (SRO) hotel. Our study team is recruiting clients onsite at HIV emergency SRO hotels and we met you at your SRO hotel of residence. If you volunteer to take part in this study, you will be one of about 560 people to do so.

Why is this project being done?

This study will evaluate the effects of a housing program that includes a social network intervention on the health care and health outcomes of unstably housed HIV-positive people.

What am I agreeing to by signing this Informed Consent Form?

If you sign this form, you agree to:

1) Be assigned randomly to one of two study groups.
2) Complete at least one survey and one interview.
3) Be contacted by the study team for future research.

What will happen if I take part in this study?

If you agree to be in this study, a member of the study staff will interview you about you social network, that is, people that you know. An interviewer will also ask you questions using a survey. You will be asked questions about yourself and your medical history. The questions will cover your medication use, health, and housing history. You will be asked about sex and alcohol or drug use. Some of the questions may make you feel uncomfortable. You may refuse to answer any question. You may also end the interview at any time. If you do, your refusal will not affect your access to or eligibility for health care and

other services. The survey will take about 45 minutes to complete and the interview will take 30 minutes to complete.

You will be assigned to **only one** of two study groups. Here is a description of the two study groups:

1) Group 1: Enhanced Housing Placement Assistance (EHPA). Participants get help finding a permanent place to live, up to 12 months of support services, and a social network intervention.
2) Group 2: Usual Care. Participants receive usual care in NYC. Usual care includes referral to housing and other services that you are eligible to receive.

After the survey and interview are completed, the interviewer will tell you your study group assignment. No one will know your study group assignment until after you finish the interview. Group assignment is random, or by chance, like flipping a coin. The assignment has to be random for the study to work. This means that you and the study staff member cannot change your group assignment once it has been assigned.

If you are assigned to Group 1, you will be immediately referred to a CitiWide housing specialist. The housing specialist will help you find housing and arrange for your rent to be paid through the HIV/AIDS Services Administration (HASA). If you are assigned to Group 2, you will be immediately referred to a CitiWide housing specialist. The housing specialist will help you arrange for housing or services for which you are eligible through Ryan White and other programs.

If you agree to take part in this study and complete the survey and interview, a member of the study staff will try to contact you again for two more follow-up survey and interview meetings. Follow-up meetings will take place around every six months.

What are the risks and possible discomforts from being in this research study?

There are minimal risks from being in this study. Some of the questions in the survey are about personal issues and may make you feel uncomfortable. All answers you give will be kept private. You may have more contact with housing specialists, service providers, and study staff members than before joining the study. You may refuse contact with these people if you want.

What are the possible benefits from being in this research study?

By being in this study, you may receive help with finding housing and rental payments. You may also receive services that are connected to your housing. If you are assigned to Group 1, you will receive a social network intervention. If you are assigned to Group 2, you will not receive a social network intervention.

Will information about me be confidential?

All information that you give to us will remain confidential. Your answers to the survey will be kept confidential, or private. Study forms, survey answers, and computers will be locked in a file cabinet in a locked office. Computers with study data will be protected by passwords. Any treatment records will be kept private. Only those agencies listed on this consent form will be allowed to review any of the information collected on you during the study.

What other treatments or procedures are available for my condition?

We are not trying to develop a new treatment for your medical condition. We are trying to find out how housing, short-term services, and a social network intervention can improve medical care use and health outcomes. If you choose not to participate in the study, your decision will not affect your access to health care or to other services provided outside of this study.

What will I have to pay for if I take part in this research study?

There is no cost to you to participate in this research study.

Will I be paid to take part in this research study?

You will be reimbursed a $15 gift card after completing the first survey. You will receive additional $20 gift card reimbursements for each follow-up interview you complete during the rest of the study. After this interview is complete, the interviewer will give you a card that tells you the next time and date we would like to talk to you. If you want, you can contact us on your own at that time to set up an interview. You do not have to contact us again after today if you do not want to. Otherwise, we will try to contact you to set up the follow-up interviews.

Can I leave the study at any time?

You are free to leave the study at any time. If you choose not to be in the study, your decision will not affect your right to receive any benefits, services, or care that you are otherwise entitled to now. If you do decide to take the survey now, you may still quit at any time or refuse to answer a question. If you are assigned to a study group and later decide you do not want to receive the services provided to people in that group, you have the right to refuse some or all of the services.

What should I do if I have any questions?

Before you decide whether to take part in this study, please ask any questions that you have now. If you have questions about the study later on, you can contact the investigator, John Rojas at (347) 396-7428.

If you have questions about your rights as a participant or if you feel that you have been harmed in any way, call the Institutional Review Board Office at the New York City Department of Health and Mental Hygiene at (347) 396-6052.

Participant's Statement of Understanding

I understand that I have the right to revoke this authorization at any time by notifying one of the two Study Investigators named above. I understand that I may revoke this authorization except to the extent that action has already been taken based on this consent.

I understand that signing this authorization is voluntary. I understand that refusing to be in the study will not affect my right to receive any benefits, services, or care from the agency or organization from which I was recruited.

I understand that I may ask for and receive a copy of this form after I sign it.

The programs seeking this authorization will not receive any compensation in exchange for using or disclosing my information.

Do you have any questions about this study?

Please sign below only if you 1) agree to be randomly assigned to one of two study groups, 2) agree to be interviewed, and 3) agree to be contacted later for two to four more interviews later in the study.

Participant Signature _____ Date _____

Date on which this Authorization will expire: This consent will end five (5) years after the date that this consent is signed.

Statement of Study Staff

- I have explained the study, enrollment procedures, and the randomization process to the client, and
- I have answered all questions about this research study to the best of my ability.

Staff Signature _____ Date _____

If declined:

We understand that you have decided not to participate in the study. Could you please take a moment to answer a few questions?

We're interested in knowing why people do not want to do this study. Would you mind telling me which of the following best describes the reason you do not want to do this study?

- ❑ You are not comfortable with random assignment
- ❑ You are not interested in any additional services
- ❑ You are not interested in taking part in research
- ❑ You do not have time to participate in the survey and interview
- ❑ You are not willing to permit the required releases of information (privacy concerns)
- ❑ You are not sure about whether to participate and won't consent while unsure
- ❑ You do not think the gifts ($15 gift card with the first interview and $20 gift card with each additional interview) are enough to make up for the time and effort of taking part in the study
- ❑ Other (specify:_____)
- ❑ You'd rather not say why

Year of birth (yyyy) _____

❑ Refused

2) Age range:

❑ 18-29

❑ 30-44

- ❑ 45-54
- ❑ 55+
- ❑ Refused

3) ZIP code __ __ __ __ __
- ❑ Refused

4) Borough or county of current residence (please check one)
- ❑ Manhattan
- ❑ Brooklyn
- ❑ Bronx
- ❑ Queens
- ❑ Other area (please specify: _____)
- ❑ Refused

5) Gender (please check one)
- ❑ Male/Man
- ❑ Female/Woman
- ❑ Transgender (check below if applicable)
  - ❑ - male to female
  - ❑ - female to male
- ❑ Other (please specify: _____)
- ❑ Refused

6) Ethnicity (please check one)
- ❑ Hispanic/Latino(a)
- ❑ Not Hispanic/Latino(a)
- ❑ Refused

7) Race (check all that apply)
- ❑ African American/Black
- ❑ White/Caucasian
- ❑ Asian
- ❑ Native Hawaiian/Pacific Islander
- ❑ Native American/Alaskan Native
- ❑ Other (please specify: _____)
- ❑ Refused

8) Current HIV/AIDS status (please check one)
- ❑ AIDS diagnosis
- ❑ no AIDS diagnosis
- ❑ Refused

9) Demographic data source:
- ❑ Collected from refusing individual
- ❑ Filled in by interviewer