NYU Langone MEDICAL CENTER

Enrollment Informed Consent Form
Heart to Heart2

Title of Study:

Using MOST to optimize an HIV care continuum intervention for vulnerable populations, "Heart to Heart2"

Study #: s15-01480

Principal Investigator:
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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 "subjects" or "research subjects". Before you can decide, 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 talk about this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, we will note your consent for our records. We will give you a copy of this form for you to keep.

2. What is the purpose of this study?

This is a research study of people living with HIV called Heart to Heart2 or "HTH2." The study tests different ways of helping people living with HIV who are not taking HIV medications and have trouble getting to HIV medical care make their own *personal decisions* about medical care, medications, and other services, without pressure or judgment.

You have been chosen to participate because you received a study coupon from a friend, acquaintance, or study staff member.

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

This part of the study will last about 12 months. Approximately 1280 people will participate in this study.

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

This study has a number of parts. These parts are confidential, which means we will keep all the information you provide private. We will create a code number for you that will help us keep track of your participation in the different parts of the study. Your participation is voluntary, which means you do not have to participate. Your personal choices and decisions will be respected in every part of the project.

If you agree to participate, this is what will happen:

A. Computer surveys

At the beginning of the study, we will ask you to complete a survey about your health, medications, use of health services, mental health, and use of drugs and alcohol. Some of the questions will be asked by a study staff member. Other questions you will answer by yourself into the computer. The survey will take about one hour.

We will ask you to return in 4, 8 and 12 months to complete more computer surveys asking similar questions so we can see how things are going with your health and life while you're in the study.

All of these surveys are confidential and will not ask for your name or other information that could identify you personally. And the surveys are voluntary, so you may choose to not answer any question at any time.

B. First counseling session and HTH2 study programs

We will ask you to come to a confidential session with a counselor so we get to know you and you can get to know more about the study. We will ask you about your thoughts on your health, your personal decisions, and we will provide information about HIV disease and treatment. This first counseling session will take about an hour and be scheduled at a time that is good for you at a field site in NYC.

You will be randomly assigned to join up to five different HTH2 study programs. Being "randomly assigned" means that you and every person in the study have an equal chance of being placed in any or all of these 5 programs. Everyone gets at least one program. Most people will be randomly assigned to participate in 3 or 4 of the programs. All the programs are scheduled at times that are convenient for you. Some of the programs are short and do not require a lot of your time, and the programs are stretched out over time so they are not a burden or an inconvenience to you.

The programs are: 1) four **counseling sessions** (lasting about 1 hour each) with a study counselor to discuss your health decisions, and discuss what you think about HIV care and treatment; 2) in-person or phone contacts with a supportive and knowledgeable study **peer mentor** over a four month period; 3) **support groups** with other persons living with HIV led by a study counselor that meet 6 times over about four months; 4) practical **preparation** about how to get ready to take HIV medication, IF you wanted to do that, which includes a session with a study counselor at your home (if you agree to that), plus 1-4 weeks of practice runs for taking HIV medications using vitamins (as a reminder, it is your choice whether or not you take HIV medications); 5) three or six months of **patient navigation**, which includes weekly "check-in" contacts (a combination of in-person and by phone/text/email) with a study counselor to provide referrals for any services you might need, not just related to HIV, and provide support for concerns you might be having that affect your health, including HIV and other concerns.

There are some parts of the study that you can decline to participate in, but there are some that you need complete in order for you to participate.

To stay in the study, you will need to agree to come to the first confidential session and to be randomly selected to participate in any of these programs. However, you do not need to participate in any of the programs you are assigned to if you do not want to.

If you use your phone to send text messages, we will ask your consent to send you text messages to remind you of your appointments and to check in with you. These texts are for communication with the research study only and are confidential. That is, we would not show them to anyone outside the research team. But text messages are not encrypted or secure during their transmission and could be intercepted. We strongly recommend you password protect your cell phone as an additional step to protect your privacy. You can choose to not allow us to send you text messages and still participate in

the study. **If we texted you, we would not mention anything that would disclose your personal health information or state anything specific about you or your health behavior. We would not use the word "HIV" in any text.** You are also free to text the research study staff members at any time. You can agree to receive text messages from us and change your mind at any point.

Depending on which programs you get chosen for, these programs could last 3 to 8 months. We will explain in more detail the programs for which you do get chosen.

C. Blood draws

At your first visit after signing this form, we will ask you for a blood specimen (about 3 tubes of blood). A trained phlebotomist will use a needle and vacuum tube to take blood from a vein in your arm or hand. We will test your blood to measure the amount of HIV virus in your blood (your “viral load”) and the amount of CD4 cells in your blood (a “CD4 test”). Your name will not be on the blood sample, only your ID number, and the test results will not be placed in any medical record, only the research record. The tests are being done for research purposes only.

To be in the study, you will need to give a blood sample at your first visit.

We will ask you for blood samples again in 4 and 8 months (about 2 tubes of blood, for viral load testing), and in 12 months (about 3 tubes of blood, for viral load and CD4 testing). You may choose not to give us these blood samples and still be in the study.

D. In-person interview

We may ask you to take part in one or more open-ended in-person interview(s) with a study staff member (not on the computer) lasting 60-90 minutes. We will ask you about your experiences with health and services and the Heart to Heart2 program. We will ask if we can audio-record this/these interview(s). You can do the interview(s) even if you do not want them recorded, and you can choose not to do the interview(s) and stay in the study.

E. Health information from your primary care provider

At your visits in 12 months we will contact your HIV primary care provider to confirm some of your health information, such as the dates of your recent health care appointments, and whether you have decided to take HIV medication. If you don’t have a primary care provider or don’t want us to contact him/her, you can stay in the study.

4. What are the possible risks or discomforts?

Some of the questions in the survey or programs may make you feel uncomfortable. All answers you give will be kept private. You do not have to answer any questions at any time for any reason.

Drawing blood may cause temporary discomfort from the needle stick, bruising, bleeding, light-headedness, and local infection.

The study may involve other risks that are unknown at this time.

5. What are the possible benefits of the study?

This study may help us learn what people living with HIV know and think about HIV medication and how to help people make decisions about taking HIV medications and going to HIV medical care. This study may help develop better services for people living with HIV.

You may or may not get any direct benefit from being in the study.

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

You are free to choose not to participate in the study.

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

There is no cost to you for participating in the study. The study will pay for all study-related activities.

a. You will receive $25 for each computer survey.

b. You will receive $25 for the first counseling session you attend

c. Depending on which HTH2 programs you get chosen for, you will receive:

- $25 for each of the four sessions with a counselor
- $50 total for the preparation program
- $25 per month for the “peer mentor” contacts
- $15 for each HIV support group
- $25 for each month of patient navigation and “check-in” contacts from a counselor

d. You will receive $15 for each blood sample you give us.

e. You will receive $25 for each in-person interview, if selected.

You will also receive compensation for round-trip public transportation for these activities if they take place in-person.

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

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator’s name and phone number are listed at the top of page 1 of this consent form.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

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

This study is completely VOLUNTARY. You are not giving up any legal claims or rights for being a part of this study. If you agree to participate, you are free to quit at any time. You may refuse to answer any question.

We may decide to withdraw or pull you out of the study for certain reasons. Some reasons would be that you have already participated in this study or the study has been stopped. If we learn that you have been incarcerated after you have agreed to take part in this study and as a result you will not be able to take part in study activities, we may need to stop your participation in the study.

10. How will my information be protected?

NYU Silver School of Social Work is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to take part in this study.

We have obtained a Certificate of Confidentiality from the National Institutes of Health, which means the researchers cannot be forced to disclose your study information, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except if personnel of the United States Government demand to use information that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information you provide about current child/elder abuse, or if there are threats to harm yourself or others. We are required to report this to the authorities.

A. What information about me may be used or shared with others?

The following information may be used or shared in connection with this study among research study staff: Information in your medical record and research record, for example, laboratory tests, and procedures.

If you agree to be in this study, Dr. Marya Gwadz and her study team will ask you to participate in several activities. These may include: completing a locator form, participating in interviews, sessions and programs, blood tests, and getting information from your health care provider. They will use these test results both to help you get medical care (if you would like) and to complete this research. Results of tests and information you give just for this study and not as part of your regular medical care will not be included in your medical record.

B. Why is my information being used?

Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

C. Who may use and share information about me?

The following individuals may use, share or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- The study sponsor: National Institutes of Health.
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites.

- Data Safety Monitoring Board/Clinical Events Committee.
- The Patient Advocate or Research Ombudsman (CTSI).

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306- 7450. These agencies are responsible for protecting your rights.

D. How long may my information be used or shared?

Your identifying study information will be kept for at least six years or until after the study is completed, whichever is longer. At that time the information identifying you will be removed from your research record.

E. 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 health 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 this study.

11. Optional permission for future use

NYU Langone Medical Center (NYULMC) would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. 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.

NYULMC 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 NYU Silver School of Social Work or its research partners.
  Subject Initials _____

12. 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.

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

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 subject, you should speak with the Principal Investigator listed on top of the 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.

You have read or had read to you the explanation of this study, you have been given a copy of this form, the opportunity to discuss any questions that you might have and the right to refuse participation. I am going to ask for your consent to participate in this study. Your name, signature and the date will be captured electronically and saved in a secure database that is only accessible to study staff.

A. Do you agree to take part in the first counseling session and to be randomized to the HTH2 programs?
YES_____NO_____ **If you do not agree to participate in the session or be randomized, you may not participate in this study.**

B. Do you agree to give us blood samples? **If you do not agree to give us a first blood sample, you may not participate in this study.**
YES_____NO_____

When you sign your name, 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 Subject (Print)	Signature of Subject Date	Date
_____	_____	_____
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date