Consent to Act as a Research Subject

Treatment Education for Black/African Americans Living with HIV

You are being asked to participate in Project Rise, a research study. Your participation is voluntary. You should feel free to ask questions and should understand the study completely before you agree to participate.

WHO IS DOING THIS STUDY?
APLA Health and RAND Corporation's Health Unit are doing the study. The National Institutes of Health is paying for the study.

WHAT IS THE PURPOSE OF PROJECT RISE?
The purpose of this study is to test a new program designed to support HIV-positive Black/African Americans stay healthy and take HIV medications on schedule. We are recruiting 350 Black/African Americans who take antiretroviral medications.

WHAT WILL YOU BE ASKED TO DO?
If you are eligible and decide to participate in the study, your participation will involve the following:

Rise Program. You may be asked to participate in the 6-month Rise program, which consists of 5 to 9 individual counseling sessions. Because there are a limited number of spots available in this study, we will randomly select who is enrolled in the program and who is not (similar to flipping a coin). If you are randomly selected for the program:

- You will attend three 1-2 hour individual sessions with a treatment counselor for the first month of the program, starting in about a month after today, and
- You will attend 2-6 more individual sessions after that. The number of sessions will depend on your needs.

The sessions will be audiotaped (recording of voices only) for purposes of monitoring how well the counselor is conducting the intervention. If you do not agree to have your sessions audiotaped, you may still take part in the study.

If you are not assigned to the program, you will receive your regular care from your healthcare provider, and you will not receive the individual counseling sessions.

Medication Adherence Assessment: Today, we will give you an electronic cap to put on your HIV medication bottle. The cap will record the time and date the bottle is opened. The cap is easy to use. It will not prevent you from taking your medications as prescribed. You will use the cap throughout the study and bring it with you to each session. We will collect information from the cap to see how you take your HIV medications. If you bring back your cap in a month, we will check the cap and then officially enroll you in the study.

Surveys: You will complete three 1-2 hour surveys at APLA. You will complete a survey today, and again in about 7 and 13 months. You will complete the survey in a private room. The survey will ask questions about your experiences with and perceptions of medical care and medications, your mental and physical health, your sexual behavior and drug use. You will read the survey and can listen to the questions on the computer, or you can ask the interviewer to read them to you.

HIV Laboratory Test Results: We will ask you to bring your most recent HIV laboratory test results for viral load and CD4 cell count to your next study visit (in about a month), and to the last two survey visits. We will also ask you to bring us your updated laboratory tests whenever you have new HIV laboratory tests done. With your permission, we will also ask your medical provider to provide this information to us directly.

Blood Draws: We will ask you to have blood drawn three times (in a month, in about 7 months, and in about 13 months) so that we can test your HIV viral load. You may choose to not have blood drawn. If your HIV laboratory test results show that your HIV viral load was measured in the last month, we will not ask for a blood draw at that time.

Check-ins with Study Staff: Once you are officially enrolled in the study, we will check in with you at 3, 5, 9 and 11 months after today to review your electronic pill bottle caps and make sure your contact information is current.

Staying in Contact: To ensure contact with all participants, we will ask you to give us contact information of people who could help us reach you. We will only contact them if we cannot find you. You can give as much or as little information as you feel comfortable sharing. We will not tell them your personal information. If you give us permission, we will only say that we are trying to contact you about a health study. If we cannot reach you through these methods, we may also search public records, such as public databases.

WHAT ARE SOME POTENTIAL RISKS OF DOING THIS STUDY?
Talking about HIV, treatments, sexual behavior, discrimination, or other issues may cause you to feel uneasy or sad. If you are uncomfortable or sad and feel that you need someone else to talk to, we can provide you with contact information for a counselor. If you have suicidal thoughts due to difficulties in your life currently, you can also call the suicide hotline 24 hours a day at 1-800-273-8255.

You can take a break during the counseling or survey sessions, or end them at any time. Ending the counseling or survey sessions will not affect your relationship with APLA Health.

WHAT ARE POTENTIAL BENEFITS OF DOING THIS STUDY?
You may find it helpful to talk about your health, treatments, or HIV. The study will also provide information to APLA Health and other AIDS service organizations about how to improve their services. You might not receive any benefits from participation.

HOW WILL YOUR CONFIDENTIALITY BE PROTECTED?
We will keep the information that you provide confidential. Only qualified members of the study team will look at your private information. We will store your survey responses, the information we obtain from your medication caps, and your HIV status separate from your name and contact information. Any information you give us will be connected to a unique ID number and not your name. All material, including surveys, forms, and notes will be stored in a locked file cabinet in

secure buildings. After the study, all information such as your name and contact information will be destroyed.

To protect confidentiality, no identifying information will be placed on audiotape labels of the treatment counseling sessions. The audiotapes will be erased once they are fully analyzed, within a year of the study being completed.

A Certificate of Confidentiality from the National Institutes of Health protects your research data further. With this Certificate, the researchers cannot be forced to disclose information that may identify you, 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 as explained below.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily without your consent, information that would identify you as a participant in the research project under the following circumstances: if we think you are at immediate risk of seriously harming yourself or others we may be legally obligated to notify others, such as calling 911 emergency services. In addition, if we learn about current child abuse or elder abuse, we may discuss it with you and seek help from authorities to protect you or another person. In such cases, we would first ask you to speak with a study supervisor who would assess the situation and offer referrals.

WHAT WILL YOU GET FOR PARTICIPATING?

You can receive up to $230 if you do all of the assessments:

- You will receive $30 for the visit (and survey) today.
- If you are enrolled in a month, you will receive $30 for the first blood draw and enrollment session (or $10 if you choose not to do the blood draw).
- You will receive $40 for the 7-month follow-up and $50 for the 13-month follow-up (or $20 per session if you do either the survey or blood draw).
- You will get $20 for each of the four check-in sessions.

In addition, if you are selected for the Rise program, you will also receive $10 for each individual treatment counseling session (five to nine sessions depending on your needs, or up to $90).

We will pay you at each visit. If you leave a visit before it is over, we will still pay you for that visit.

IS PARTICIPATION VOLUNTARY?

Yes. You can decide whether to participate in this study or not. You can choose whether to finish the visits and individual sessions with the treatment counselors or not. You can leave a visit at any time without anything bad happening. You may also skip questions you don't want to answer and still be in the study. If you tell us that you do not want to be in the study, we will not make any more attempts to contact you.

QUESTIONS ABOUT THE STUDY?

If you have questions about the study, or if you have concerns about the study after you sign up, please contact the study investigators, Dr. Matt Mutchler at (213) 201-1522 or Dr. Laura Bogart, at (310) 393-0411 extension 7281.

You are not giving up any legal claims, rights, or remedies because of your participation in this research study. If you have questions about your rights as a research participant or need to report a research-related injury or concern, you can contact RAND's Human Subjects Protection Committee toll-free at (866) 697-5620 or by emailing hspcinfo@rand.org. If possible, when you contact the Committee, please reference Study #2016-0940.

Questions to Ensure Participant Understands Voluntary Informed Consent:

1. What is the study about?
2. Do you have to participate in the study?
3. What will you be asked to do in the study?
4. If you don't take part in this study or you stop taking part will you still be able to receive services?
5. Do you understand the information covered in this sheet?
6. Do you have any questions about it?

Blood Draw
Do you agree to have blood samples taken three times?

Yes___ No___

Audiotaping of Sessions
If you are in the first group, do you agree to have the counseling sessions audiotaped?

Yes___ No___

Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you may have about the study. Your signature also indicates that you agree to be in the study and have been told that you can change your mind and withdraw your consent at any time. You have been given a copy of this consent form. You have been told that by signing this consent for you are not giving up any of your legal rights.

_____
Name of participant (*please print*)

_____
Signature of Participant ***Date***

_____
Signature of Investigator ***Date***