BROWN

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION
Positive STEPS
(Strategies to Enhance Problem-solving Skills)
Version 10 March 7, 2019

KEY INFORMATION:
You are invited to take part in a research study with Brown University, Miriam Hospital, Fenway Health, Lurie Children's Hospital, and Howard Brown Health Center. Your participation is voluntary.

If you are between the ages of 16-17 years old, you will require an advocate present during the informed consent process. A parent or guardian may be your advocate or we can appoint an advocate for you. This individual will not be a member of our research team. The advocate will be present during the consent process to help answer any questions you may have and can assist in determining if you would like to enroll in the study.

- **PURPOSE:** The study is about testing a new intervention that helps young people with HIV take their medication. The intervention is called Positive STEPS.
- **PROCEDURES:** You will be asked to use an electronic pill box for your HIV medication, provide a blood sample at each research visit to check your viral load, have a hair sample collected, and you may receive text message reminders and have meetings with a specially- trained counselor.
- **TIME INVOLVED:** The study will last about 12 months. Depending on the group assignment you may attend up to 10 visits.
- **COMPENSATION:** You will receive up to $310 for your time.
- **RISKS:** Questions and counseling related to depression, drug and alcohol use, and sexual risk may be upsetting to some people; if you receive text messages there may be risk that someone may see the text message that was not intended to; and there may be some discomfort associated with blood draw.
- **BENEFITS:** You may not experience any direct benefit from being in this study.
- **ALTERNATIVES TO PARTICIPATION:** The alternative is to not be in this study. If you do not join, your medical care will not be affected.

1. **Researcher(s):** Matthew J. Mimiaga, ScD, MPH (401) 863-6559 at Brown University, Curt Beckwith, MD(401)793-4397 at Miriam Hospital, Kenneth Mayer, MD (617)927-6087 at Fenway Health; Robert Garofalo, MD, MPH (312) 227-6110 at Lurie Children's Hospital, and Kristen Keglovitz-Baker PA-C, AAHIVS (773)388-9875 at Howard Brown Health Center

We are going to explain the purpose of this research study, how it is designed, and how it may help you or others. We will also tell you about any risks you may face and what you will be asked to do. After you learn about the study, we will ask you if you want to take part. If you decide to be a part of the study, you will be asked to sign this consent form to participate. Signing this form will show that you understand the study, agree to participate and know your rights as a research participant. This process is called informed consent. You will be given a copy of the form to keep as a reminder of your rights.

2. What is this study about?

This study is funded by the National Institute of Nursing Research. Our goal is to help HIV-positive adolescents and young adults take their medications on schedule. Our approach involves utilizing an electronic pill box, sending text message reminders and scheduling meetings with specially- trained counselor.

You are eligible to be in this study if you meet the following criteria:

- You are willing and able to come to all study visits
- You are 16 to 29 years' old (if recruited from Miriam Hospital, you are 18 to 29 years old per Lifespan policy).
- You are HIV-positive (confirmed at enrollment)
- You are currently taking antiretroviral therapy (ART – HIV medication) for at least 3 months
- You have difficulty taking your antiretroviral therapy (ART – HIV medication) and have missed 1 or more dose in the past week or 4 or more doses in the past month
- You have daily access to a cell phone
- You are not participating in another ART intervention study
- You are able and willing to provide consent

3. What will I be asked to do?

If you agree to join this study, you will be asked to do the following:

Attend four study visits and one group assignment visit. The study visits will occur at baseline and 4, 8, and 12 months from baseline. Each visit will last between 1.5-2.5 hours. At these visits you will complete research assessments. In the study research assessments, you will be asked about your age and what your education has been. You will also be asked about what HIV medication you take, if you use alcohol or drugs and your sexual activity. Some of the more sensitive assessments about your mental health and sexual activity will be conducted on an audio computer assisted self-interview (ACASI). These assessments will not be reviewed by a research study staff member. All participants will receive a resource list with referrals for services at each visit should you require additional support. You can skip any questions that you do not want to answer.

Use an electronic pill box called a Wisepill device. This is an electronic pill box you will use to hold your HIV medications. A message will be sent to us every time you open it to take your medication. We will provide Wisepill to you at your baseline visit and train you on how to use this device for the course of the study.

Have your blood collected. At your first study visit, we will confirm your HIV status and measure the amount of HIV in your body (viral load) by drawing 1 tube (about 1 teaspoon) of blood. If we are unable to confirm your HIV status, you may be ineligible to participate in the study. At each follow-up visit, we will draw one tube of blood to measure the amount of HIV in your body (viral load). Additionally, you will be asked to sign a release of medical information to request viral load laboratory results from your HIV doctor in the event we are unable to draw your blood at a research visit. You are not required to sign this release to participate in the study. Your blood samples will not be used for commercial profit.

Have a sample of your hair collected. At your four and twelve month research visit we may collect a small sample (approximately 10 strands) from the hair on your head as a way to measure levels of ART medication.

Participate in 1 of 2 study groups. The study is called a randomized control trial. That means you will be randomly put in to 1 of 2 groups. You will find out which group you have been randomized to at your group assignment visit 2-weeks after baseline.

If you get assigned to Group A: Standard of Care, you will have 1 counseling session about the importance of taking your HIV medications.

If you get assigned to Group B: Positive STEPS Intervention, you will:

- Receive daily text messages from study staff reminding you to take your HIV medication.
- Between 1 and 3 months of starting the study, you may also be asked to come in for 5 individual counseling sessions led by a trained counselor.
- In these sessions the counselor will work with you to take your HIV medication
- There will be 1 week between each session.
- The sessions will last about 1 hour and take place in a private room.
- The sessions will be audio-recorded, but your name will not be recorded on the tapes. All data will be stored in locked cabinets in a secure area of the study site.

Topics for the counseling sessions will include things like:

- What do you know about your HIV medication(s)?
- How do you store your medication(s)?
- What are some things for you that make it hard to take all your HIV medication(s) on time?
- How does your mood, alcohol use, or drug use change your ability to take your HIV medication(s)?
- How do your relationships with friends and/or family members change your ability to take your HIV medication(s)?

Your participation in this study may last up 12 months. If you change medical providers while on the study it will not affect your participation

4. Will I be paid?

If you choose to take part in this study, you will be paid up to $310 in cash for the following:

- $40 Baseline (enrollment)
- $50 For each follow-up assessment (4, 8, and 12 month)
- $20 Group assignment (randomization) and Wisepill "run in"
- $20 For each counseling session (up to 5 sessions)

Depending upon your cell phone plan, standard rates may apply when you receive text messages as a part of the research intervention.

5. What are the risks?

1. There may be a risk of social harm. Social, psychological, and interpersonal harms may include being discriminated against, feeling stigmatized, emotional distress, as well as feelings of discomfort and embarrassment. We do not anticipate discomfort or distress during the research study visits and we will make every effort to create a secure and trustworthy environment. However, it might feel embarrassing to talk about problems you don't talk about with other people. Questions and counseling related to depression, drug and alcohol use, and sexual risk-taking have the potential to upset some participants. You can skip any question that you don't feel comfortable answering. You can also leave the session at any time if you feel like it's too uncomfortable. You will have access to a masters-level counselor who can help you deal with any feelings and/or questions you have that may arise. All information disclosed to the researcher will remain confidential. Only researchers will be able to see your research assessments and listen to audio taped sessions. Your name will not be used in any reports that may result from this study.

2. There may be a risk that the text message might be read by someone that it was not intended for. All participants in the Group B will receive text messages. These messages are supposed to help you remember to take your HIV medication. The messages will not have any information about your health. The message will also not have information about your HIV status. If the text messages make you uncomfortable, you can choose to stop receiving them. All texts will be automatically sent from a phone number that cannot be called or traced back to the study. Your data will not be given to anyone except when required by law. You will not be contacted via your cell phone number for study reminders, unless you agree to the study reaching you this way. Security measures are used to protect your data from unauthorized access and to maintain data accuracy to help ensure that your data is stored securely and remains confidential.

3. You may experience some discomfort from drawing blood. We will draw your blood (about 1 teaspoon) to measure the amount of HIV in your body, through viral load. You may feel a slight pinch when we draw your blood and you may experience bruising from the needle. However, bruising is not likely to occur. The person drawing your blood is certified to do so.

6. What are the benefits?

You may not directly benefit from being in this research study. You will receive at least one counseling session that you may find beneficial to improving how you take your HIV medication. You may receive an intervention that may help with taking your HIV

medication(s). In addition, you may help other HIV-positive people in the future by being in this study.

7. How will my information be protected?

In order to protect your confidentiality, all your records will be stored on a password protected computer and in a locked file cabinet at collaborating institutions (Brown University, Miriam Hospital, Fenway Health, Lurie Children's Hospital and Howard Brown Health Center). Your name will not be publicly disclosed at any time and the records will be maintained according to current legal requirements. This applies to any:

- written records
- research assessments
- test results

Information from this study may be reviewed and photocopied by state and federal regulatory agencies such as the Office of Human Research Protection as applicable, the Institutional Review Board of Brown University, and collaborating institutions (Brown University, Miriam Hospital, Fenway Health, Lurie Children's Hospital and Howard Brown Health Center). Information from this study may be published; however, your name will not be used in any publications.

There is no time limit for using and disclosing your de-identified data and information. Researchers will use your data for many years. This study information (which does not contain your identity) may also be published.

Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluating federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

There are limits of confidentiality; most notably, the disclosure of suicidal thoughts, suicide attempts, or abuse or neglect. If you are under age 18, disclosure of violence or victimization relating to a family member/other individual will require reporting and/or notifying appropriate authorities. Additionally, if you inform study staff of any ongoing abuse or neglect involving a person under the age of 18, we will notify the authorities when indicated by state procedures and laws. Consistent with state-mandated abuse and/or neglect reporting requirements, should a report to the authorities be required, the information provided will be from the PIs. No mention of the study site or the participation in this particular research protocol will be disclosed.

8. **Who will my information be shared with? *[FENWAY Participants Only]***

You may have the right to find out if information collected for this study was shared with others for research, treatment, or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again.

You can withdraw from the study and end your permission for Brown University or Fenway Health to use or share the information that was collected as part of the research; however, you cannot get back information that was already shared with others. Once you remove your permission, no more identifiable information about your health ("health information") will be collected. If you wish to withdraw your health information, please contact the research team.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research visits, tests, interviews, and questions.

Your health information is protected by a law called the Health Information Portability and Accountability Act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. The following people may see, use, and share your research health information:

- Research staff at Brown University and Fenway Health involved in this study;
- Medical staff at Fenway Health directly involved in your care;
- Other research investigators and centers that are a part of this study, including people who oversee the research;
- People at Fenway Health who oversee, advise, and evaluate research and care, including the Fenway Health Institutional Review Board;
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;

- Sponsors or others who fund the research, including the government or private sponsors;
- Federal and state agencies that oversee or review research information, such as the FDA, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Fenway Health, such as laboratories;
- Public health and safety officials (for instance, if we learn information that could mean that harm could come to you or others we may need to report this, as required by law);

The main reasons why we may share this information include:

- To conduct the study;
- To make sure the study meets all legal and organizational requirements;
- To monitor the safety of participants in the study.

We will use and disclose your protected information only as described in this form; however, people outside Fenway Health or Brown University who receive your information may not be covered by this promise. We will try to ensure that everyone who needs to see your information keeps it confidential, but we cannot guarantee this.

Because research is ongoing, we cannot give you an exact time of when we will destroy this information. Researchers may continue to use your data for many years.

9. Are there any alternatives to this study?

The alternative is to not be in this study. If you do not join, your medical care will not be affected.

10. What if I want to stop?

If you wish to stop participating, please tell us right away. If you leave the study early, it will not affect the medical care that you currently receive including care at at our participating sites (Brown University, Miriam Hospital, Lurie Children's Hospital, Howard Brown Health Center or The Fenway Institute). You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

You can also still ask us about different programs that help with HIV treatment and get information about other types of services (for example, mental health services).

11. What will happen if I am hurt as a result of this study?

It is unlikely that you will be at any risk for physical harm in this study. If you get hurt during your participation, we will do what we can to treat your injuries. The study staff will direct you where to go if you need additional medical care. If this occurs the cost for the related treatment may be charged to your insurance company or to you.

Brown University, Miriam Hospital, Fenway Health, Lurie Children's Hospital or Howard Brown Health Center cannot provide free long-term care. We cannot pay you for other things like lost work or childcare expenses. Some insurance companies may not pay for costs resulting from research.

The National Institutes of Health will not pay for injuries. You can still seek payment for injuries in other ways, like with a lawyer.

12. Will I be told of any new findings or information while I am participating in the study?

You will be told about any important new findings that may be helpful or harmful to you. We will also tell you about findings that might change your mind about being in the study.

13. Why will I be taken off the study?

You may be removed from the study if we are not able to confirm you are HIV positive. If we are not able to confirm you are HIV Positive. You might be taken off of the study seems that the study would hurt you or if we cancel the study. You may also be asked to leave the study if you do not follow instructions or if you miss appointments. There may be other reasons to take you out of the study that we do not know at this time.

If any of the study activities seem too upsetting to you, the counselor can recommend that you do not continue. This could happen even if you want to continue. The researchers will make the decision and let you know if you need to leave the study. If you must drop out because the researchers ask you, you will still be paid the full amount for the study visit.

14. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call Jennifer Olson at (401) 552-4375 or email Jennifer_olson1@brown.edu in Rhode Island and Massachusetts, and Sam Hoehlne (872) 228-9051or email SHoehlne@luriechildrens.org in Chicago, Illinois.

15. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

Consent questions only required for participant's age 16 and 17

1) Name things you will be expected to do during the study:_____
   _____
   _____
   _____
   _____
2) Explain what you would do if they no longer wished to participate in the study:_____
   _____
   _____

_____
_____

3) Explain what you would do if they experienced distress during the study:_____
_____
_____
_____
_____

4) Identify potential risks for participating in the study:_____
_____
_____
_____

16. Consent to Participate

Participant's statement of informed consent and signatures
I have explained to_____the purpose of the research, the procedures required and the possible risks and benefits to the best of my ability.

Investigator's Signature_____ **Printed Name**_____**Date**_____
(or Investigator's Representative)

I confirm that I have been informed about the purpose of the research study, the procedures that I will undergo, and the possible risks, discomforts, and benefits I may experience, and had all of my questions answered. Alternatives to my participation in the study have also been discussed. I understand that I am free not to participate in this research at all. I understand that I will receive a signed copy of this consent form. I may refuse to sign this form. By choosing to do so, I will not lose any rights or benefits to which I might otherwise be entitled. However, I will not be able to enroll in this research study without signing this form.

I agree to give my consent to participate as a subject in this research study. I give permission to Brown University, Miriam Hospital, Fenway Health, Lurie Children's Hospital and Howard Brown Health to use and disclose my study data as described above.

_____	_____	_____	___/___/___
Participant's Signature	**Printed Name**	**Date**	**DOB**

_____	_____	_____
Witness's Signature	**Printed Name**	**Date**

***Witness signature only required for participants age 16 and 17**