ADOLESCENT MEDICINE TRIALS NETWORK FOR HIV/AIDS INTERVENTIONS

CONSENT/ASSENT

Adaptive Antiretroviral Therapy (ART) Adherence Interventions for Youth Living with Human Immunodeficiency Virus (HIV) through Text Messaging (SMS) and Cell Phone Support (CPS) Embedded within the Sequential Multiple Assignment Randomized Trial (SMART) Design

NCT03535337

Sponsor:	National Institute of Child Health and Human Development (NICHD) National Institute on Drug Abuse (NIDA) U19HD089875
Study Chair/Lead:	Marvin E. Belzer, M.D. Children's Hospital Los Angeles Los Angeles, CA, USA
Study Co-Chair/Co-Lead:	Karen MacDonell, Ph.D. Wayne State University Detroit, MI, USA
Recruitment & Enrollment Center:	Hunter College PRIDE Health Research Consortium
Analytic Core Analyst:	Samiran Ghosh, Ph.D. Wayne State University
Study Procedure Guide Version Date:	December 15, 2020

Permission to Take Part in a Human Research Study

Title of research study: Adaptive Antiretroviral Therapy Adherence Interventions for Youth Living with Human Immunodeficiency Virus through Text Messaging and Cell Phone Support Embedded within the Sequential Multiple Assignment Randomized Trial (SMART) Design

Investigators: Marvin Belzer, Karen MacDonell, and Sylvie Naar

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Introduction

You are invited to participate in a research study of a program to help youth living with HIV adhere to their medications. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

First, we want you to know that:

> Taking part in research is entirely voluntary**.**
>
> You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled.
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> You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of research procedures they would want to receive. If you have such beliefs, please discuss them with the research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone on the Florida State University (FSU) research team, or with family, friends or your personal physician or other professional.

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

You were selected as a possible participant in the SMART study because you are between the ages of 15 and 24 years old, are living with HIV, are currently prescribed an antiretroviral therapy (ART) medication regimen, have an unsuppressed viral load and/or report having low adherence to your ART medication regimen, and own a mobile phone or device that can receive calls and text messages.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Permission to Take Part in a Human Research Study

Why is this research being done?

This study is being conducted by Marvin E. Belzer, M.D. at Children's Hospital Los Angeles, Karen MacDonell, Ph.D. at Wayne State University, and Sylvie Naar, Ph.D. at Florida State University College of Medicine. It is funded by the National Institute of Child and Human Development (NICHD) and the National Institute on Drug Abuse (NIDA).

The purpose of the study is aimed at testing an intervention to help youth and young adults living with HIV adhere to their antiretroviral therapy and achieve and maintain viral load suppression. This study will compare two types of mobile health interventions – cell phone support calls versus text messaging. In total you will be in the study for approximately 9 months. This could be a bit longer if you're not able to provide a viral load test result and/or complete the computer survey within 28 days after the scheduled 3-month assessment since these items are needed to progress to the following intervention.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 9 months.

You will be asked to provide proof of your viral load and complete a survey at each of the baseline and 3 follow-up assessments at approximately 3, 6, and 9 months after the baseline survey. Each assessment should take approximately 1 to 1.5 hours to complete. After your baseline assessment you will be randomly assigned to an intervention of either text messaging or cell phone support calls for daily ART medications reminders. After 3 months of this intervention, you will be randomized again, except this randomization will depend on how you responded to the original intervention. You might continue to receive the same number of cell phone calls or text messages, or these could be reduced to 2 times per week. You might stop receiving all cell phone calls or text messages. Or, you might change to receive the other SMART intervention.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life, standard medical care or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of some questions asked in the computerized assessments and the intervention phone calls. There is a risk of loss of confidentiality during the calls or text messages.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Based on experience with this type of intervention program, researchers believe it may be of benefit to adolescents and young adults like you to adhere to their ART regimen and achieve and maintain a suppressed viral load. Of course, because everyone responds differently, no one can know ahead of time if it will help you.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Permission to Take Part in a Human Research Study

There are no therapeutic alternatives available at this time. An alternative is for you not to participate in this research study. Participants always have the option not to participate in this study, and referrals to community based organizations are available to all study participants.

Permission to Take Part in a Human Research Study

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints about this study now or in the future, or think the research has hurt you, you may contact the following researchers: Sylvie Naar at FSU (850) 644-3516, or Marvin E. Belzer at Children's Hospital Los Angeles, (323) 361-4758.

If you would like to talk to someone other than the Principal Investigator, you are encouraged to contact the Florida State University Institutional Review Board (IRB) at 2010 Levy Street, Research Building B, Suite 276, Tallahassee, FL 32306-2742, or 850-644-7900, or by email at humansubjects@fsu.edu.

You will be given a copy of this information to keep for your records.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

You will be part of a group of 90 participants who are taking part in the study nationally.

What happens if I say "yes" to being in this research?

Study Procedures

If you agree to be in the study, you will be asked to complete the following activities:

(1) **Viral Load Assessment:** Provide proof of your viral load or provide blood specimens for HIV viral load measurement at each of the follow-up assessments (approximately 3, 6, and 9 months after you complete your baseline survey). You can provide proof of your viral load if it was performed approximately two weeks before your scheduled assessment until approximately 4 weeks after your scheduled assessment. If you do not have a copy of your viral load, you can either obtain this in writing from your doctor or ask your doctor to send your results to the SMART team at Hunter College. If you have not had a viral load test around the time of your assessment, you can have testing done at no cost to you at a participating clinic or at a central lab (such as Quest Diagnostics).

(2) **Assessments:** You will participate in a baseline assessment and 3 follow-up assessments at approximately 3, 6, and 9 months after the baseline survey. At each assessment you will complete a computer-based survey that will ask about your adherence to your medications, substance use, depression, sexual behavior and other questions related to HIV. At the baseline

assessment, we will also collect demographic information about you. Each assessment should take approximately 1 to 1.5 hours to complete.

All assessments can be completed by clicking on a link that we will send to the contact information (email address, cell phone number, etc.) you provide.

(3) **Intervention**: After your baseline assessment you will be randomly assigned to an intervention. The intervention you will participate in is aimed at helping you increase your adherence to ART medications as prescribed to decrease your viral load. The 3-month intervention will be delivered via text messaging or cell phone support calls depending on which program you are randomly assigned to (like flipping a coin). You have an equal chance of being assigned to either intervention.

Cell phone support calls will be provided by an adherence facilitator who will call you each weekday to ask if you have taken your ART medication(s) and provide brief problem solving support. They will call you on weekdays, but not holidays, at a time you agree upon in advance. These calls will be audio recorded for quality assurance purposes.

For text messaging support, we will send you a customized text to determine if you took your medication(s), and you will text back whether or not you have taken your medication. The text messages will be sent to you every day at a time agreed upon in advance.

After 3 months of this intervention, you will be randomized again, except this randomization will depend on how you responded to the original intervention. You might continue to receive the same number of cell phone calls or text messages, or these could be reduced to 2 times per week. You might stop receiving all cell phone calls or text messages. Or, you might change to receive the other SMART intervention. For example, you might change from receiving cell phone calls to receiving text messages. No matter what happens, you'll still continue to complete the surveys approximately every 3 months until you've been in the study for approximately 9 months.

As mentioned before, you may get randomized to receive only 2 cell phone support calls or text messages for the next 3 months, or you'll stop receiving the calls or text messages completely. If you're randomized to receive the calls or texts 2 times per week, those will end after the additional 3 months (after being in the study for 6 months).

On the other hand, you may be randomized to receive the same intervention as the first 3 months (continue on the cell phone support calls or the text messaging) or you might switch to the other intervention, as described above. During these 3 months, you will be eligible for an incentive as described in the Compensation section below. After those 3 months (approximately 6 months from when you started the study), the cell phone calls or text messages will decrease to 2 times per week for 3 months.

If you do not provide viral load test results, nor report your adherence to your ART medication, 14 days prior or 28 days after your scheduled 3-month assessment, you will not be randomized for a second time. Consequently, you will no longer receive the intervention. Cell phone support calls or text messaging will be discontinued; however, the researchers may still ask you to complete the computer-based surveys at the 6-month and 9-month assessments, for which you are still eligible to receive compensation.

The researchers will also ask for some medical information from your HIV care provider. This may include: 1) your most recent CD4+ T-Cell absolute count before you enrolled in the study; 2) your viral load results for up to a year before you started the study and while you're participating in the study; and 3) your prescribed ART medications while you're in the study. If you have this information, you can send this to us. Otherwise, you may be asked to contact your HIV care provider or we can contact your HIV care provider to have this information sent to the SMART research team at Hunter College.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to provide proof of your viral load or blood specimens for HIV viral load measurement, complete computer-based surveys, and own a mobile phone or device that can receive calls and text messages.

There will be no costs to you for your participation in this research study; there is no cost to you for study-related viral load. If you obtain viral load through your medical provider as part of your standard care, the cost of the viral load may be billed to your insurance or other third-party payer. You may be responsible for any co-pays or deductibles for viral loads measured as part of your standard care.

What happens if I say "yes," but I change my mind later?

You can leave the research at any time; it will not be held against you.

Voluntary Nature of the Study

Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part you can change your mind later and withdraw from the study. Questions in the computer survey cannot be skipped, but if you do not want to answer a question in the computer survey you may just close the survey link. The survey will then remain incomplete. If you have an incomplete survey your participation in the study will continue unless you decide to withdraw from the study. You can withdraw from the study at any time. Your decision to withdraw will not change any present or future relationships you may have with Florida State University, the health clinic, any of their affiliates or Hunter College.

It is important to the study that we continue collecting data at follow-up assessments. If you decide to withdraw from the study, please inform the study staff of your decision via an email to SMARTatn@prideresearch.org. We will ask you about whether you would be willing to continue with the follow-up study assessments but you may choose not to continue. We will also ask you about your decision to withdraw your participation in order to get your feedback about ways to help improve future studies. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the data collected prior to your withdrawal. The data will be used in analyses to address the aims of the study.

Is there any way being in this study could be bad for me? (Detailed Risks)

The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life, standard medical care or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of some questions asked in the computerized assessments and the intervention phone calls. There is a risk of loss of confidentially during the calls or text messages.

Costs

There will be no costs to you for your participation in this research study; there is no cost to you for study-related viral load. If you obtain viral load through your medical provider as part of your standard care, the cost of the viral load may be billed to your insurance or other third-party payer. You may be responsible for any co-pays or deductibles for viral loads measured as part of your standard care.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Confidentiality

Every effort will be made to keep all of the material related to you private and confidential. All your laboratory specimens, questionnaires, evaluation forms, reports, and other records will be identified by a code and will be identified only by that code number. All records with personally-identifying information will be kept in a locked, limited access area (such as a locked file cabinet). All computer entry and networking programs will be done with coded numbers only. Clinical information will not be released without your written permission (and parent or legally authorized representative, when applicable), except as necessary for monitoring by the researchers or the study sponsors.

However, research information that identifies you may be shared with the FSU Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

Permission to Take Part in a Human Research Study

Your information will be kept confidential – we will only use this information to contact you for the purposes of this study. Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; these data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your anonymous data.

The biological specimens collected for the purposes of this study will not be used to conduct any future research and will be destroyed after analysis is completed. Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

To help protect your confidentiality, a Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). 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.

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 Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

We will keep your records private unless we are required by law to share any information. The law says confidential information you share has to be told to legal authorities if you are a minor and reveal you are experiencing a legally reportable form of sexual or physical abuse, if you might hurt yourself or someone else, or if you reveal that a child or elderly person may be the victim of abuse.

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.

Data for Future Use

The research team, authorized staff, and government agencies that run this type of research may have access to research data and records in order to check on the research. Research records given to approved researchers will not have your name, phone number, or email address. If a researcher requests our data, they will be special permission from the Research Compliance Administrator. We may publish the results of this research. However, we will keep your name and other identifying information confidential to the extent allowed by law. Publications and/or presentations that result from this study will not identify you by name, phone number, or email. Data collected during this research study may be used for future research purposes. The data stored will not have your name, phone number, or email.

Your answers will be kept private – the data will be collected and stored securely at our research offices. Identifying facts such as your name, email, address, and phone number will be collected for research purposes. We will only use this to contact you for the purposes of this study.

Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; this data will be saved for future use and may be shared with other researchers. By being part of study, you are agreeing to allow us to save and share your anonymous data.

Data that can be linked to you individually (i.e., identified data) will be stored and managed at Hunter College for a minimum of 3 years and subsequently deleted. This identified data includes the audio recordings for the cell phone support intervention. In the future, these recordings may be used to develop strategies and recommendations for future trials, and serve as contributions to Communication Science.

Biological samples collected for the purposes of this study will not be used to conduct any future research. They will be destroyed after analysis is completed.

At the end of the study, data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

Protected Health Information (PHI):

Federal law provides additional protections of your medical records and related health information. These are described in an attached document. Your PHI created or received for the purposes of this study is protected under the federal regulations known as HIPAA. Refer to the HIPAA authorization for details concerning the use of this information.

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name and date of birth.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

1. During the course of the interview or assessment it becomes clear that you do not meet study eligibility criteria,
2. Physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If we feel that it is in the best interests of your health, and/or
4. If we feel you are providing inaccurate or false information.

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff. You may still be invited to complete the follow up survey.

What else do I need to know?

This research is being funded by the National Institute of Child and Human Development (NICHD) and the National Institute on Drug Abuse (NIDA).

Permission to Take Part in a Human Research Study

Instead of being in this research study, your choices may include: An alternative is for you not to participate in this research study. There are no therapeutic alternatives available at this time. Participants always have the option not to participate in this study, and referrals to community based organizations are available to all study participants.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

Research Related Injury

No funds have been set aside to pay any costs if you are harmed because of this study. If you think that you were harmed because of this study, let the study Principal Investigator know right away. By agreeing to participate in this study, you do not give up your right to seek payment for harm you receive while participating in this study.

Compensation

For taking part in this research study, you may receive up to $500 in compensation. See table below for a summary of the compensation amounts for each study assessment. If you do not have viral load results around the time of your assessment, you can go to a participating clinic or central lab (such as Quest Diagnostics) for a free viral load test.

Baseline Assessment Compensation	**$ 80.00**
Submission of the viral load result	$ 30.00
Completion of the survey	$ 30.00
Submitting the viral load result within two weeks of the screened eligible date (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
3-Month Assessment Compensation	**$ 90.00**
Submission of the viral load result	$ 35.00
Completion of the survey	$ 35.00
Submitting the viral load result within two weeks of the date link is sent out (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
6-Month Assessment Compensation	**$ 100.00**
Submission of the viral load result	$ 40.00
Completion of the survey	$ 40.00
Submitting the viral load result within two weeks of the date link is sent out (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
9-Month Assessment Compensation	**$ 110.00**
Submission of the viral load result	$ 45.00
Completion of the survey	$ 45.00
Submitting the viral load result within two weeks of the date link is sent out (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
Total Compensation (upon completion of all 4 assessments)	**$ 380.00**

If you are randomized into the incentivized intervention (either cell phone support or text messaging) at the 3-month assessment, you may receive up to an additional $150 in compensation. During this 3-month period, you may receive $50 at the end of each month if you reply to 75% or more of the cell phone calls or text messages. If you are randomized to receive cell phone calls, you may call back

within 30 minutes if a call is missed for the call to count towards your monthly total. In summary, if you are randomized to the incentivized intervention, you may be compensated up to a possible total of $150, in addition to the aforementioned $380.

You will be compensated the amounts specified above via electronic gift cards.

Conflict of Interest

Florida State University reviews staff researchers for conflicts of interest.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Permission to Take Part in a Human Research Study

Title of research study: Adaptive Antiretroviral Therapy Adherence Interventions for Youth Living with Human Immunodeficiency Virus through Text Messaging and Cell Phone Support Embedded within the Sequential Multiple Assignment Randomized Trial (SMART) Design

Investigators: Marvin Belzer, Karen MacDonell, and Sylvie Naar

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

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You are invited to participate in a research study of a program to help youth living with HIV adhere to their medications. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

First, we want you to know that:

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Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone on the Florida State University (FSU) research team, or with family, friends or your personal physician or other professional.

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

You were selected as a possible participant in the SMART study because you are between the ages of 15 and 24 years old, are living with HIV, are currently prescribed an antiretroviral therapy (ART) medication regimen, have an unsuppressed viral load and/or report having low adherence to your ART medication regimen, and own a mobile phone or device that can receive calls and text messages.

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We expect that you will be in this research study for 9 months.

You will be asked to provide proof of your viral load and complete a survey at each of the baseline and 3 follow-up assessments at approximately 3, 6, and 9 months after the baseline survey. Each assessment should take approximately 1 to 1.5 hours to complete. After your baseline assessment you will be randomly assigned to an intervention of either text messaging or cell phone support calls for daily ART medications reminders. After 3 months of this intervention, you will be randomized again, except this randomization will depend on how you responded to the original intervention. You might continue to receive the same number of cell phone calls or text messages, or these could be reduced to 2 times per week. You might stop receiving all cell phone calls or text messages. Or, you might change to receive the other SMART intervention.

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Based on experience with this type of intervention program, researchers believe it may be of benefit to adolescents and young adults like you to adhere to their ART regimen and achieve and maintain a suppressed viral load. Of course, because everyone responds differently, no one can know ahead of time if it will help you.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

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There are no therapeutic alternatives available at this time. An alternative is for you not to participate in this research study. Participants always have the option not to participate in this study, and referrals to community based organizations are available to all study participants.

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If you agree to be in the study, you will be asked to complete the following activities:

(1) **Viral Load Assessment:** Provide proof of your viral load or provide blood specimens for HIV viral load measurement at each of the follow-up assessments (approximately 3, 6, and 9 months after you complete your baseline survey). You can provide proof of your viral load if it was performed approximately two weeks before your scheduled assessment until approximately 4 weeks after your scheduled assessment. If you do not have a copy of your viral load, you can either obtain this in writing from your doctor or ask your doctor to send your results to the SMART team at Hunter College. If you have not had a viral load test around the time of your assessment, you can have testing done at no cost to you at a participating clinic or at a central lab (such as Quest Diagnostics).

(2) **Assessments:** You will participate in a baseline assessment and 3 follow-up assessments at approximately 3, 6, and 9 months after the baseline survey. At each assessment you will complete a computer-based survey that will ask about your adherence to your medications, substance use, depression, sexual behavior and other questions related to HIV. At the baseline assessment, we

will also collect demographic information about you. Each assessment should take approximately 1 to 1.5 hours to complete.

All assessments can be completed by clicking on a link that we will send to the contact information (email address, cell phone number, etc.) you provide.

(3) **Intervention**: After your baseline assessment you will be randomly assigned to an intervention. The intervention you will participate in is aimed at helping you increase your adherence to ART medications as prescribed to decrease your viral load. The 3-month intervention will be delivered via text messaging or cell phone support calls depending on which program you are randomly assigned to (like flipping a coin). You have an equal chance of being assigned to either intervention.

Cell phone support calls will be provided by an adherence facilitator who will call you each weekday to ask if you have taken your ART medication(s) and provide brief problem solving support. They will call you on weekdays, but not holidays, at a time you agree upon in advance. These calls will be audio recorded for quality assurance purposes.

For text messaging support, we will send you a customized text to determine if you took your medication(s), and you will text back whether or not you have taken your medication. The text messages will be sent to you every day at a time agreed upon in advance.

After 3 months of this intervention, you will be randomized again, except this randomization will depend on how you responded to the original intervention. You might continue to receive the same number of cell phone calls or text messages, or these could be reduced to 2 times per week. You might stop receiving all cell phone calls or text messages. Or, you might change to receive the other SMART intervention. For example, you might change from receiving cell phone calls to receiving text messages. No matter what happens, you'll still continue to complete the surveys approximately every 3 months until you've been in the study for approximately 9 months.

As mentioned before, you may get randomized to receive only 2 cell phone support calls or text messages for the next 3 months, or you'll stop receiving the calls or text messages completely. If you're randomized to receive the calls or texts 2 times per week, those will end after the additional 3 months (after being in the study for 6 months).

On the other hand, you may be randomized to receive the same intervention as the first 3 months (continue on the cell phone support calls or the text messaging) or you might switch to the other intervention, as described above. During these 3 months, you will be eligible for an incentive as described in the Compensation section below. After those 3 months (approximately 6 months from when you started the study), the cell phone calls or text messages will decrease to 2 times per week for 3 months.

If you do not provide viral load test results, nor report your adherence to your ART medication, 14 days prior or 28 days after your scheduled 3-month assessment, you will not be randomized

for a second time. Consequently, you will no longer receive the intervention. Cell phone support calls or text messaging will be discontinued; however, the researchers may still ask you to complete the computer-based surveys at the 6-month and 9-month assessments, for which you are still eligible to receive compensation.

The researchers will also ask for some medical information from your HIV care provider. This may include: 1) your most recent CD4+ T-Cell absolute count before you enrolled in the study; 2) your viral load results for up to a year before you started the study and while you're participating in the study; and 3) your prescribed ART medications while you're in the study. If you have this information, you can send this to us. Otherwise, you may be asked to contact your HIV care provider or we can contact your HIV care provider to have this information sent to the SMART research team at Hunter College.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to provide proof of your viral load or blood specimens for HIV viral load measurement, complete computer-based surveys, and own a mobile phone or device that can receive calls and text messages.

There will be no costs to you for your participation in this research study; there is no cost to you for study-related viral load. If you obtain viral load through your medical provider as part of your standard care, the cost of the viral load may be billed to your insurance or other third-party payer. You may be responsible for any co-pays or deductibles for viral loads measured as part of your standard care.

What happens if I say "yes," but I change my mind later?

You can leave the research at any time; it will not be held against you.

Voluntary Nature of the Study

Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part you can change your mind later and withdraw from the study. Questions in the computer survey cannot be skipped, but if you do not want to answer a question in the computer survey you may just close the survey link. The survey will then remain incomplete. If you have an incomplete survey your participation in the study will continue unless you decide to withdraw from the study. You can withdraw from the study at any time. Your decision to withdraw will not change any present or future relationships you may have with Florida State University, the health clinic, any of their affiliates or Hunter College.

It is important to the study that we continue collecting data at follow-up assessments. If you decide to withdraw from the study, please inform the study staff of your decision via an email to SMARTatn@prideresearch.org. We will ask you about whether you would be willing to continue with the follow-up study assessments but you may choose not to continue. We will also ask you about your decision to withdraw your participation in order to get your feedback about ways to help improve future studies. Because withdrawing data threatens the scientific integrity of the study, we plan to securely store and later use all of the data collected prior to your withdrawal. The data will be used in analyses to address the aims of the study.

Is there any way being in this study could be bad for me? (Detailed Risks)

The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life, standard medical care or physical/psychological tests. However, there is some risk of emotional discomfort or distress due to the personal nature of some questions asked in the computerized assessments and the intervention phone calls. There is a risk of loss of confidentially during the calls or text messages.

Costs

There will be no costs to you for your participation in this research study; there is no cost to you for study-related viral load. If you obtain viral load through your medical provider as part of your standard care, the cost of the viral load may be billed to your insurance or other third-party payer. You may be responsible for any co-pays or deductibles for viral loads measured as part of your standard care.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Confidentiality

Every effort will be made to keep all of the material related to you private and confidential. All your laboratory specimens, questionnaires, evaluation forms, reports, and other records will be identified by a code and will be identified only by that code number. All records with personally-identifying information will be kept in a locked, limited access area (such as a locked file cabinet). All computer entry and networking programs will be done with coded numbers only. Clinical information will not be released without your written permission (and parent or legally authorized representative, when applicable), except as necessary for monitoring by the researchers or the study sponsors.

However, research information that identifies you may be shared with the FSU Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes of Health (NIH) and the Office for Human Research Protections (OHRP).

Permission to Take Part in a Human Research Study

Your information will be kept confidential – we will only use this information to contact you for the purposes of this study. Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; these data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your anonymous data.

The biological specimens collected for the purposes of this study will not be used to conduct any future research and will be destroyed after analysis is completed. Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

To help protect your confidentiality, a Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). 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.

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 Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

We will keep your records private unless we are required by law to share any information. The law says confidential information you share has to be told to legal authorities if you are a minor and reveal you are experiencing a legally reportable form of sexual or physical abuse, if you might hurt yourself or someone else, or if you reveal that a child or elderly person may be the victim of abuse.

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.

Data for Future Use

The research team, authorized staff, and government agencies that run this type of research may have access to research data and records in order to check on the research. Research records given to approved researchers will not have your name, phone number, or email address. If a researcher requests our data, they will be special permission from the Research Compliance Administrator. We may publish the results of this research. However, we will keep your name and other identifying information confidential to the extent allowed by law. Publications and/or presentations that result from this study will not identify you by name, phone number, or email. Data collected during this research study may be used for future research purposes. The data stored will not have your name, phone number, or email.

Your answers will be kept private – the data will be collected and stored securely at our research offices. Identifying facts such as your name, email, address, and phone number will be collected for research purposes. We will only use this to contact you for the purposes of this study.

Data that cannot be linked to you individually (i.e., de-identified data) will be kept indefinitely; this data will be saved for future use and may be shared with other researchers. By being part of study, you are agreeing to allow us to save and share your anonymous data.

Data that can be linked to you individually (i.e., identified data) will be stored and managed at Hunter College for a minimum of 3 years and subsequently deleted. This identified data includes the audio recordings for the cell phone support intervention. In the future, these recordings may be used to develop strategies and recommendations for future trials, and serve as contributions to Communication Science.

Biological samples collected for the purposes of this study will not be used to conduct any future research. They will be destroyed after analysis is completed.

At the end of the study, data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may be shared with other researchers. By participating in this study, you are agreeing to allow us to save and share your data anonymously.

Protected Health Information (PHI):

Federal law provides additional protections of your medical records and related health information. These are described in an attached document. Your PHI created or received for the purposes of this study is protected under the federal regulations known as HIPAA. Refer to the HIPAA authorization for details concerning the use of this information.

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name and date of birth.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

1. During the course of the interview or assessment it becomes clear that you do not meet study eligibility criteria,
2. Physical or psychological problems arise which would interfere with your voluntary participation in this study,
3. If we feel that it is in the best interests of your health, and/or
4. If we feel you are providing inaccurate or false information.

In addition, the research team may dismiss you if you engage in any hostile behavior toward the staff. You may still be invited to complete the follow up survey.

What else do I need to know?

This research is being funded by the National Institute of Child and Human Development (NICHD) and the National Institute on Drug Abuse (NIDA).

Permission to Take Part in a Human Research Study

Instead of being in this research study, your choices may include: An alternative is for you not to participate in this research study. There are no therapeutic alternatives available at this time. Participants always have the option not to participate in this study, and referrals to community based organizations are available to all study participants.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

Research Related Injury

No funds have been set aside to pay any costs if you are harmed because of this study. If you think that you were harmed because of this study, let the study Principal Investigator know right away. By agreeing to participate in this study, you do not give up your right to seek payment for harm you receive while participating in this study.

Compensation

For taking part in this research study, you may receive up to $500 in compensation. See table below for a summary of the compensation amounts for each study assessment. If you do not have viral load results around the time of your assessment, you can go to a participating clinic or central lab (such as Quest Diagnostics) for a free viral load test.

Baseline Assessment Compensation	**$ 80.00**
Submission of the viral load result	$ 30.00
Completion of the survey	$ 30.00
Submitting the viral load result within two weeks of the screened eligible date (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
3-Month Assessment Compensation	**$ 90.00**
Submission of the viral load result	$ 35.00
Completion of the survey	$ 35.00
Submitting the viral load result within two weeks of the date link is sent out (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
6-Month Assessment Compensation	**$ 100.00**
Submission of the viral load result	$ 40.00
Completion of the survey	$ 40.00
Submitting the viral load result within two weeks of the date link is sent out (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
9-Month Assessment Compensation	**$ 110.00**
Submission of the viral load result	$ 45.00
Completion of the survey	$ 45.00
Submitting the viral load result within two weeks of the date link is sent out (bonus)	$ 10.00
Completing the survey within one week of the date is sent out (bonus)	$ 10.00
Total Compensation (upon completion of all 4 assessments)	**$ 380.00**

If you are randomized into the incentivized intervention (either cell phone support or text messaging) at the 3-month assessment, you may receive up to an additional $150 in compensation. During this 3-month period, you may receive $50 at the end of each month if you reply to 75% or more of the cell phone calls or text messages. If you are randomized to receive cell phone calls, you may call back within 30 minutes

if a call is missed for the call to count towards your monthly total. In summary, if you are randomized to the incentivized intervention, you may be compensated up to a possible total of $150, in addition to the aforementioned $380.

You will be compensated the amounts specified above via electronic gift cards.

Conflict of Interest

Florida State University reviews staff researchers for conflicts of interest.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

Do My Parents or Guardians Need to Know About This?

[DISPLAY FOR YOUTH UNDER 18, WHO WILL BE PLACED AT RISK OF HARM FROM PARENT KNOWLEDGE AND NEED WAIVER OF PARENTAL CONSENT]

You do not need consent or permission from a parent or guardian to be a part of this study, but you are welcome to share with your parents that you are participating in this study, if you feel comfortable doing so. This will not impact your participation in this study.

[DISPLAY FOR YOUTH UNDER 18, WHO WILL NOT BE PLACED AT RISK OF HARM]

For youth under 18, who will not be placed at risk of harm, parental permission is required to take part in the study.

Does the parent or legal guardian grant permission for your participation in this study? **Only by clicking on a "Yes" response will you be permitted to take part in the study.**

☐ Yes ☐ No [If the answer is no, the individual cannot participate.]

Please indicate how you obtained parental permission.

☐ My parent checked the "Yes" box. ☐ My parent told me to check the "Yes" box.

Permission to Take Part in a Human Research Study

Statement of Assent

[WE WILL DESIGN QUALTRICS SO THAT THE FOLLOWING QUESTIONS MUST BE ANSWERED APPROPRIATELY BEFORE THE INDIVIDUAL CAN PROCEED TO THE SURVEY.]

I am 15-24 ☐ Yes ☐ No [If the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I have read and understand the information above. ☐ Yes ☐ No [If the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I am willing to produce proof of ART prescription. ☐ Yes ☐ No [If the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I have access to my own cell phone that receives calls and text messages. ☐ Yes ☐ No [If the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

I want to participate in this research and continue with the survey. I understand that my participation is voluntary and I may stop my participation at any time. ☐ Yes ☐ No [If the answer is no, the individual cannot participate and should not be allowed to proceed to the next question.]

[WE WILL DESIGN THE WEB PAGE SO THAT THE FOLLOWING QUESTIONS MUST BE ANSWERED BEFORE THE INDIVIDUAL CAN PROCEED TO THE SURVEY.]

Questions to Verify Participant Understands Assent

It is important to us that we know you understand what this study entails. Please answer the following questions:

1. **True** or False: Participating in the study is my choice and I can choose to stop participating at any time, even if I agree today.
2. **True** or False: Every participant will be asked to complete online surveys and provide HIV Viral Load results or complete HIV Viral Load testing every three months for the full year of this study.
3. **True** or False: If I ask, the SMART research team may contact my provider to share information such as whether I need a refill of my medications or other quality of life matters.
4. **True** or False: The HIV Viral Load testing performed for this study is free. I am not responsible for the cost of a study related HIV Viral Load Test.
5. **True** or False: If I already have HIV Viral Load results I can provide these to the research team if the results are recent.

[IF AN INCORRECT ANSWER IS INDICATED ABOVE, THE FOLLOWING RESPONSES WILL BE PROVIDED.]

Permission to Take Part in a Human Research Study

1. Correct answer: ***True*** – Your participation in this research study is completely up to you. You are allowed to end your participation in the study at any time, whether that is now, ten minutes into the first survey, or a year from now. There is no penalty for stopping your participation.
2. Correct answer: **True** –You will be sent a link to complete an online survey and we will ask that you send us your recent HIV Viral Load results or complete HIV Viral Load testing at no cost to you every three months for one year.
3. Correct answer: **True** – The researchers will only share your information with other SMART researchers and providers you name. We will not contact a provider unless you ask. Every effort will be made to keep all of the material related to you private and confidential. However, in rare circumstances, we may provide your contact information to protect you or others ONLY in certain situations. The law says confidential information you share has to be told to legal authorities if you are a minor and reveal you are experiencing a legally reportable form of sexual or physical abuse, if you might hurt yourself or someone else, or if you reveal that a child or elderly person may be the victim of abuse.
4. Correct answer: **True**: If you or your provider is not able to send us a recent HIV Viral Load result then the study will provide HIV Viral Load testing for free. You will not be responsible for the cost of a study related HIV Viral Load Test.
5. Correct answer: **True:** If you already have HIV Viral Load results, you can provide these to the research team if the results are recent.

Permission to Take Part in a Human Research Study

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Signature of child	Date

Printed name of child

[DISPLAY FOR YOUTH UNDER 18, WHO WILL NOT BE PLACED AT RISK OF HARM]

Signature of parent or individual legally authorized to consent to the child's general medical care	Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent	Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

- ❑ [DO NOT PROGRAM] The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

[DO NOT PROGRAM FIELDS BELOW]

[Add the following block if you will document assent of children]

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

[Add the following block to all consents]

Signature of person obtaining consent and assent	Date

Printed name of person obtaining consent

[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date

Printed name of person witnessing consent process