

Form Approved

OMB No. 0920-New
Expiration Date: XX/XX/XXXX

Using Real-time Prescription and Insurance Claims Data to Support the
HIV Care Continuum

Attachment 12a

PositiveLinks verbal consent and enrollment

Public reporting burden of this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Note: Participants in Phase 2 will be offered PositiveLinks after cold handoff referrals and before warm handoff referrals. The consent process for PositiveLinks takes place at the time it is offered. The consent process is

separate from and prior to agreement to the PositiveLinks terms of use.

Not Interested

<u>Offer PositiveLinks</u>	
<i>Participants in Phase 2 will be offered PositiveLinks prior to warm referrals.</i>	
We've thought together about resources that can help you take your HIV medication. I've given you some information about some resources that may help. We can talk soon about connecting you directly to some other resources. First, I'd like to tell you about PositiveLinks, a mobile app platform that can help you feel supported to take your HIV medicine.	
Can I tell you more about it?	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not right now
reset	
That's fine. You will not be able to use the PositiveLinks mobile app. But I can still connect you to resources that can help you take your HIV medication.	
<i>Move on to warm referral.</i>	

Not Available Right Now

Offer PositiveLinks

Participants in Phase 2 will be offered PositiveLinks prior to warm referrals.

We've thought together about resources that can help you take your HIV medication. I've given you some information about some resources that may help. We can talk soon about connecting you directly to some other resources. First, I'd like to tell you about PositiveLinks, a mobile app platform that can help you feel supported to take your HIV medicine.

Can I tell you more about it?

- Yes
- No
- Not right now

[reset](#)

Alternative time identified

I understand. It would be great to tell you more about PositiveLinks. When would be a good time to tell you about it?

* must provide value

- Available another time
- Not available another time

[reset](#)

Schedule alternative call.

* must provide value

26-05-2021 D-M-Y

[Click to identify day for alternative call.](#)

11:45 H:M

[Click to schedule time for alternative call.](#)

Thank you. I appreciate your time and will call you back at [participant's phone number] on [scheduled date] at [scheduled time].

Move on to warm referral.

Alternative time not identified

I understand. If you change your mind, you can always let me know if you become interested in learning more, and I will give you my phone number before we end our call today. I will still connect you to resources that can help you take your HIV medication. Let's talk more about that now.

Move on to warm referral.

Interested in learning more, available now

Offer PositiveLinks

Participants in Phase 2 will be offered PositiveLinks prior to warm referrals.

We've thought together about resources that can help you take your HIV medication We can talk soon about connecting you directly to some other resources. First, I'd like to tell you about PositiveLinks, a mobile app platform that can help you feel supported to take your HIV medicine.

Can I tell you more about it?

- Yes
 No
 Not right now

[reset](#)

Part of our quality improvement research study involves the PositiveLinks mobile app platform.

- **PositiveLinks is a mobile app platform for people living with HIV.**
- **PositiveLinks has tools and resources to help you take better care of yourself.**
- **To learn more, we will review some information about PositiveLinks.**
- **To join, we will ask you to agree to our Terms of Use.**
- **The care you receive from your doctors will not change if you choose not to join.**
- You will have access to **PositiveLinks** for at least 12 months, which is the duration of this study.

The PositiveLinks mobile app platform promotes better personal health. The app provides self-monitoring tools, educational resources, and a secure, anonymous community board for users. PositiveLinks can help you understand when you need more support. It can also help you communicate preferences about this support to appropriate study staff. Study staff will work with you to help effective referrals occur.

It will take 8-10 minutes to tell you about PositiveLinks and how it will be used in our quality improvement research study. I must tell you about PositiveLinks and how it will be used in the study if you want to join. You can interrupt me to ask questions or to take a break at any time. You can also stop me at any time if you decide you don't want to join PositiveLinks.

The PositiveLinks research study is about a support for taking your prescribed medication and staying healthy. The research is being done as part of a quality improvement initiative at Virginia Medicaid. The PositiveLinks mobile app platform is an optional component of the research study in which you are participating. Virginia Commonwealth University (VCU) is implementing the study on behalf of Virginia Medicaid. Virginia Medicaid and VCU are working together to learn about challenges that Virginia Medicaid members have in taking their prescribed medication. To do this, we are implementing and evaluating a program called Antiretroviral Improvement among Medicaid enrollees (AIMS). This program is designed to support members to fill HIV prescriptions. We think this support, including the PositiveLinks mobile app platform, may increase how often HIV prescriptions are filled. We hope that the AIMS program can improve your health and increase HIV viral suppression.

The Virginia Department of Health, University of Virginia, the Centers for Disease Control and Prevention, and the National Institutes of Health are also study partners. The study is funded by the Centers for Disease Control and Prevention and the National Institutes of Health.

We are asking you to be in this additional research study because we believe you have a refill for your HIV medication that has been late for an extended period of time. We believe this because there is no insurance record for an HIV prescription that was expected to be filled.

Participating in this additional research study is voluntary. You do not have to participate unless you want to. If you do participate, you can withdraw at any time. There is no penalty of any kind if you withdraw or decide not to take part in this additional research study involving PositiveLinks. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't want to take part, you still have access to the support provided as part of the original research study. This includes recommendations about resources that can support you in filling your HIV prescription(s), connecting you directly to some of these resources, and giving you contact information for other resources. These resources will be based on your own individual needs and might involve your health plan, your provider, your pharmacy, or specialized resources in the community.

In this additional research study, you will be asked to:

- 1) Download the PositiveLinks mobile app onto a smartphone or tablet, with my help.
- 2) You will be asked to agree to the terms of use, which are the rules for how to use the PositiveLinks mobile app. You'll also agree to share some information, like your phone number or email address, so that we can set up your PositiveLinks account. The terms of use tell you how you can use the PositiveLinks mobile app platform, what to expect in the PositiveLinks app, what to expect in terms of communication through the app, and rules for how you can, and cannot, use PositiveLinks to ensure the app is a safe and welcoming space for all users. It will take about 5 minutes to explain the terms of use.
- 3) You will be asked to participate in the PositiveLinks mobile app platform. Participation will involve things like privately responding to weekly quiz questions about general health or living with HIV. Participation will also involve daily check-ins about your mood or commenting in the anonymous (to other users) community message board. You can participate as much or as little as you want. Daily use of the platform typically takes about 5 minutes of your time per day.
- 4) You will be asked to give permission to follow-up with you. This might happen if you ask for help directly by messaging the study team through the app, if you have not used the app in a while, or if we think you need additional help. In these cases, someone from the study team will message you directly through the app or call you to talk about how we can help. If needed, we will help connect you to resources that can help you, including emergency services. If we believe you or someone else is at risk of imminent harm, we may call 911 to help. We think that contacting you about additional resources will be rare and limited to serious events that involve your safety. Should this occur, we will contact you only to help you and will not collect further data on the event.

- 5) **You will be asked to give permission for us to review how you use the app. This includes anything you write in messages to study staff. It also includes anything you post on the community message board; this board is anonymous to other users, but the study team will know who wrote what. And it includes usage data like how often you log in or whether you respond to quiz questions, and some data from your device like your IP address. We will also collect some health information that you report via the app about your mood, stress level and medication doses you report on the app. We will only collect this information from the PositiveLinks app; this information will not be added to your personal health records nor will we collect any information from your personal health record.**

PositiveLinks is a tool to help you keep track of your own self-care behaviors. It is not an experimental mobile app platform, but the intervention to connect you to this resource is. Some health care settings in Virginia and beyond offer the PositiveLinks mobile app platform. However, it is not available to everyone. As part of this study, we will create a PositiveLinks account for you only if you give us permission to do so.

You may not want to answer all PositiveLinks quiz questions or daily mood check-in questions, or you may not want to post or comment on the anonymous community message board. You may use the app when you want; you are not required to use it. You can message me or another team member through the app if you feel uncomfortable or need help. If you choose to participate in the PositiveLinks mobile app platform, you can withdraw from the study or delete the app at any time.

There is a risk that you may feel upset if you reflect on your mood during the daily mood check-ins or participate in the community message board. There are small social or legal risks of unauthorized or unintentional disclosure of your HIV status. This risk is no greater than disclosure by a medical professional. We take many precautions to prevent this from happening, including implementing protocols on who can access to your health information, how it is stored and accessed, and verifying your identity during study procedures. The app itself is downloaded from the App Store or Google Play Store. It requires that you have an account with either app store, and a username and password to log in. It will not sync with other apps on your phone and any calls made through the app will not be visible in your phone's call log. There are no other known physical, financial, social, or legal risks associated with the study.

There are some potential benefits to participating in this research study. This additional study on PositiveLinks could help you, but that cannot be guaranteed. The study may help you monitor your mood, learn about managing your health, and connect anonymously with a larger support network of individuals with similar experiences and challenges with filling their HIV prescriptions. The PositiveLinks app may help you fill your HIV prescriptions and take your HIV medication more consistently.

You will not be compensated for participating in this additional research study. You will be able to join the PositiveLinks mobile app platform. You will not have to pay to join the PositiveLinks mobile app platform. If you do not have a smartphone, your health plan should be able to provide one. Your health plans should already provide this benefit to you. You do not have to participate in the PositiveLinks mobile app study to receive this smartphone benefit if it is covered under your plan.

Your participation in this additional research study will involve about 30 minutes of your time. This includes time spent to set up the PositiveLinks mobile app on your device and to learn how to use it. It does not include time you may spend using the app after we set it up, or any phone calls if you need further assistance. Daily participation in the app will involve about 5 minutes per day of your time. Daily participation can be as little or as much as you want.

Not all participants in the original parent study will have the opportunity to join PositiveLinks. You have the opportunity to join the PositiveLinks mobile app platform based on characteristics of your health provider and our insurance records of how you have filled your HIV prescriptions. Other participants will be offered different resources.

As I said before, participating in this quality improvement research study is voluntary. If you decide not to participate in this study, you will receive the same benefits from your health plan that you would receive if you were not in the study. If you decide not to participate, it will not affect your relationship with your medical providers or your medical care. If you decide not to participate or contribute your health information, you will not be able to join the PositiveLinks mobile app platform. However, you can still be referred to resources by our study evaluation team. If you decide to no longer participate in the original study, you will no longer be able to use the PositiveLinks mobile app platform. In this case, you will still have access to support from your healthcare providers, pharmacists, and health plan, along with community support services. We can provide you information for these supports even if you choose to no longer participate in the original study.

About 1,000 members will participate in this study.

It will take me just a few more minutes to describe the study. What questions do you have now?

Record any questions from participants.

As I said, it will take me just a few more minutes to describe the additional research study. You can interrupt me to ask questions or to take a break at any time. You can also stop me at any time if you decide you don't want to join PositiveLinks or participate in this additional study.

To be involved, we will collect information. This information will be about when and how you use the app, messages you write to the study team or post on the community message board, and other information like your device type and IP address to help with app functionality. We will also ask you for your phone number and/or email address so we can send you an invitation to join the platform. We will have access to your username so that we can assist you in setting up your PositiveLinks account. We will not have access to your PositiveLinks password; only you will be able to access and change the password.

We will keep your information confidential and securely stored by limiting who will be able to access your private information. The CDC and the National Institutes of Health, which are study partners, will not have access to information that can be used to personally identify you. Your data will be stored on a secure network server.

This study has something called a Certificate of Confidentiality from the federal government to make sure we can best protect your privacy. The certificate means that we cannot be forced to tell people about your participation, even if we are asked by courts or police.

However, sometimes we cannot keep your information or participation confidential. If we find out that keeping your information or participation private could put you or someone else in danger, we may have to tell agencies to protect you or another person. Researchers may also have to give your information if the study is audited.

We disclose the potential for conflict of interest, but have taken steps to minimize this. Drs. Rebecca Dillingham and Karen Ingersoll from the University of Virginia are on the Board of Directors of Warm Health Technology (WHT), a non-profit organization that disseminates a version of PositiveLinks to clinics outside of Virginia. Dr. Dillingham is also a paid consultant for Warm Health Technology. Neither Dr. Dillingham nor Dr. Ingersoll will have any direct involvement in the recruitment, consent, or follow-up of participants or in the analysis of research data. Dr. Ingersoll is part of the study team that may contact you if there is a mental health crisis.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- **The study Sponsor, representatives of the sponsor and other collaborating organizations**
- **Representatives of VCU and the VCU Health System**
- **Officials of the Department of Health and Human Services**

We will not publish your identifiable information or present it to the public. At the end of the study, we will tell you the results and explain what they mean. However, we will not provide to each participant their individual research study results.

The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

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.

I want to make sure that any questions you have are answered. I can answer any questions you may have right now. Dr. April Kimmel, the principal investigator evaluating the study, and other study staff can also answer your questions. They can be reached at [study email] and [study phone number].

If you think that you have not been treated fairly in the study, you can contact Dr. Kimmel and the study staff. You can also call VCU's Office of Research and Innovation at (804) 827-2157.

What questions do you have? Yes No reset

** must provide value*

Questions from eligible participants

Record any questions from participants.

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Questions to assess understanding of study

I really appreciate your time so far. It's important to me that you understand the study and your rights as a participant.

I will ask you some questions to be sure that I have been clear.

I'm going to read you 6 statements about this study. Please indicate 'true' or 'false' after each statement.

This additional research study is about how the PositiveLinks mobile app program can help with filling HIV prescriptions. True False reset

** must provide value*

You do not have to participate in this additional research study. We will still connect you with the resources we discussed earlier if you do not participate in the PositiveLinks research study. True False reset

** must provide value*

If you participate, you will be asked to download the PositiveLinks mobile app and create an account. You will not receive compensation for participating. True False reset

** must provide value*

If you participate, you can withdraw at any time and for any reason. You can skip any questions that you do not want to answer. You can delete the app at any time. True False reset

** must provide value*

If you decide not to participate or to withdraw, your benefits from [member's Medicaid Care Organization] will not change. The care you receive from your doctor will not change. You will still be connected to the resources we discussed earlier.

- True
 False

[reset](#)

* must provide value

The study team cannot use your information unless you give permission to use it. We cannot be forced to tell someone you participated in the research study.

- Yes
 No

[reset](#)

* must provide value

Note: if the answer to any of the above items is false, the following text will populate:

Actually, that's true: (repeat item).

Discuss with participant to ensure comprehension before moving on.

Thank you so much. Now I'm going to ask you if you consent to participate in this additional study.



Consents

Do you consent to participate in this additional research study and join the PositiveLinks mobile app platform?

Yes
 No

[reset](#)

* must provide value

Consent date and time   Now Y-M-D H:M

* must provide value

Move on to PositiveLinks terms of use and set-up, beginning with: "Great! To begin, do you have a smartphone or a tablet you can use for this app?"

Does not consent

Do you consent to participate in this additional research study and join the PositiveLinks mobile app platform?

Yes
 No

* must provide value

I understand. If you change your mind, you can always let me know if you become interested in learning more, and I will give you my phone number before we end our call today. I will still connect you to resources that can help you take your HIV medication. Let's talk more about that now.

Move on to warm referral.

Wants to join PositiveLinks

Great! To begin, do you have a smartphone or a tablet you can use for this app?

Yes
 No

No smartphone and warm referral is to Medicaid Care Organization (MCO)

That's fine. Your health insurance plan actually provides a smart phone for free. We can ask about it when we call your health plan in just a moment.

Before we call your health plan, let's schedule a follow-up call. I will check that you have received a phone from your health plan then. I can also help you set up PositiveLinks then.

Y
No
e
s

Yes

No

Schedule time to call back and set up PositiveLinks. Aim for 2-3 weeks from current date.

| Today | D-M-Y

| Now | H:M

Go to Referral Script for warm hand-off for recommended primary referral.

No smartphone and warm referral is NOT to MCO

That's fine. Your health insurance plan actually provides a smart phone for free. Let me give you their number so you can ask about this benefit. The number is [member's Medicaid Care Organization phone number] and you can ask for the benefit called **phone benefit**.

Before we talk about referrals, let's schedule a follow-up call. I will check that you have received a phone from your health plan then. I can also help you set up PositiveLinks.

Schedule time to call back and set up PositiveLinks. Aim for 2-3 weeks for current date.

| Today | D-M-Y

| Now | H:M

Go to Referral Script for warm hand-off for recommended primary referral.

PositiveLinks Terms of Use

Before we can set up PositiveLinks, I will read you the app's Terms of Use. Anyone who joins PositiveLinks must agree to these Terms. Agreeing to the Terms means you can use the PositiveLinks app on a mobile device. You are not required to enroll in PositiveLinks. Your health care will not be affected in any way if you do not agree to the Terms of Use. I will still refer you to other resources to help you with your medication, even if you do not want to use PositiveLinks.

Here are the Terms of Use:

You WILL NOT use PositiveLinks to communicate if there is an emergency. If there is an emergency, you agree to call 911 or go to the ER.

You understand that PositiveLinks is not a program through which clinical diagnoses, treatment recommendations, or treatment are provided.

You agree to receive three check-ins through PositiveLinks each day: "Have you taken your meds yet?"; "What is your stress level right now?"; "How are you feeling?" You agree to receive a weekly quiz question on pop culture, general health, or living with HIV.

The Appointments feature in the app allows you to create appointment or calendar reminders for your own use. These reminders exist only on the PL app and will not sync with any other calendar apps you may have on your phone.

The app offers a community board where you can post and others can see and respond to your posts. There are many rules about participants' posts on the board. All of these rules relate to the need to ensure that participants have a safe space to share.

- 1. You understand there is a community board you can use to post comments or ask questions of other app participants. This community board is intended to provide a safe place to share, so there are a few rules about this. Your personal reflections and ideas are welcome. You agree that the community board will not be used to make insulting or rude comments towards app participants or study staff. You also agree not to promote any political candidate. Those kinds of comments would interfere with the intention of the board as a place to give and get support.**
- 2. You understand and acknowledge that the community board is monitored by study staff to ensure these rules are followed. You understand that posts violating these rules will be removed by study staff, and we may discuss those posts that do not follow the rules with you. Violation of these rules may result in a 10-day suspension from the board or permanent removal from the board. These decisions are determined by study staff on a case by case basis. Our intention in this is to ensure that the community board remains a safe and welcoming space.**
- 3. You WILL NOT post personally identifying information—including yours or anyone else's name, phone number, address, or social media information—on the app's community board. The community board is a space where participants can share information anonymously and you will respect the privacy of others posting on the board. In the event you post personally identifying information on the board, the study staff cannot guarantee immediate removal of the content and you understand that other participants would be able to see that information.**

4. You understand that only app participants and study staff will have access to the community board. Your care providers will not have access to posts on the community board and this is not a means to communicate with your providers.

You understand that you will have access to resources and answers to frequently asked questions. The resources will include links, videos, and audio files on topics like stress reduction, mindfulness, financial wellness, and general HIV information.

You understand that you will have access to a contact list that will include contacts that you create. When you include a phone number for the contact listing, you will be able to call that contact from within the PL app. This contact feature is kept securely within the PL app and does not sync with any other Contacts app you may have on your phone.

You understand you will only be able to send private messages through the PositiveLinks platform to study staff. The staff member will be able to send a reply to your PositiveLinks inbox. You will not be able to send or receive messages from any other contacts or other PL participants.

You understand that normal operating hours for study staff are Monday through Friday 8am to 5pm. If you message outside of these hours, or if a staff member is out of the office, you understand that they may not respond until they are next available. Study staff may take up to 48 hours to respond to my message and you agree to call your provider or emergency services with all time-sensitive or medical needs.

You understand that the PositiveLinks mobile platform requires a password to access and has other security features to protect your information in PositiveLinks. The password is unique for each participant and YOU will only be able to change it by calling a PositiveLinks staff member. You will not share your password with others.

You understand that you can revoke your agreement to these terms at any time with or without reason. To remove yourself from the platform you will notify the study staff, in person or over the phone, that you are withdrawing from the PositiveLinks platform.

You understand that if you do not abide by the terms in this agreement your participation and continued receipt of PositiveLinks services will be reviewed and may be suspended or terminated as determined by the study staff.

Do you agree to the Terms of Use?

- Yes
- No
- Not yet

If no:

That's fine. You will not be able to use PositiveLinks. But I can still connect you to resources that can help you take your HIV medication.

Go to Referral Script for warm hand-off for recommended primary referral.

If not yet, send Terms of Use:

I understand. Can I mail you the Terms of Use so you can think them over?

- Yes
- No

I will send you a copy of the Terms of Use. Do you mind providing your mailing address?

Record mailing address.

Great. Let's schedule a time to talk after you've had time to think about the Terms of Use.

Schedule an alternate date/time within 2 weeks of current date.

Go to Referral Script for warm hand-off for recommended primary referral.

| Today : D-M-Y

| Now : H:M

If not yet, do NOT send Terms of Use:

I understand. Can I mail you the Terms of Use so you can think them over?

Yes

No

If yes:

Record timestamp of agreement to PositiveLinks Terms of Use.



Set up participant's PositiveLinks username and fill in contact information.

Ask for email address or phone number to send the download link.

Then:

Would you like assistance setting up PositiveLinks?

Yes

No

If no assistance is needed:

Okay, I'll send the PositiveLinks self-installation instructions to the [participant's phone number] or [participant's email address] you just gave me. You can call me back at [Linkage Coordinator's phone number] or reach out through the app if you have any questions.

Send self-setup instructions to the phone number or email address to which the download link was sent. Move on to warm referral.

If assistance is needed:

Great. First, are you planning to install PositiveLinks on the same device you're calling me from?

Yes

No

If installing PositiveLinks on same device:

Please click the download link on the device where you'd like to install PositiveLinks. I can send you a new link if you need.
:

Are you currently connected to Wi-Fi?

- Yes
- No

If participant is not connected to Wi-Fi:

That's fine. You won't be able to install the app while you're on the phone with me. I'm going to ask you to hang up, click the download link I just sent you, and install the app. I'm going to call you back in 2 minutes to finish our conversation.

End the phone call, wait two minutes, and call the participant back. Do not reset the call start time. When you call back, set up the app with the participant.

If participant is connected to Wi-Fi:

Okay great, let's get started.

Follow set-up steps:

[Set-up steps]

- 1. Determine if participant is using iOS or Android and tailor accordingly*
- 2. Walk through the login, including setting up password and enabling fingerprint/eye scan if applicable*
- 3. Describe home page features*
- 4. Send test messages*
- 5. Explain where contacts are; participant practices putting in contacts*
- 6. Set up calendar and reminders*
- 7. Have participant demonstrate understanding of app features*
- 8. End PL orientation and continue to targeted referrals*

Once finished:

You should be ready to start using PositiveLinks now. Thanks for joining the app! If you have any questions, you can reach out to me through the app, or you can call me at [Linkage Coordinator's phone number].