YEHE Informed Consent Form

Study Title: Youth Ending the HIV Epidemic - Automated Directly Observed Therapy Pilot: Improving HIV Care Among Youth
National Clinical Trial Number: NCT05789875
IRB Study Number: 22-36721
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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Youth Ending the HIV Epidemic (YEHE)

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This is a research study about using technology to improve adherence to antiretroviral therapy. The Principal Investigator, who is the person in charge of the study, or another member of the study team from the UCSF Center for AIDS Prevention Studies will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are 18-29 years of age and have access to a smartphone.

Why is this study being done?

The purpose of this study is to try out a mobile health application (also known as "app") which will be used to help young adults living with HIV improve adherence to antiretroviral therapy. The app tracks when someone takes their HIV medication by recording a video, and gives a small reward for each day they take their medication.

This study is funded by the National Institutes of Health.

How many people will take part in this study?

About 30 people will take part in this study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

Enrollment and Baseline Survey

- After we receive your consent, we will ask you for various ways of contacting you in case we have a hard time reaching you by phone. This will include the names of people

who may know how to find you, however you may ask us at any time to no longer contact these people.
- We will also ask for your permission to request your medical records from your AHF clinic.
- Then, we will help you download the app on your phone and demonstrate how to use it. We will ask you to demonstrate taking your medication using the app to see if you have any questions.
- We will also ask you to take a baseline survey to learn more about you, your current experience taking medication, and how you use technology.

Using the App
- For 3 months, whenever you take your HIV medication, we will ask you to record yourself in the app.
- We will also check in with you monthly to ask you about using the app and answer any questions you have.

Exit Survey
- After using the app for 3 months, we will ask you to complete another survey to get your feedback about the app and see how it may have changed how you take your medication.

Interview
- 15 participants will be selected to participate in an interview, where we can get more feedback about the app and suggestions for improvement.

Study location: All study procedures will be done in your home or at a private location of your choosing.

How long will I be in the study?

Participation in the study will take a total of about 9 hours over a period of 3 months.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

If you withdraw from the study, any data we have already collected from you will remain part of the study records. After you withdraw, the researchers may still get information from your medical records if it is relevant to the study (e.g., laboratory results, treatment courses, health outcomes). You must tell the study team you do not want this information to be collected when you withdraw, otherwise it will be collected.

Also, the study researcher may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- Loss of confidentiality is the main potential risk associated with participation in this study, however we will do our best to make sure your information is kept private. Security and privacy are our top priority. Only the research team will be able to view your information from the app, and the app icon doesn't mention anything about HIV or the study.
- Some of the survey questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or to withdraw from the study at any time.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

You may or may not benefit from participating in this study.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may use the information collected for future research studies or share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information. We cannot guarantee that this will prevent future researchers from determining who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the AIDS Healthcare Foundation
- Representatives of the University of California
- Representatives of the National Institutes of Health

This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena/court order or otherwise) about research participants.

The Certificate DOES NOT:

- stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs.
- stop disclosures required by the federal Food and Drug Administration (FDA).
- prevent your information from being used for other research if that is allowed by federal regulations.

The Certificate does not stop you:

- from releasing information about your involvement in this research.
- from having access to your own medical record information.

Will I be paid for taking part in this study?

In return for your time and effort, you will be paid up to $154 for taking part in this study, as follows:

- Baseline survey: $20
- Taking your medication using the app: $0.75/dose x 28 days x 3 months = $63
- For each week that you take all 7 doses using the app, you will get a bonus: $0.25/dose x 28 days x 3 months = $21
- Exit survey at 3 months: $50

You will be paid in the form of an e-gift card which will be sent to you via email; or through a mobile payment app like Venmo.

Will I be reimbursed if I pay expenses related to my participation in this study?

You will not be reimbursed for expenses if you take part in this study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can contact the study team with any questions, concerns, or complaints you have about this study at 415-735-1507.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent