UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project:

Preventing HIV/STI Among At-Risk Adolescents Via a mHealth Primary Care Intervention

Company or agency sponsoring the study:

Health and Human Services, Department of National Institutes of Health

Principal Investigator: David Cordova, Ph. D., School of Social Work, University of Michigan

GENERAL INFORMATION

You may be eligible to participate in the research study if you are between 14-21 years old and live in Southeastern Michigan.

What is the point of this research study?

The study team led by Dr. David Cordova has a program, Storytelling for Empowerment (SFE), which has helped improve teen health and decrease sexual risk behaviors and alcohol and drug use in teens. The main goal of this research is to determine whether an mHealth application (app) version of SFE (S4E) that focuses on improving HIV and STI testing, as well as reducing and preventing HIV and sexually transmitted infections (STIs) and alcohol and drug use, will work and will improve patient communication with their clinician. This goal is important because teens are at risk of engaging in sexual and drug use risk behaviors, which increase the risk for HIV/STIs.

What will you be asked to do?

Study Treatment Options: There will be two treatment options. You will be in one of them. You cannot choose which treatment option you will receive. The study team will not know which treatment option you will be in, but everyone will have an equal chance of being in each treatment option. Below is a description of each treatment option:

Treatment Option 1: In this treatment option, you will be using the S4E web-app on your mobile device, computer, or on an iPad in the waiting room or in a private room. The S4E app will be focused on 1) activities with information about sexual risk behaviors and substance use and their effects on health, 2) discussion about prevention, 3) the importance of HIV and STI testing, and 4) helping you talk to your clinician about your needs and concerns. The study team will provide you a website link that will ask you to complete surveys that cover personal information, health risk behaviors, including sexual and substance use behaviors, HIV and STI testing, and your visit with your clinician. This survey will take 20-45 minutes. After you complete the survey, the next screen will welcome you to the S4E intervention. If you leave the survey unattended, or do not respond to a question after 10 minutes the intervention will log you out.

Your use of the S4E web-app and completion of the remaining surveys at the clinic will take approximately forty-five minutes to an hour. As part of this treatment option, you will also receive information about sexual and substance use risk prevention as part of your health care at the Corner Health Center. You have the option to continue to use the web-app outside of the Corner Health Center for the duration of the study by accessing via the link the study team provides on your phone or personal device or computer. The study team will ask you to return three months after your visit and then six months after to complete the same surveys again.

Treatment Option 2: In this treatment option, you will continue to receive the same services as you normally do at the Corner Health Center. The study team will provide you a website link that will ask you to complete surveys that cover personal information, health risk behaviors, including sexual and substance use behaviors, HIV and STI testing, and your visit with your clinician. This survey will take about 20-45 minutes. The study team will also ask you to come back three months after your visit and then six months after to complete the same surveys again. If you leave the survey unattended, or do not respond to a question after 10 minutes the intervention will log you out.

Additionally: We will ask you to provide us with three contact persons. This information will only be used in case we are not able to reach you. We will maintain your confidentiality and only explain that you are participating in a study with the University of Michigan and will not disclose the topic of the study. This is completely voluntary and you still can participate in the study if you decide to not give any additional contact information.

Can anything bad happen from being part of this study?

The study team does not think that you will be hurt from being part of this project. But, you may learn some facts that might bother you and or make you feel embarrassed sad, uncomfortable, and/or angry. If that happens, the study team will stop and give you some information to local mental health and community health centers. There is also a risk of breach of confidentiality, and we have measures in place to protect the confidentiality of your records-these measures are described below. Because you will be completing these assessments and intervention activities on a mobile device, tablet, or computer, the research team cannot guarantee confidentiality in the instance that someone next to you is looking at your responses. Therefore, to protect your privacy, please complete the survey in private.

What are the benefits of being part of this study?

There may be no benefits to you for being a part of this study. But, you may be less likely to use drugs and/or take part in risky behaviors, such as having sex without a condom. Also, you may be able to talk to your clinician and/or family more easily about these topics.

Incentive.

You will get $30 in cash once you complete the study surveys (Health Behavior Survey, Post Clinician Visit Survey) and complete your clinic visit, $40 in cash when you return after three months, and $50 in cash when you return after six months, for a total of $120 in cash. The University of

Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

Right to Decline or Withdraw:

Your participation in this study is voluntary. You can exit this study at any time or you can even change your mind later. Your participation will not affect the care you get from the Corner Health Center. The investigator reserves the right to remove you without your consent at such time that they feel it is in your best interest such as:

1) If you experience discomfort or any other adverse reaction to using the S4E app.
2) If you express no longer wanting to participate.
3) If you move out of the targeted community and can no longer participate.

What will be done with your information?

The information will be used to figure out if the intervention works and if clinicians and adolescents would like to use it. Only the study team will have to access your answers to all surveys. One of the surveys will be completed on the web-app, the responses to this survey will be seen by your clinician. The study team will consider your records confidential. All research records, including this consent form, will be transmitted to a secure server at the University of Michigan. The study team will not share information that may identify you regarding what you tell them. Nothing you say will be added to your health records or shared with people outside of the Corner Health participating staff. For those in Treatment Option 1, your answers on the app are transmitted to a secure server at the University of Michigan. This happens as you respond, so none of your answers are stored on the iPad. If you complete the intervention on the iPad, please return the iPad to the research team member.

The study team will never put your name in any report on this data. Your data will be coded so that only that number connects you to your answers. Data will be kept for future research. The study team will keep a list matching names and code numbers in locked files. Only the study team will be allowed to look at them. Your name will not be kept with the data.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should

understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

A description of this clinical trial may be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed below (under Contact Information).

It's possible that the researchers or others will need access to information about you during or after this study. For example:

- The researchers may need the information to make sure you can take part in the study.
- The University of Michigan or a government agency may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to, make sure the study is done safely and properly, learn more about side effects, or analyze the results of the study.
- Federal or State law may require the study team to give information to the Food and Drug Administration (FDA) or other government agencies. For example, to prevent harm to you or others, or for public health reasons.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.med.umich.edu/hipaa/npp.htm. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Dr. David Cordova
Mailing Address:
University of Michigan School of Social Work
1080 S. University
Ann Arbor, MI 48109
cordovad@umich.edu
Telephone: (734)763-3372

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

SIGNATURES

Sig-A

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

☐ Yes, I understand and agree to participate in this study

☐ No, I do not agree to participate in this study

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my information. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

☐ Yes, I agree to let the study team keep my information for future research.

☐ No, I do not agree to let the study team keep my information for future research.