Informed Consent Form

Title: iTransition: Pilot Testing a Multilevel Technology Based Intervention to Support Youth Living With HIV From Adolescent to Adult Care

NCT Number: NCT04383223

IRB Approval Date: 09/10/2019

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 22 people who are being studied, at Emory and elsewhere.

Why is this study being done?

This study is being done to develop a program to improve healthcare transition for youth living with HIV. You are being asked to be in this research study because of your clinical and/or personal expertise in this area.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate in approximately 6-12 meetings. The researchers will ask you to do the following: (1) share barriers and facilitators of HCT from yours and other colleagues' experience; (2) suggest components to include in an HCT intervention; and/or (3) test out the functionality of our newly developing web app. .

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. We hope that this work will help youth living with HIV, and providers working with them, in the near future.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The main risks would be potential discomfort during discussion. We will not delve into very personal topics, but some people might feel bad about past behavior as a provider or patient.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: iTransition: Developing a Multilevel Technology-Based Intervention to Support Youth Living with HIV from Adolescent to Adult Care

Principal Investigator: Sophia Hussen MD, MPH

Sponsor: National Institutes of Health

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to develop an app that will help providers and patients through the process of healthcare transition from pediatric to adult-oriented care.

What will I be asked to do?
You will be asked to attend several meetings (up to 6-12 per year) and provide feedback on iTransition as we develop it. Meetings are likely to last 60-90 minutes. In the initial meetings, we will be brainstorming content that will help providers and patients to navigate healthcare transition from pediatric to adult care. In later meetings, we will be working with a prototype web app and asking for feedback on aesthetics and functionality.

Who owns my study information and samples?
If you join this study, you will be donating your study information (i.e. your feedback on our program). If you withdraw from the study, feedback that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are: potential discomfort in discussing history of care engagement or provision, and potential breach of confidentiality. That is, you may feel uncomfortable talking honestly about challenges you have faced in providing care to youth living with HIV. Additionally, it is possible that another person in the group could disclose your participation to others.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about the barriers and facilitators of transitioning to adult care. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get $50 for each completed study visit quarter (i.e. every three months), as a small token of appreciation for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed.

What are my other options?

If you decide not to enter this study, it will not impact your employment.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [The Food and Drug Administration, the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Expiration of Your Authorization

Your IIHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at:

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed

to do so by the laws that cover them. The researchers, the Sponsor, and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [study contact person(s)] at [telephone number(s)]: Sophia Hussen [redacted]

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**