Model Informed Consent

Version 4.0

February 24, 2021

ATN 160 – TechStep: Technology-based Stepped Care to Stem Transgender Adolescent Risk Transmission

Funded by:

The Eunice Kennedy Shriver

National Institute of Child Health and Human Development (NICHD)

with co-funding from:

The National Institute on Drug Abuse (NIDA)

The National Institute of Mental Health (NIMH)

The National Institute on Minority Health and Health Disparities (NIMHD)

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Friends Research Institute

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Protocol Co-Chair: **Keith J. Horvath, PhD**

San Diego State University

San Diego, CA

Trial Registration: ClinicalTrials.gov NCT04000724

RCT ASSENT/CONSENT

Assent/Consent to Participate in a Research Study
Participants age 15-24 years

UNC IRB Study # 18-0519

Consent Form Version Date: v4.0; 24-February-2021

Title of Study: ATN 160 – TechStep: Technology-based Stepped Care to Stem Transgender Adolescent Risk Transmission

Co-Principal Investigators: Cathy J. Reback, PhD, Friends Research; Keith Horvath, PhD, San Diego State University
Sponsor: The University of North Carolina at Chapel Hill (UNC-CH)

Funding Source: National Institutes of Health (NIH)

Study Site Investigator: [Site PI]
Study Contact: [SRV contact]
Study Contact telephone number: [SRV phone number]
Study Contact email: [SRV email]

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study at any time, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this form. You can ask the researchers named above, or study staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
We are conducting a technology-based study for transgender, nonbinary, and gender nonconforming youth and young adults (hereafter: trans youth). The study, TechStep, is designed to provide information and support to trans youth and help them reduce their HIV risk. Through a random process, you will receive daily text messages, access to a social media-style webapp, or access to a transgender health and HIV information website. Additionally, some people will be paired with an online coach to discuss issues that trans youth often face.

How many people will take part in this study?
If you decide to participate, you will be one of about 275 people in this part of the study.

How long will your part in this study last?
Your participation will be required for 4 in-person or online visits. Each of these visits can last up to 3 hours. You will be actively engaged in the study for 6 months, and will have a final follow-up-visit at 9 months after you enroll in the study.

What will happen if you take part in the study?
If you choose to be in the study, you will be asked to sign this form before you begin the study.

After you have provided your consent, you will give the study staff a list of ways to contact you, such as your e-mail address and phone number, as well as the phone number of a relative or friend who knows how to get in contact with you. Study staff will not leave phone messages unless you give permission. The study staff will also not tell your relative or friend anything about this study, your participation in the study, or give any information about you unless you give permission. Your contact information will be used to remind you to come in for your study visit and to help you with transportation to your study visit, if needed. You also can choose not to give any information that you do not want to give.

You will be asked to complete 4 study visits in person or online – today's enrollment visit and follow up visits after 3, 6, and 9 months. Online visits will take place over a secure videoconferencing platform. For online enrollment visits, you will meet with research study staff over secure video chat or the phone and they will guide you through the visit. You will review and sign the consent.

You will answer a questionnaire at your first visit and the follow up visits at 3, 6, and 9 months following enrollment. The questionnaires ask some demographic items, questions related to your healthcare access, your experience as a trans youth, your drug and alcohol use, and your sexual behavior, as well as questions about your smartphone and other technology use. All of your responses are confidential and only accessible by people working on the study team. The online survey is hosted on Alchemer and we will use SSL encryption for transfers of information online. Data will be stored in the secure, HIPAA-compliant servers of SurveyGizmo. We don't share your information with other people (like your family, friends or teachers).

In addition to completing a questionnaire, we will ask you to perform the following tests during today's enrollment visit and at the in person or online 3, 6, and 9 month visits. For online study visits, a kit will be mailed to the address of your choice for you to collect the specimens listed below. We will provide you with instructions for how to collect the samples and you will mail this kit back to the lab within 90 days. Study staff will check with you before a kit is mailed to make sure you are comfortable receiving the kit. If you are not in a space where you feel comfortable to receive the kit and collect the samples, we will not mail you a kit. However, if you are not able to receive the kit and complete at least the HIV test portion within 90 days after the enrollment visit, you will not be able to continue in the study. We ask that you self-collect as many of the specimens as you can. We will be available to schedule a time to go over the kit with you after you receive it, and can even stay on a secure video call with you while you complete portions to help answer questions and make sure you're comfortable.

Urine: We will ask you to give a urine sample. For in person visits, the urine sample will be tested for gonorrhea and chlamydia and recent drug use. The results of the drug test are for research purposes only and will not be entered into your medical record. For online visits where we mail you a self-collection kit, the urine sample you send back will be tested for gonorrhea and

chlamydia but we will not test for drug use. The results of the gonorrhea and chlamydia test (either in person or via self-collection mail kit) may be entered into your medical record for treatment purposes.

Rectal swab: You will be given a kit with instructions and we will ask you to swab your rectum to collect a rectal sample in order to test for gonorrhea and chlamydia.

For in person collection of the above urine and rectal samples, you will be directed by the study staff to a private restroom with a locking door. You will also be instructed where to leave these samples. For self-collection mail kits, you will be provided with instructions on how to collect the sample(s) in a room or location of your choosing.

Throat swab: A throat swab will be collected to be tested for gonorrhea and chlamydia. You can self-collect it after receiving instructions on how to do so at either the in person visit or via selfcollection mail kit. At in person visits, a staff member can collect it for you if you prefer.

Oral HIV test stick:
Self-collection for online visits: For self-collected mail kits, you will perform an at-home rapid HIV test. Research staff will be available to remotely (via secure video chat) walk you through the process and help you understand your results. You will need to show them your results via secure, live video chat, or by uploading a photo of the test results to a secure survey website. The test will involve you sliding a test stick across your upper and lower gums before placing the test stick into a liquid solution. The test takes 20 minutes to develop before the results are ready. If you do not want to conduct the rapid test at home, you will also have the option of conducting a separate HIV test at home that will be sent to a lab for processing.

Blood Collection:
In-person visits: For in person visits, you will be asked to test for HIV using a rapid HIV-antibody blood test. This may require that your finger be pricked for blood, or blood may be drawn. You may be asked to complete a second rapid-HIV antibody blood test if the results of the first test are inconclusive or show a reactive or preliminary positive result. If you report starting or continuing to use PrEP, you will also be asked to participate in a finger prick for this additional blood test.

A trained phlebotomist, a person who is trained and certified to withdraw blood, will collect a sample of blood from a vein to test for syphilis during an in-person visit. Using a new, sterilized needle, about 30 ml of blood (about 2 tablespoons) will be taken from your vein. Blood from this blood draw may be used in place of a finger prick for HIV rapid testing and/or PrEP adherence testing.

Blood, urine, rectal, and throat samples will be shipped via courier to a professional testing laboratory along with a test requisition form containing a non-name code. Your birthdate may be shared with the laboratory, but your name or other identifying personal information will not be released to the laboratory or anyone else for any other purposes.

Self-collection for online visits: For self-collect mail kits, you will self-collect and mail back a blood sample via finger prick to test for HIV and syphilis and measure the amount of PrEP in your blood. If you have a positive syphilis test result, you may be asked to provide an additional blood sample to confirm the result.

The kit that you will use to collect the test samples will be mailed to you and you will mail them back to a certified testing laboratory, Molecular Testing Labs (MTL). Your information including

name and mailing address will be entered by study staff into an online ordering portal where MTL will process the shipment.

Regardless of whether you had an in-person or online visit, you will be notified if you test positive for HIV or any sexually transmitted infections (STIs) once results are received. If you test positive for any sexually transmitted infection, we will help you to find appropriate treatment. If you test positive for HIV, we will help you to find confirmatory testing and treatment. If you test positive for HIV at any point in the study, you will no longer be able to participate in the study. Positive test results will be sent with your personally identifying information such as your name and address to the local health department as required by law.

Once you have been randomized, you will receive instructions in person, online via secure video chat or over the phone on how to use the technology and set up any subsequent visits. Depending on your randomization assignment, you may be asked to receive text messages or use a website.

At the 3-month follow up visit, you may be asked to begin participating in secure, online video meetings with an eCoach. This would include around 5 to 8 weekly sessions with an eCoach lasting around 20 to 30 minutes each, though the amount of time per session would vary. The eCoaching sessions will be online video conference sessions, and you will have the option whether or not you want to turn on the video for the eCoach to see you. You may be asked to download a secure video conferencing app onto your phone. During eCoaching, you may discuss topics including but not limited to your access to healthcare, experience as a trans or nonbinary individual, your drug and alcohol use and your sexual health. Coaching sessions will be audio recorded to ensure that e-coaches are delivering the highest quality care to all study participants. Any information you share will be confidential. If you are asked to meet with an eCoach, we will provide the eCoach with the contact information that you provide during today's enrollment visit. You may also be asked to provide the same type of contact information to the eCoach that you are providing during today's enrollment visit.

What are the possible benefits from being in this study?

If you engage in sexual behaviors that may put you at risk for HIV transmission, this study may help you reduce these behaviors and lower your risk of getting HIV. Of course, because individuals respond differently, no one can know in advance if the study will benefit to you. The information learned from this study will assist us in learning about how studies, like TechStep, may be most helpful to young people like you.

What are the possible risks or discomforts involved from being in this study?

You may find some of the questions a little embarrassing or difficult to answer. The questions are important to us, but your participation is entirely voluntary. You may choose not to answer any question or withdraw from the study at any time.

We will make every effort to protect your confidentiality. Your study ID number will only be linked to your name and contact information within the study's secure, HIPAA compliant enrollment database. This database will not be linked to any of your other study records or data you provide during the study. Only approved research staff members at the SRV site and at Emory University can access this database using a secure server, password, and cell phone confirmation. All of your study records and study data are stored in a separate, unlinked HIPAA compliant database that does not include your name or contact information, only your study ID number. Research staff members involved in this study are required to sign a form stating that they will protect and keep private all information on every person in the study.

You may also be asked to refer members of your social network to participate in the study. However, referring peers to participate in the study is optional – you may choose to refer your peers or not. If you do choose to refer peers to this study, this may cause some embarrassment or discomfort. To avoid this, we will train you on how to present the referral coupons to your friends and acquaintances in a way that does not require disclosing any private information about yourself.

You may also feel some discomfort from using the oral and rectal swabs for STI testing, and the oral swab for HIV rapid testing. We will give you instructions on how to use the swabs in an effort to make them as comfortable as possible for you.

Additionally, the blood draw or finger stick for syphilis, HIV, and PrEP adherence testing may cause discomfort, bleeding, or bruising where the needle enters the body. There is a small risk of minor infection occurring at the blood draw or finger prick site. In rare cases, lightheadedness and fainting may occur.

The process of HIV and STI testing and learning of a reactive/preliminary positive HIV and/or positive STI test result can involve emotional distress and anxiety. If you have a preliminary positive HIV test result, you will be offered immediate evaluation and HIV counseling here at this site, or a rapid referral to another facility for a confirmation test and treatment (if applicable). If you have a positive STI test result, study staff will refer you for treatment if you are not already connected to care.

We make every effort to ensure mailed home blood collection kits are packaged discreetly. Test kits will be mailed in a generic USPS mailer so that the contents will not be visible to anyone unless the mailer is opened. However, there is the risk that someone in your home could see the kit or open it. If you choose to take an at-home rapid HIV test, you will be asked to show the test result via secure videoconferencing or by taking a photo of the results and uploading them to a secure survey website. There is a risk that someone could see the photo of the HIV test result on your phone. We recommend that you delete the photo after the photo has been successfully uploaded to the survey website.

You will be informed if the study staff learns of any new risks.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions, have undermined the right or privacy of another participant, or because the entire study has been stopped.

How will your privacy be protected?

Your participation in this study will be kept confidential and private as permitted by law. This includes the information you provide during study visits, on surveys, the audio and video recording of interviews or e-coaching sessions, and anything you enter on the TechStep website.

Every effort will be taken to protect your identity as a participant in this study. You will not be identified by name in any report or publication of this study or its results. Instead, you will be known only through a study ID number. Any data linking your name to your study ID number will be kept in a locked cabinet in a locked room at the study site, but separate from where your study records are stored. Staff members involved in this study are required to sign a form

stating that they will protect and keep private all information on every person in the study.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, this study site and the researchers will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of this study site, the University of North Carolina at Chapel Hill (UNC-CH), research sponsors, or government agencies for purposes such as quality control or safety.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

The kit that you will use to collect test samples will be mailed to you and you'll return them to a certified testing laboratory, Molecular Testing Labs (MTL). Participant information including name and mailing address will be entered by study staff into an online ordering portal where MTL will process the shipment. None of the information you share in the surveys you take as part of your study visits will be included with the participant addresses that study staff share with MTL. Test kits will be mailed in a generic USPS mailer so that the contents will not be visible to anyone unless the mailer is opened.

MTL is a Centers for Medicare and Medicaid Services (CMS) Designated "Covered Entity" sworn to uphold all HIPAA Considerations. Use of encryption is required on applicable communications. Laboratory Information System access is protected per HIPAA Guidelines.

At the end of the study, all of your information from the study will be coded and stored at Emory University in Atlanta, Georgia.

A description of this study will be available on http://clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can access this website at any time.

To help further protect your privacy, the Adolescent Trials Network (ATN) has obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). It adds special protection for research information that identifies you. It says that we do not have to identify you, even under a court order or subpoena. 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.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

Still, we may report medical information (if you need medical help), probable harm to yourself or others, or probable child abuse or neglect, and the government may see your information if it audits us. This Certificate does not mean the government approves or disapproves of our study. 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.

Every effort will be made to keep your participation in the study and any personal information about you private and confidential. However, absolute confidentiality cannot be guaranteed. For example, if a study staff member learns something that would immediately put you or others in danger, the study staff member is required by law to take steps to keep you and others safe. This means that study staff members have to report to the authorities (hospital, police, or social services) any information you say that suggests that you might be in danger, such as telling study staff that you plan to hurt or kill yourself, hurt or kill someone else, or if someone is abusing or neglecting you.

In addition, your records may be reviewed by certain agencies or people who make sure that the study staff are doing what they are supposed to and everyone in the study is being protected. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the National Institutes of Health (NIH) and the UNC IRB may look at your records. If your study records are reviewed, your identity could become known to them. However, these persons are expected to maintain your individual confidentiality. This means that they will not tell others information about you or that you are in the study. By signing this form, you are allowing such access.

In this study, you will be tested for HIV and syphilis. If you have a positive test for HIV or an STI, state law may require us to report that positive test to the state health department for purposes of statistics and service planning. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested for HIV or an STI at a doctor's office or a clinic outside of this research study.

Will you receive anything for being in this study?

You will receive $230 in total for completing all study activities. The amount you receive at each study visit is:
Visit 1 (Today): $50
Visit 2 (3-months): $55
Visit 3 (6-months): $60
Visit 4 (9-months): $65

The total time spent at this visit, including reviewing the consent form and getting compensation will take about two hours.

You may be asked to complete a biospecimen self-collection kit at some or all of the study visit time points (enrollment, 3, 6 and 9 months), particularly for online study visits. You will receive $50 each time you return the kit (up to 4 times). This would be in addition to the study visit compensation amounts listed above.

You may be asked to refer members of your social network to participate in the study. For each person you recruit who screens eligible and completes initial enrollment steps, you will receive an incentive of $10. You will receive this $10 incentive for up to 5 of these referrals for a maximum of $50.

Are there any costs to you for taking part in this study?

You will not be charged for anything that is done for this study. This includes consuming any food

or refreshments. You or your health insurance company will have to pay for any medical care that is not part of this study, as you would usually do.

Who is sponsoring this study?
This research is being sponsored by the University of North Carolina at Chapel Hill and funded by the National Institutes of Health (NIH). This means that the sponsor, the University of North Carolina at Chapel Hill (UNC-CH), is providing money from NIH to this study site to help conduct this study. The researchers do not, however, have a direct financial interest with the sponsor or funding source or in the final results of the study.

What if you are an employee of this site?
Taking part in this research is not a part of your work duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research at any time before, during, or after your participation. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

The investigators and/or someone they appoint in their place, will try to answer all of your questions. If you have questions, complaints, or concerns at any time, related to the research, you may speak with a member of the study staff during working hours (8am – 5pm).

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the University of North Carolina at Chapel Hill (UNC-CH) Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

UNC IRB Study # 18-0519

Title of Study: ATN 160 – TechStep: Technology-based Stepped Care to Stem Transgender Adolescent Risk Transmission

Site Investigator: [Site Investigator]

Participant's Agreement (for online assent/consent)
If you select yes below to the first question, you are voluntarily agreeing to take part in this research study.

Do you agree to participate in the study?
- ○ Yes, I agree to participate in the study.
- ○ No, I do not agree to participate in the study.

Participant's Agreement (for online assent/consent)
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

_____

Electronic Signature of Research Participant

Participant's Agreement (for in-person assent/consent):

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____

Date

_____

Signature of Person Obtaining Assent/Consent

_____

Printed Name of Person Obtaining Assent/Consent