ANN & ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO
INSTITUTIONAL REVIEW BOARD
Adult Consent to Participate in a Research Project

Investigators at Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's) and Chicago House and Social Service Agency (Chicago House) invite you to consider participating in a research study entitled:

Evaluation of TransLife Center: A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection

Sponsored by: The Centers for Disease Control and Prevention (CDC) and carried out by Lisa M. Kuhns, PhD, MPH and Judy Perloff, MSW.

This consent form describes a study being done at Lurie Children's and Chicago House. Research studies help us learn more about conditions and possible new treatments. Research studies are voluntary, which means that it is your choice whether to participate in the study. The study staff will also explain the study to you and answer any questions that you may have before you make a decision.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if the TransLife Center (TLC) helps transgender women prevent HIV and other infections. You are being asked to participate in this study because you are an HIV-negative transgender woman (or identify along the trans feminine spectrum) and are seeking services through the TLC.

WHAT IS INVOLVED IN THE STUDY AND HOW LONG WILL I BE IN THE STUDY?

If you agree to be in this study, we will ask you to come in to Chicago House or Lurie Children's 3 times over the next 8 months. Each visit will take about an hour. In these study visits, up to 5 things will happen:

1. You will answer questions on a computer. Some of these you will do with a staff person and some by yourself. The questions will ask about your experiences with sex, alcohol and drugs, health care and mental health, and your experience as a transgender woman.
2. If you have taken a pill in the past few weeks to prevent HIV, (also called PrEP or pre-exposure prophylaxis), we will also ask for a sample of your hair (100 hairs) to test for the medicine in your body. If we are not able to get hair, we will prick your finger and put a small amount of blood on a paper card.
3. We will swab your mouth to test for HIV or prick your finger to get a small amount of blood to test for HIV and syphilis. If you have had syphilis before, we will need to take blood from your arm to do the test. If the tests tell us you might be positive, we will take about a teaspoon of blood from your arm to make sure.
4. We will ask you to give a urine sample and do an anal swab to test for Chlamydia and gonorrhea. You will go to a private area and pee into a cup. Then you will put a cotton swab about 2 inches into your butt, make a circle, take it out, and then place the swab in a tube.

5. We will ask you about the services you might want at the TLC, such as the drop-in center, housing, jobs, legal, health and other services.

In 10 to 14 days from your visit we will give you the results of all your tests for HIV and STI tests. If you are positive on any tests, we will set up a visit for you with a clinic where you can get free or low-cost treatment.

While you are in the study, we will also keep track of which programs and services at Chicago House that you use.

In order to get the results of your HIV and STI tests and if you are taking PrEP, we will ask you to fill out a form so that we can ask the clinics about your test results and clinic visits.

About 150 participants will be enrolled in this study at Chicago House and Lurie Children's.

ARE THERE BENEFITS (GOOD THINGS) TO TAKING PART IN THE STUDY?
You may enjoy your participation in this study and benefit from being tested for infections and the housing, employment and legal services provided by the TLC. The information we learn may also help to prevent HIV risk among transgender women.

WHAT ARE THE POSSIBLE RISKS OR SIDE EFFECTS (BAD THINGS) OF THE STUDY?
You may find some questions unpleasant or hard to answer. You may leave any question blank if you wish. Study staff will try to answer any questions you have. You may be nervous about taking the tests. Staff will provide pre-test counseling and answer your questions to make sure you understand the process and your options if you test positive for HIV, syphilis, Chlamydia or gonorrhea. If you test positive you will also be referred for care and treatment. The risks of taking blood include pain or discomfort, temporary bruising and very rarely, infection. The study staff will take care to prevent these or to correct them, should they arise**.**

WHAT OTHER OPTIONS ARE THERE?
You do not have to take part in the study. You can still access the TLC services and HIV testing and counseling services. You are also free to stop participating at any time.

WHAT ARE THE COSTS?
There will be no costs to you as a result of being in this research study. If you test positive for HIV or any STI, you and/or your insurance company are still responsible for your usual, ongoing medical care that is necessary to treat these conditions.

Lurie Children's may be able to provide some financial assistance to eligible patients. To obtain more information about this program ask the study staff or visit the website http://luriechildrens.org/en-us/care-services/billing-medical-records/Pages/financial-assistance.aspx.

WILL I BE TOLD ABOUT NEW INFORMATION?
We will tell you if we learn new information that may lead you to change your mind about being in this study.

WHAT DO I DO IF I AM INJURED?
If you are injured, medical facilities and treatment will be available. However, you may be required to pay a reasonable fee for such care. You can still receive medical benefits if otherwise entitled. If you have any questions or desire further information concerning the availability of medical care, you may contact Dr. Michael Kelleher, Chief Medical Officer, Lurie Children's, 225 East Chicago Avenue, Box #2, Chicago, Illinois, 60611 (312) 227-4270.

WHO WILL KNOW ABOUT WHAT I DID IN THE STUDY OR HAVE ACCESS TO MY PRIVATE INFORMATION?
Every effort will be made to keep your personal health information private. A study number, rather than your name, will be used on study records wherever possible. However, it may be necessary for certain offices and people overseeing the research to look at study records, including your personal health information.

By signing this consent form, you give permission for Lurie Children's and Chicago House to provide your medical records, personal health information, and the results of the study to the following people, agencies, organizations, or companies to review and use in this research study

- Lurie Children's and Chicago House study staff
- Lurie Children's Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who participate in research studies)
- Representatives of the Centers for Disease Control and Prevention (CDC)
- Representatives of the Office of Human Research Protections (OHRP) or other regulatory/government agencies and public health authorities.

Your name and other facts that might point directly to you will not appear when we present this study or publish its results.

Positive test results for HIV and STIs will be reported by name to the Department of Public Health. We are required to make these reports so that the Department of Public Health can track these infections.

This signed consent form will be placed in your medical record at Lurie Children's with a copy placed in the Principal Investigator's research file. Some or all of the research results may be included in your medical records. If you do not have a medical record at Lurie Children's, then this signed consent form will only be kept in the Principal Investigator's research file.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
By signing this consent form, you agree to take part in this study. You are not giving up any of your legal rights or releasing this hospital from responsibility for carelessness.

You may cancel your consent and take yourself out of this study at any time without penalty or loss of benefits. Your treatment by, and relations with the doctor(s) and staff at Lurie Children's and Chicago House, now and in the future, will not be affected in any way if you refuse to take part, or if you enter into the study and then withdraw from it.

You may be taken out of the study if you test positive for HIV infection at the first study visit. If this happens you can continue to access any services at the TLC, as needed. We may also take you out of the study if your behavior is disruptive or causing trouble for other participants or study staff.

At any time, you can tell Lurie Children's and Chicago House not to use or give out your study information or other information from your medical record to other people, agencies, organizations, or companies. Withdrawal of this permission must be in writing. Any study information or other information from your medical record collected before your written notice of permission withdrawal may still be used for the study, if that information is necessary for the study. Because the purpose of this study is to collect information about how well the study intervention works, if you refuse to release your study information, you will not be able to start, or continue taking part in this study. Your decision will not affect your regular care and the study staff will not change their feelings about you.

If you agree to take part in this research study, you will not be able to look at or ask for a copy of your health information collected only for this study, while you are taking part in the study. If you wish, you will be able to ask for this study research information when the study is over or when you are no longer taking part in the study. This does not affect your right to see your medical record or the results of tests related to regular medical care that is given during the same time as the research study.

If you have any questions about the research methods, you should contact the principal investigators, Lisa Kuhns, PhD, MPH by calling 773-303-6055 or Judy Perloff, MSW, at 773-248-5200 during a workday.

If you have any questions about your rights as a research subject, wish to discuss problems, concerns, and questions, wish to obtain information, or wish to offer input to someone who is not directly involved with this study, you may contact Catherine Powers, Office of Research Integrity and Compliance, 225 East Chicago Avenue, Box #205, Chicago, IL 60611, (773) 755-7489; cpowers@luriechildrens.org.

You will be given a copy of this consent form.

TOKEN OF APPRECIATION

You will receive $50 as a token of appreciation after completing each study visit. There are a total of three visits that you may complete over 8-months (total up to $150). You will only get a token of appreciation for the visits you take part in.

SIGNATURES

The study has been explained to me and I have read this consent form, have been given the opportunity to consider my decision, and have had all my questions answered. I agree to take part in this study as explained in this consent form. I agree to let Lurie Children's and Chicago House use and give out my health information in the way it is described in this consent form until the end of the research study. I agree to be contacted to participate in future studies for which I may be eligible.

Date	Signature of Participant (≥18 years) or Legally Authorized Representative (LAR) *(If non-English speaking, the parent/LAR should only sign consent or short form in his/her native language.)*
	Printed Name of Research Participant or LAR

I certify that I have explained the above to the participant and believe that the signature(s) was affixed freely. I also agree to answer any questions that may arise.

Date	Signature of Person Obtaining Consent (Investigator or designee)
	Printed Name of Person Obtaining Consent