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 Semi-structured Interviews

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?

You are being asked to take part in an interview because you are a participant or staff member of the TransLife Center (TLC) at Chicago House. This interview will help us learn more about the TLC intervention for adult HIV-negative transgender women, including the successes, challenges and experiences with the intervention.

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

If you choose to be in the study, you will complete an interview either in person in a private office at Chicago House or Lurie Children's. The interview will be take about 60 minutes and will be audio-recorded. About 20 TLC participants and 10 staff will complete interviews at Chicago House and Lurie Children's.

ARE THERE BENEFITS (GOOD THINGS) TO TAKING PART IN THE STUDY?

There are no direct benefits to you for participating in this interview. The information learned from this interview may help the researchers learn more about implementation of programs to prevent HIV risk behavior in adult HIV-negative adult transgender women.

WHAT ARE THE POSSIBLE RISKS OR SIDE EFFECTS (BAD THINGS) OF THE STUDY?

You may find some questionnaire items difficult to answer. You may skip any question that you do not want to answer.

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WHAT OTHER OPTIONS ARE THERE?

An alternative would be not to take part in the study.

WHAT ARE THE COSTS?

There will be no costs to you as a result of being in this research study other than your time.

WHO WILL KNOW ABOUT WHAT I DID IN THE STUDY OR HAVE ACCESS TO MY PRIVATE INFORMATION?

By completing this interview, you give permission for Lurie Children's and Chicago House to provide your answers to the following people, agencies or companies to review and use in this research study: Lurie Children's and Chicago House 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 at Lurie Children's) and representatives from the funding agency, the Centers for Disease Control and Prevention (CDC).

The study interview will not be linked to your name. Please do not include your name or other information that could be used to identify you in your interview. The audio-recorder used to record the interview will be password protected. The audio-recording of the interview will be transcribed (typed out in an electronic file), and once removed from the audio-recorder, will be stored on a password-protected server at Lurie Children's. Any accidental inclusion of your name or other identifying information in the interview audio-recording will be left out of the interview transcription (typed electronic file). The audio-recording will be destroyed immediately after it is transcribed (typed out) and verified (compared to the audio-recording)

You will not be identified individually in any written or oral reports of this study to professionals or the media.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

By doing this interview, you agree to take part in this study. You are not giving up any of your legal rights or releasing Lurie Children's or Chicago House from responsibility for carelessness.

You may cancel your consent during the interview and take yourself out of this study without penalty or loss of benefits. The answers that you provide in the interview may still be used if you stop the interview and do not finish. Any question you do not answer will not be collected. 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.

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 interview responses.

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.

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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 the interview.

The study has been explained to me and/or I have read this consent statement, I have been given the opportunity to consider my decision, and I have had all my questions answered. By completing this interview, 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 responses in the way it is described in this consent form.

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