

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

**Attachment 4a
TLC Eligibility Screener**

Privacy Act Statement:

This information is collected under the authority of the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)). This information is also being collected in conjunction with the provisions of the Government Paperwork Elimination Act and the Paperwork Reduction Act (PRA). This information will only be used by the Centers for Disease Control and Prevention (CDC) staff to evaluate TransLife Center (TLC) as an HIV prevention intervention for transgender women.

Public reporting burden of this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Hi, My name is (*name*) and I'm one of the staff members working on the Trans Life Care study, also known as the TLC study, which is being conducted at Chicago House and Social Service Agency (Chicago House), in collaboration with Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). The TLC offers supportive services to transgender women, such as help with housing, employment, legal and medical services. The purpose of this study is to see if the TLC helps prevent HIV and other infections in trans women. You will be compensated for your time and effort as part of this study. Are you interested in hearing more about it?

Response: If yes, continue. If no, thank them for their time and discontinue screening.

If you are eligible and decide to join this study, you will be in it for up to 8 months. Due to restrictions associated with the COVID-19 pandemic, participation will include access to web and telephone-based services at the TLC, and some limited in-person services, such as HIV testing. At the first visit, we will ask you to complete an HIV test and an evaluation questionnaire on a computer. The questionnaire asks about your experiences with sex, alcohol and drugs, health care and mental health, and your experience as a transgender woman. We will ask you to complete questionnaires again in 4 months and then 8 months. You will have the choice to complete your questionnaires and an initial HIV test in the offices at Chicago House with COVID-19 restrictions or remotely. If you choose to enroll remotely, we will deliver an HIV home test to you and you will complete the initial questionnaire on your own, at home.

You will receive \$50 each time you complete the questionnaire at each of 3 study visits, for a total of up to \$150 for completion of all questionnaires.

If you are eligible and decide to participate we will keep all information we collect from you private, and only the evaluation team will have access to this information. We will need to ask you for contact information so that we can invite you to complete follow-up assessments.

Please remember that participation in the study, including answering any of the screening questions, is completely voluntary. You can refuse to answer any of the questions or decide that you do not want to participate in the study at any time. You can also decide to participate in TLC services, but not the study component. If you have questions about this study, you can contact the Principal Investigator, Judy Perloff or the Coordinator of the TLC at Chicago House at 773-248-5200 or the Principal Investigator at Lurie Children's, Lisa Kuhns at (312) 227-7760.

To find out if you're eligible to participate in this study, I'll need to take about 4 minutes to ask you some questions. Some of these questions are quite personal and sensitive; however, your answers to these questions will be kept private. One of the reasons we stress privacy is that we do ask some very personal questions, and it is very important that you be as honest and as accurate as you can be with your answers. It is only if you are eligible and interested in participating that I will ask for your name and contact information. Your contact information will be stored separately from your answers to this questionnaire and be linked only by an identification number.

Answering these questions is completely voluntary. You can choose not to screen for this study if you don't want to. Whether you choose to screen for this study or not will not impact your relationship with Chicago House or Lurie Children's or any staff of either organization. Are you willing to answer some questions to determine if you are eligible for the study?

Response: If yes, continue with Screening Questions. If no, ask for reasons why:

- | | | |
|--------------------------|---|----|
| <input type="checkbox"/> | No interest | 01 |
| <input type="checkbox"/> | Worried about anonymity | 02 |
| <input type="checkbox"/> | Project takes too long | 03 |
| <input type="checkbox"/> | Afraid of evaluation/guinea-pig | 04 |
| <input type="checkbox"/> | Rather not say | 05 |
| <input type="checkbox"/> | Other | 06 |

If other, specify _____

Thank the participant for their time.

INSTRUCTIONS: Participant ID numbers will only be assigned (a) after the screening questions determine the volunteer to be eligible for this study and (b) after the participant signs the consent form. Regardless of whether or not the volunteer is eligible, record their responses to all questions.

1. First, how did you find out about this project?

- Brochure/flyer/sign: _____
- Recruited by project staff: _____
- Community event (parade, street fair, etc.): _____
- Counseling and testing program: _____
- Community based organization/agency: _____
- Friend/family: _____
- Other, specify: _____

2. How old were you at your last birthday?

____ years **(If not at least 17 years old, check *ineligible and continue*)** Ineligible

3. What sex were you assigned at birth, on your original birth certificate*?

- Male
- Female
- Refused
- Don't know

** Very nearly everyone is assigned a sex at birth – including persons with Disorders of Sex Development (DSDs) who are sometimes called Intersex. If a respondent mentions this, ask them again what their birth certificate says. If they are unclear or unsure, they are ineligible.*

4. Do you currently describe yourself as male, female, or transgender?

- Male
- Female
- Transgender
- None of these

5. Just to confirm, you were assigned [FILL from #3] at birth, and now describe yourself as [FILL from #4]. Is that correct?

- Yes
- No
- Refused
- Don't know

Assess combination of response to 3, 4 and 5, eligible participants must self-identify as transgender with a birth sex of male. Talking through these responses is expected, as many women who are eligible may respond to both 3 & 4 as Female. Remind participants that this project is for trans women.

**If participant does not meet sex/gender identity requirements,
check ineligible and continue**

Ineligible

5. Have you had sex with a man in the past 4 months?

- Yes
- No
- Don't know/refused

If "No" or "Don't know/refused" check ineligible and continue

Ineligible

6. What was the result of your most recent HIV test?

- Never tested
- Positive
- Negative
- Indeterminate
- Don't know/refused

If "Positive," check ineligible and continue

Ineligible

7. Are you able to speak and understand English?

- Yes
- No (**Check ineligible and continue**)

Ineligible

8. Have you received services through the TLC in the past 4 months?

- Yes (**Check ineligible and continue**)
- No

Ineligible

9. Do you plan on staying in the Chicago area for the next 8 months?

- Yes
- No (**Check ineligible and continue**)

Ineligible

Questions 10-13 are for the interviewer only.
DO NOT ASK THESE QUESTIONS OF THE VOLUNTEERS.

10. Does the volunteer seem cognitively functioning and able to understand the assent/consent process?
 Yes
 No (**Check *ineligible and continue***) Ineligible (If ineligible based on this criterion, refer to supervisor to conduct ineligible script and provide referral.)
11. Does the volunteer seem distraught or emotionally unstable (i.e. suicidal, manic, exhibiting violent behavior)?
 Yes (**Check *ineligible and continue***) Ineligible (If ineligible based on this criterion, refer to supervisor to conduct ineligible script and provide referral.)
 No
12. Does the volunteer seem intoxicated or under the influence of psychoactive agents?
 Yes (**Check *ineligible***) Ineligible (If ineligible based on this criterion, refer to supervisor to conduct ineligible script and provide referral.)
 No
13. Aside from eligibility criteria, does the volunteer appear to be a good fit for the study?
 Yes Ineligible (If ineligible based on this criterion, refer to supervisor to conduct ineligible script and provide referral.)
 No (**Check *ineligible and briefly explain below***)
-
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INSTRUCTIONS: If any of the above ineligible boxes are checked, read the INELIGIBLE script. If none of the ineligible boxes are checked, read the ELIGIBLE script below.

SCRIPT FOR INELIGIBLE VOLUNTEERS:

Participants in this study are selected based on the questions you were just asked. Based on your answers, it turns out you're not eligible to participate in the study. Would you be interested in being contacted for other programs or research studies that you may be eligible for or if the eligibility criteria for this study changes in the future?

- No (Thank volunteer and end interview)
 Yes (Fill out contact information)

SCRIPT FOR ELIGIBLE VOLUNTEERS:

Thank you very much for the information you provided. Based on your answers to these questions, you are eligible to participate in this study.

To participate in this study, you will be asked to complete questionnaires and an initial HIV test in the offices at Chicago House with COVID-19 restrictions or remotely. To determine if you can participate in a remote visit, please answer the following questions:

1. Do you have access to a smart phone, laptop, or another device that you can use to participate in a video call (e.g., Skype, FaceTime, Zoom) with a Chicago House staff member?
 Yes No
2. Do you have access to data/WiFi so that you can participate in a video call with a Chicago House staff member?
 Yes No
3. Do you have someplace private (like your apartment, your room) where you can participant in a video call to with a Chicago House staff member?
 Yes No
4. Do you have an email address that you can check during the video call where we will send the questionnaires and other information?
 Yes No
5. Are you comfortable with completing a home HIV test that a Chicago House staff member delivers to you? You will complete the test with a Chicago House staff member on the video call and they will counsel you through the test as they would if you came into our offices.
 Yes No

INSTRUCTIONS: If any of the above boxes are checked “no”, read the ONSITE VISIT script. If all of the boxes are checked “yes”, read the ONSITE/REMOTE VISIT script below.

ONSITE VISIT SCRIPT

You are eligible to enroll in this study if you come to the Chicago House office now located at 2229 S. Michigan Avenue, Suite 304, Chicago, Illinois, in the South Loop to enroll.

Are you interested in taking part in this study?

Response: If “NO”, thank them for their time. If “YES”:

Great! Before we go any further, I need to get your name and then schedule an appointment with you to complete the initial appointment. (continue to scheduling sheet)

ONSITE/REMOTE SCRIPT

You are eligible to enroll in this study either by coming to the Chicago House office now located at 2229 S. Michigan Avenue, Suite 304, Chicago, Illinois, in the South Loop to enroll, or by completing a remote visit. If you choose to enroll remotely, we will deliver an HIV home test to you and you will complete the initial questionnaire at your home. Part of the visit will be conducted by a Chicago House staff member via a video call and we will email you the questionnaires and other information.

Are you interested in taking part in this study?

Response: If "NO", thank them for their time. If "YES":

Would you prefer to complete the enrollment visit by coming into the offices at Chicago House with COVID-19 restrictions or remotely from your home via a video call?

Onsite at Chicago House

Remotely at home

Great! Before we go any further, I need to get your name and then schedule an appointment with you to complete the initial appointment.

THE INFORMATION BELOW INCLUDES IDENTIFYING INFORMATION, STORE SEPERATELY FROM SCREENING DATA.

Preferred name (name you go by): _____
Preferred pronoun (she/her, he/him, etc): _____

What's a good time for you to come in? |__| |__| |__| |__| |__| |__| at ____:____ AM / PM

And if we miss you at that time, what's a good way to contact you to follow up?

Phone: _____ Ok to LVM?

a. **What name should we use to ask for you at this number?** _____

b. **What pronoun should we use to ask for you at this number?** _____

Email: Ok to email?
Facebook: Ok to message?

_____ Initials of person completing this screening form

Entered into screening database

_____ Initials of person entering information into screening database