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

OMB 0920-New

Section A: Supporting Statement

October 9, 2018

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- **Goals of the study:** To evaluate a locally developed and potentially effective intervention, the Translife Center (TLC), which provides combination HIV prevention services to adult transgender women at high risk for HIV infection.
- **Intended use:** Data collected through this study will be used to evaluate a locally-developed HIV prevention intervention for transgender women.
- **Methods to be used to collect data:** TLC intervention participants will complete quantitative assessments at three intervals (baseline, 4-month, and 8-month) throughout the study period. Semi-structured interviews will also be conducted with a subset of intervention participants and TLC staff.
- **The subpopulation to be studied:** 150 HIV-negative adult transgender women who have sex with men and living in the metropolitan Chicago area will be asked to participate in the intervention. Additionally, 20 of the 150 intervention participants and 10 TLC staff will be asked to participate in the semi-structured interviews (Total enrollment = 160).
- **How data will be analyzed:** This study will use a pre-post design to compare pre-intervention levels of HIV risk to those at 4 and 8-months post baseline. Analysis will be conducted to assess the effect of intervention participation on the primary outcome (condomless anal sex acts not protected by PrEP adherence). Qualitative data will be analyzed to describe intervention experiences and barriers and facilitators for implementation of the intervention.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for 2 years of data collection for a research study entitled, "Evaluation of Translife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection" as a new information collection.

This study will evaluate a locally developed intervention, Chicago House's Translife Center (TLC), which provides combination (i.e. biomedical, behavioral, social/structural) HIV prevention and care services to adult transgender women at high risk for HIV infection, in a culturally specific and accessible environment. To date, there is only one evidence based or evidence informed HIV prevention intervention for transgender women listed in the CDC compendium.[1] Before this intervention can be disseminated more broadly, it needs to be evaluated in a structured trial, necessitating the proposed information collection. However, this is an exploratory evaluation designed for a preliminary assessment of efficacy. In designing this study, we considered feasibility in terms of the number of clients served by the TLC and the ethics of withholding or delaying services for a vulnerable, hard-to-reach population. Within these parameters, we determined that a limited pre/post evaluation without a control group would provide the information needed (i) for a preliminary assessment of the intervention, and (ii) to inform the design of a future, more rigorous controlled study.

Combination interventions to reduce disparities in HIV infection for transgender women who have sex with men are sorely needed, as this population is one of the highest risk and most underserved groups in the United States.[2] Transgender women are a key population at high risk of HIV infection, with HIV prevalence estimates in the U.S. of 28% (laboratory confirmed)[3] and evidence of very high rates of previously undiagnosed HIV infection.[4] Evidence suggests that socioeconomic marginalization (e.g.,

unemployment, incarceration, homelessness) is prevalent among transgender women[5-9] and drives HIV-related risk behaviors.[8-10] Pre-exposure prophylaxis (PrEP) is a new HIV prevention approach in which individuals who are at high risk take anti-retroviral medications to prevent HIV infection. This approach, specifically daily dosing with two medications (tenofovir and emtricitabine) was approved by the US Food and Drug Administration (FDA) in 2012 for the prevention of HIV infection. While PrEP is indicated and potentially effective in preventing HIV infection among transgender women, [11,12] knowledge about PrEP and uptake among transgender women, outside of clinical trials, is low, [13,14] indicating a need for comprehensive HIV prevention efforts targeted to their unique circumstances and vulnerabilities.

The TLC intervention provides biomedical services including HIV/STI testing and referral/linkage to PrEP for HIV prevention. The TLC intervention also addresses the specific structural and social drivers of HIV risk among transgender women, drawing on a social determinants theoretical model of HIV risk. Social determinants of health are the overlapping social structures, conditions, economic systems and circumstances that influence health and drive health inequities,[15] including in HIV-related outcomes. [16,17] There is mounting evidence that social and economic factors are associated with high rates of HIV transmission and adverse HIV-related outcomes.[17] Access to basic services (housing, employment, legal aid, health services) via the TLC intervention may promote protective processes, including affirmation of gender identity and collective and supportive experiences among transgender women, reducing HIV-related risk. [18,19] To our knowledge, no study has evaluated a combination (biomedical, behavioral, social/structural) HIV prevention intervention for transgender women.

The project is in alignment with several national HIV prevention goals[2]:

- 1.A.2 Focus on high-risk populations (specifically including transgender women and noting the particularly high burden of HIV among Black transgender women)
- 1.B.1 Design and evaluate innovative prevention strategies and combination approaches for preventing HIV infection in high-risk populations and communities, and prioritize and promote research to fill gaps in HIV prevention science among the highest risk populations and communities
- 1.B.2 Support and strengthen integrated and patient-centered HIV and related screening (sexually transmitted infections [STI], substance use, mental health, intimate partner violence [IPV], viral hepatitis infections) and linkage to basic services (housing, education, employment)
- 1.B.3 Expand access to effective prevention services, including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).
- 3.B Adopt structural approaches to reduce HIV infections and improve health outcomes in high-risk communities

The following section of the U.S. Federal Code is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of “research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.” (**Attachment 1**)

2. Purpose and Use of the Information Collection

The awardee of the cooperative agreement, Chicago House & Social Service Agency, and their partners, Ann & Robert H. Lurie Children’s Hospital of Chicago and University of Illinois at Chicago, will be responsible for collecting all data for this study. In addition, Heartland Health Outreach (HHO) is the ongoing medical provider for the overall TLC program. The purpose of the information collection is to evaluate the pre-post efficacy of the TransLife Center (TLC) intervention. All

participants will have access to all TLC services as part of the intervention. The TLC intervention directly addresses the structural barriers to effective health promotion among transgender women through a coordinated screening and service model, including direct access to transgender-specific services most needed and requested by transgender women: employment, housing, legal, and health services, following a social determinants of health conceptual model.[14] Information collected from this activity will be used to determine whether changes in sexual and HIV prevention behaviors, including uptake of PrEP, can be demonstrably linked to participation in this intervention. The study will assess changes in intervention participants' behaviors at baseline, 4 and 8-months.

The TLC Intervention follows a patient-centered case management and service delivery model and is delivered through a one day per week drop-in center (TransSafe) and through on-going interactions with TLC staff, i.e., to provide referral and linkage to housing, employment, legal and medical services. Participants enter the TLC program through direct referral or through drop-in to TransSafe. Basic services needs are assessed upon entry into the TLC program through a brief intake with a staff member (to identify areas of service need/interest) and linkage to services (housing, employment, legal, medical) as needed, which are delivered over the entire 8-month enrollment period. As such, researchers deemed it unethical, at this time, to withhold (control group) or delay (waitlist control) access to needed services within the TLC intervention for such a hard to reach population with myriad needs. Additionally, statisticians from both the grantee and CDC evaluated power analyses and determined that having a control group would require the need for a larger sample size and with such a small population in the local jurisdiction it was deemed not feasible. The researchers also recognize that the study design is not a gold standard, randomized control trial (RCT), but is an exploratory evaluation of the possible efficacy of the intervention while fully knowing that an RCT would be necessary in future research to definitively attribute the effect of the intervention on the outcomes.

The specific aims of the study are as follows:

1. To determine the pre-post efficacy of the TLC intervention in a single arm trial on the primary outcome: number of condomless anal sex acts without protection by PrEP in the last month among 150 sexually active, HIV-uninfected adult TW, with assessments at baseline, 4 and 8 months.
    a. To assess the dose response relationship by intervention exposure (i.e., the proportion of intervention components received/expressed need) as well as exposure to specific components (i.e., employment, housing, legal, and health) on reductions in the primary outcome.
    b. To assess mediation of intervention effects on protective processes (gender affirmation, collective self-esteem, social support) theorized to increase with intervention exposure;
2. To examine the implementation experiences of TLC intervention participants and staff through semi-structured interviews with 20 TLC participants and 10 TLC and Chicago House staff members involved in delivery of services through the TLC intervention.
3. Exploratory Aims:
    a. To describe the trajectory of PrEP indication, uptake, retention and adherence in the community-based sample over an 8-month follow-up period and evaluate the impact of the TLC intervention on the PrEP continuum of care.
    b. To explore whether reductions in HIV risk are associated with epidemiologically-linked moderators including age and race/ethnicity.

Primary Hypotheses**:** We hypothesize that participants in the TLC intervention will demonstrate a reduction in number of condomless anal sex acts not protected by PrEP pre-post intervention.

Primary Outcome: The primary outcome of interest is the number of condomless anal sex acts without protection by pre-exposure prophylaxis (PrEP) reported in the previous month.

One hundred and fifty adult HIV negative transgender women who have sex with men will be recruited to the study and then assessed over 8 months. The transgender women recruited into the study will be diverse, comprised mainly of racial/ethnic minority participants, and reside in the greater metropolitan Chicago area. Recruitment will be carried out by study front-line staff, who will be members or allies of the target population (**Attachment 3**). Interested participants will complete a brief screening process for eligibility (**Attachment 4a**). Immediately following screening, participants who are eligible and interested in participating will be consented for participation (**Attachment 5a**) and contact information will be collected (**Attachment 4b**). Participants will also be asked to sign an authorization to release medical information (**Attachment 5c**). Consent will occur prior to the occurrence of any research activities. TLC intervention participants will complete computerized assessments through interviewer and self-administration modes at three separate assessment visits: baseline, 4, and 8 months. Study assessments will include report of demographic characteristics and psychosocial factors (substance use, mental health symptoms), sexual risk behavior- the primary outcome, PrEP care engagement- the secondary outcome, intervention mediators (gender affirmation, collective self-esteem, social support) and intervention satisfaction (4 and 8-months only) (**Attachments 4c and 4d**).

We will also examine the implementation experiences of TLC intervention participants and staff through semi-structured interviews with 20 TLC participants and 10 TLC and Chicago House staff members involved in delivery of services through the TLC intervention (**Attachment 4e**). Eligible participants will be consented for participation prior to the interview (**Attachment 5b**).

The study protocol and all data collection instruments have been approved by Lurie Children's Hospital IRB (**Attachment 6a**).

Exhibit 2.1: Overview of Key Variables

Measures	Data Collection Tool
Quantitative Assessment	
• Sexual risk behaviors • Gender affirmation • Collective self-esteem • Social support • Acceptability and satisfaction questions • PrEP linkage, initiation, retention and adherence • Demographics • Substance use • Depressive symptoms • Anxiety symptoms • Victimization	• ARBA[a] (**Attachments 4c and 4d**, section 2)[20] • Gender affirmation (**Attachments 4c and 4d**, section 4)[21] • CSES[b] (**Attachments 4c and 4d**, section 5)[22] • Social support (**Attachments 4c and 4d**, section 6) • CSQ-8[c] (**Attachment 4d**, section 10)[23] • PrEP engagement (**Attachments 4c and 4d**, section 3) • Demographic items (**Attachments 4c and 4d**, section 1) • ASSIST[d] (**Attachments 4c and 4d**, section 7) • CESD-10[e] (**Attachments 4c and 4d**, section 8) • GAD-7[f] (**Attachments 4c and 4d**, section 9) • Victimization scale (**Attachment 4c**, section 10)
Qualitative Assessment	
• Demographics • Acceptability and satisfaction • Intervention impact on HIV risk behavior • Intervention impact on the social determinants	• Semi-structured interview (**Attachment 4e**)

[a] AIDS-Risk Behavior Assessment (computerized self-interview); [b] Collective Self-Esteem Scale/Empowerment; [c] Client Satisfaction Questionnaire; [d] Alcohol, Smoking, and Substance Involving Screening Test (World Health Organization); [e] Center for Epidemiologic Studies Depression Scale; [f] Global Assessment Generalized Anxiety Disorder Scale.

For the intervention trial, because transgender women are a unique and hidden population, with no sampling frame, multiple convenience and referral-based sampling techniques will be used to identify and recruit participants. Because we are not using random sampling methods to recruit participants to this study, the results will not be generalizable beyond the specific populations and geographic contexts in which they were obtained. Rather, the results will be used to demonstrate a relationship between receipt of the TLC intervention and improvements in sexual health and HIV prevention behaviors over time among participants in the study.
Results from this data collection will primarily be used to assess the pre-post efficacy of the TLC intervention. In addition, we anticipate that multiple manuscripts will be published in peer reviewed journals, presented at national conferences, and provided on conference websites. Links to these publications will be available through the CDC website.

3. Use of Improved Information Technology and Burden Reduction

During the recruitment, interested participants will be screened for eligibility either in person or over the telephone prior to enrollment (**Attachment 4a**). This will allow participants to complete the screening form at a place and time that is most convenient to them and will enable us to instantaneously determine study eligibility. Participants are required to present in-person to enroll in the intervention; however, this will enable staff to administer one-on-one informed consent, introduce the TLC program, identify areas of service need/interest and provide linkage to services as needed.

The quantitative assessment **(Attachments 4c and 4d)** will be conducted in-person and delivered via computer-assisted interviewer-administered format, with the exception of the most sensitive questions (i.e. regarding sexual risk and substance use), which will be delivered in self-administered format to increase the likelihood of reporting of these behaviors. [24-26] An interviewer will remain close by for the self-administered portion of the survey to answer questions and ensure item comprehension. Using computer-assisted technology to conduct the assessments will allow us to build in computer-generated skip patterns, significantly cutting down on respondent burden. In addition, data collected through a computer application can be used to automatically generate the study database, reducing data entry burden and potential interviewer and data coding errors.

The individual, in-depth interviews (IDIs) will be conducted in person. After asking for and receiving permission from the respondent, the staff will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent.

4. Efforts to Identify Duplication and Use of Similar Information

Despite research documenting high rates of sexual risk behaviors and HIV infection among transgender women, to our knowledge, only five published, non-randomized interventions, all non-biomedical, have attempted to reduce HIV risk in transgender women. [27-31] Four of these studies (Nemoto, Bockting, Taylor, Garofalo)[27-29,31] documented modest reductions in sexual risk behavior among transgender women, with some evidence that effects diminished over time (Nemoto, Bockting). [28,29] None of these interventions included biomedical components, such as HIV/STI testing or referral/linkage to PrEP (as they occurred prior to the approval by the Food and Drug Administration of PrEP for HIV prevention),

and none directly addressed the structural barriers to health promotion and preventive behavior among transgender women.

Because the information collected here will be used to evaluate TLC combination (i.e. biomedical, behavioral, social/structural) HIV prevention intervention, the Agency believes this information is not captured elsewhere. The Agency believes no other survey data collection effort has been conducted or has been planned to collect similar information for this population. CDC conducted a review of similar studies prior to the issuance of the Cooperative Agreement and determined that this study is collecting unique information from the populations. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

5. Impact on Small Businesses or Other Small Entities

This collection request does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The study will provide the quantitative and qualitative data needed to evaluate the efficacy of a combination HIV prevention intervention for transgender women. The length of data collection is 8 months, and data will be collected 3 times at 4-month intervals: baseline, 4-month and 8-month. Collecting assessment surveys less frequently than every 4 months would limit our ability to assess HIV/STI risk and PrEP uptake and adherence. The number of assessment surveys administered is the minimum required to assess any effects of the intervention and post-intervention decay.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection effort does not involve any special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-day FRN notice to solicit public comments was published on Tuesday, January 30, 2018, Volume 83, Number 20, Page 4207 (Attachment 2). One non-substantive comment was received (see **Attachment 2a**).

In addition, Chicago House &Social Service Agency, Ann & Robert H. Lurie Children's Hospital of Chicago, and the University of Illinois at Chicago were consulted for the development of this study in 2016 and 2017. There were no unresolved issues associated with the consultation process.

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9. Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for participation are an important tool used in research and are particularly important for the population in this study. This study seeks to recruit, enroll, and follow a hard-to-reach and possibly hidden population, while also asking highly sensitive questions about issues such as sexual behavior, HIV and STI status, and substance use. To enhance our ability to recruit 150 transgender women at high risk of HIV infection and retain at least 80% of that sample, we will provide participants with tokens of appreciation for their time spent completing the baseline, 4 and 8-month follow up assessments.

Investigators at the site drew upon their experience working with this population and community norms to come up with the following participant token of appreciation plan:

Participants in the TLC Intervention will be provided with a token of appreciation of $50 for completing the baseline survey. Participants will also be given a token of appreciation of $50 for completing the 4-month follow up survey and $50 for completing the final 8-month follow up survey, for a total of $150 for all three visits (baseline, 4 and 8-month). Finally, the subset of 20 TLC participants and 10 TLC staff members who complete the 60-minute in-depth interview will be given a token of appreciation of $50 for the time and effort associated with completing that interview. Interviews are not part of a TLC staff member's routine responsibilities and all staff interviews will be conducted outside of regular work hours.

A token of appreciation for multiple assessment surveys is crucial to maintaining the integrity of the sample, especially for transgender women whose overall opportunities for study engagement are fewer due to being a very hidden and difficult to access population who are often times transient. Transgender women who present to TLC with myriad needs may also prioritize having those needs met rather than participating in a research study given that this is housed within a drop-in center. They may also have fewer modes and opportunities for engaging with study activities in the four-month period between assessment surveys based on their personal life circumstances, which can be unstable. For this reason, it is essential to provide a $50 token of appreciation for the baseline, 4-month and 8-month follow-up assessment surveys as well as the in depth interviews. Without a token of appreciation for the assessment surveys and interviews, it would be very difficult to recruit and retain transgender women to participate in the research study.

The token of appreciation amount proposed for the study is based on the Investigators' experience engaging transgender women in similar research projects. Researchers from both Chicago House and Lurie Children's have been involved in prior studies with transgender women. This collaborative team

has been working together for the past three years to develop, refine and evaluate the TLC service model with funding from both philanthropic sources and the Health Resources and Services Administration (HRSA; TLC for HIV-positive transgender women). The recruitment and retention model for that study is similar to the proposed study (TLC for HIV-negative transgender women). In the aforementioned study, the incentive amount is $50 per visit. Based on that success, this study makes the same incentive proposition. The token of appreciation amounts proposed for the baseline, follow-up, and in-depth interview sessions also address the project team's concern about data quality and burden on the respondent for completion of lengthy questionnaires and in-depth personal interviews. These amounts also address the project team's concerns about making participation equitable for transgender women from a range of socio-economic backgrounds. For example, transgender women are disproportionately represented among homeless people, often as a result of estrangement from families of origin,[32] Transgender women also experience discrimination in seeking housing. [33-36] In studies of younger transgender women in Chicago and Los Angeles, 46% reported difficulty finding a safe place to sleep[5] and 47% were homeless.[37] With regard to employment, 63% reported having trouble finding a job.[5] Many transgender earn money to support themselves through sex work. [9,32,38,39] As a result, many transgender women in this already hard-to-reach population may not have adequate access to transportation and/or may have unpredictable schedules. Members of the target population reside in metropolitan Chicago, the third largest metropolitan area in the United States. Within Chicago city limits, depending on participants' economic and transportation resources, round-trip travel to Chicago House may require several hours and multiple bus lines. Transportation to and from, and participation in the 60-minute surveys and interview represent a large portion of participant's time and will require a substantial commitment.

Other forms of tokens of appreciation were considered, such as tokens of appreciation that reinforce health messages and healthy behaviors (e.g. educational materials, health promotion products). This study is designed to test potential health knowledge and behavioral outcomes associated with participation in the TLC intervention. As such, educational materials and health promotion products risk confounding the experimental conditions of the study. The purpose of this study is to evaluate the efficacy of an intervention. Given that the intervention has a substantial health education and promotion component, providing similar materials as a non-cash token of appreciation would substantially confound the results of the intervention.

In his memorandum for the president's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions…" This study seeks to recruit, enroll, and follow a hard-to-reach and possibly hidden population, while also asking highly sensitive questions about issues such as sexual behavior, HIV and STI status, and substance use. Transgender women fall within the parameters of a hard-to-find population. Recent population estimates of transgender adults suggest they make up only 0.3% of the overall population of the US.[39] Because transgender women are a small, hard-to-reach population, we believe a token of appreciation will increase the attractiveness of this study to the potential participants and better engage them in the data collection process that is critical to this evaluation of the TLC intervention.

Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates and the use of

modest tokens of appreciation is expected to enhance survey response rates without biasing responses. Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups in to research.

In a recent study of the effects of a Spanish-language HIV risk behavior intervention for Latino MSM living in South Carolina (HOLA en Grupos, OMB 0920-0942, exp. 3/31/2018), offering a token of appreciation improved participation among Latino MSM. HOLA en Grupos and comparison intervention participants were given a token of appreciation of $40.00 after completing the baseline assessment and $50.00 after completing the post-intervention 6-month follow-up assessment. Participants in both study conditions were given a token of appreciation of $40.00 for each of the 4 intervention sessions they attend. To facilitate retention, participants received $5.00 for contacting study staff to update their contact information if it changed during the study period. In total, participants who completed all activities received $250 over the intervention period. A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among this group.[41]

Remuneration has been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014), the Transgender HIV Behavioral Survey (OMB 0920-0794, exp. 12/31/2010), and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), all of which included hard-to-reach populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Officer for CDC/ATSDR has assessed this package for applicability of 5 U.S.C. § 552a and determined that the Privacy Act does apply to the overall information collection as PII is being collected. All PII is collected to maintain and track the participants throughout the study. Access to these data is restricted to specific job tasks and individuals who perform those tasks. Access to PII in study data collected for the purposes of analysis is limited to the study investigators and data manager. However, personally identifiable information (PII) will not be transmitted to the CDC or retrievable by a personal identifier.

A privacy impact assessment was conducted to ensure the protections of the collected information (**Attachment 8**). This information collection is covered under the Privacy Act system of records notice (SORN) # 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC", which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

The awardees, Chicago House & Social Service Agency, Ann & Robert H. Lurie Children's Hospital of Chicago and University of Illinois at Chicago, will be responsible for collecting all data for this study. We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the research team. Terms of the CDC Cooperative Agreement authorizing data collection require the grantee to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the

extent permitted by law. We have obtained a Certificate of Confidentiality from the CDC to further protect the confidentiality of study participants (**Attachment 9**).

As this study will collect several types of sensitive personal information – including name, phone, email, address, date of birth, social media information, and medical notes containing HIV and STI test results, PrEP use and sex behaviors – from transgender women who have sex with men, we are sensitive to the need to protect personal health information (PHI). To ensure respondents' PHI is protected, we will take several measures to separate participant names and contact information from study-related data. In addition, no participant names or contact information will be transmitted to CDC. All collected data will be de-identified prior to transmission.

All participants will be assigned a unique identification number for the study. Each participant will sign a consent form indicating that the data received and analyzed by CDC will not contain participant names or contact information, and each person's data will be identified only by study participant ID. There will be three types of files that contain participant names and contact information: consent forms, locator files and attendance records. Signed consent forms will be kept separate from all other study data, in a locked cabinet away from workstations and will only be accessed in the event of a study visit, consent amendment, or an audit. Participant contact information containing phone numbers and email address will be kept in a locked cabinet in the research area, separate from other files. Intervention attendance records will be stored in locked file cabinets or in password protected electronic files on a secure server. Access to study files will be limited to study staff.

The visit tracking data base, survey data files, case report forms and audio recordings and transcriptions will be maintained as electronic files. Computer access will be password protected. Data files will be maintained in de-identified format and stored in password-protected files on secure servers. Tracking files (i.e., linking database) will be maintained in a highly secure scheduling and monitoring database, REDCap, at Northwestern University. This database is used to schedule and track study visits and accessible only to study staff; it is completely password protected.

Survey data will be captured in web-based format via Qualtrics software, which uses Transport Layer Security (TLS) Encryption for all transmitted data; all data collected via Qualtrics will be done only by ID number and not by name. Data files will be exported from Qualtrics and imported into SPSS database for storage and analysis on a secure server at Lurie Children's Hospital. Only the study investigators and data manager will have access to these data.

All biological specimens will be labeled with coded identifiers for processing to maintain confidentiality and privacy. Biological specimens (urine, anal swabs, blood) for HIV/STI testing will be coded and transferred by local courier for processing in external laboratories used commonly in the testing programs at Lurie Children's and Chicago House. Hair samples for assessment of tenofovir disoproxil fumarate level (aka PrEP) will be coded and transferred to the Hair Analysis Lab at University of California San Francisco (UCSF) via mail courier service. All research staff will be trained for collection of hair samples by Dr. Kuhns with guidance from the Hair Analysis Lab at UCSF. HIV/STI testing will be completed by clinical providers of Heartland Health Outreach (HHO; the medical provider for the TLC program) or by non-research staff of Chicago House under contract with Chicago Department of Health. Biological specimens collected under this protocol will be used for the purposes outlined herein and not for future research.

Only Chicago House has direct interaction with study participants. As a result, coded and encrypted electronic data files, which include; program attendance records, HIV/STI screening results, Pre-exposure prophylaxis (PrEP) medical visit information, survey, and biomarker results, are transferred from Chicago House to Lurie Children's Hospital where the data are housed. Lurie's then transmits the data to the University of Chicago for analysis in a secure database for data analysis.

Semi-structured interview data will be collected in a de-identified format, data will not be linked to individual names or identifiers. The audio-recorder and audio-recordings will be password-protected to protect against breach of privacy. Audio-recordings will be transcribed verbatim, with the exception that any inadvertent disclosure of names or other identifying information will be coded or excluded. Computer data files are maintained by ID number only, and are password protected and encrypted for transfer between study sites. Audio files will be destroyed as soon as possible after transcripts are verified and no later than three years from the closure of the study protocol with the Lurie Children's IRB. For semi-structured interviews of TLC participants and staff, we have requested and received approval to waive documentation of informed consent under 45 CFR 46.117 (c). The request for waiver of documentation of consent is based on the fact that the interview data will be collected in a one-time visit, de-identified (not linked to an individual participant name or other identifiers), and is minimal risk. This waiver is not expected to adversely impact the rights of participants because the risks of study participation are minimal and the potential for breach of confidentiality is minimal. Participants in the semi-structured interviews will receive a copy of the consent form.

All biological specimens will be labeled with coded identifiers for processing to maintain privacy All identifying information will be destroyed at the end of study and specimens, survey and audio recordings will be retained no longer than three years from the closure of the study protocol with the Lurie Children's IRB.

Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. Any data made publicly available after the completion of the study will be de-identified and will not be linked to participant contact information.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This study has been reviewed and approved by the Ann & Robert Lurie Children's Hospital of Chicago IRB (**Attachment 6a**). Chicago House and Social Service Agency has ceded responsibility for the review of research to Lurie Children's IRB (**Attachment 6b**). The University of Illinois at Chicago (UIC) IRB has determined that UIC is non-engaged (**Attachment 6c**).

For semi-structured interviews of TLC participants and staff, the Lurie Children's IRB has approved our request for a waiver of documentation of informed consent under 45 CFR 46.117 (c). The request for waiver of documentation of consent is based on the fact that the interview data will be collected in a one-time visit, de-identified (not linked to an individual participant name or other identifiers), and is minimal risk. This waiver is not expected to adversely impact the rights of participants because the risks of study participation are minimal and the potential for breach of confidentiality is minimal. Participants in the semi-structured interviews will receive a copy of the consent form.

Sensitive Questions

This is an intervention trial to evaluate the effectiveness of an HIV prevention intervention for transgender women at high risk for HIV infection. As such, our study entails collected of sensitive HIV-related information. All study staff will be trained to provide respondents with referrals for prevention and care, such as mental health organizations, as needed. Sensitive questions will be asked to identify the risk level of participants. We will inform all participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimates of Annualized Burden Hours

This study will enroll 150 transgender women to participate in the intervention and assessment survey. In addition, 20 of the 150 intervention participants and 10 TLC staff will be selected to participate in a semi-structured interview. The total number of participants in the study will be 160 (150 transgender women and 10 TLC staff).

Transgender women will be recruited either online through web advertisements or in-person through venue-based sampling and outreach, print advertisements, recruitment at the TLC drop-in center, or word of mouth (**Attachment 3**). All potential participants will complete a brief screening process for eligibility (**Attachment 4a**) prior to consent and data collection. Eligible participants will be consented for participation (**Attachment 5a**) and contact information will be collected (**Attachment 4b**). For the qualitative interview, the 30 participants (20 TLC participants and 10 TLC staff) will be selected from a pre-determined list, therefore no additional screening will be required before participants are consented for participation (**Attachment 5b**). All recruitment and data collection activities will be carried out by grantee staff.

The length of the recruitment and enrollment period is 18-months. We expect to screen 300 transgender women. Of these, we expect 50% to be eligible and to enroll in TLC. We anticipate screening will take 4 minutes (**Attachment 4a**) and providing contact information will take 1 minute (**Attachment 4b**). Data collection will include 3 assessments (baseline, 4- and 8-months. The assessment will take about 60 minutes total to complete, and will be administered at baseline (**Attachment 4c**), 4-month and 8-month follow-ups (**Attachment 4d**) (3 total responses). We anticipate it will take the 60 minutes to complete each of the 30 in-depth interviews (**Attachment 4e**). The total number of burden hours over the entire 2-year data collection period is 510 hours. The estimated annualized burden (for a 12-month period) is 255 hours. Exhibits 12.1 and 12.2 provide further details about how the estimates of annualized burden hours and costs were calculated.

Exhibit 12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Eligibility Screener (Att. 4a)	150	1	4/60	10

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Contact Information (Att. 4b)	75	1	4/60	5
General Public-Adults	Baseline Assessment (Att. 4c)	75	1	1	75
General Public-Adults	Follow Up Assessment (Att. 4d)	75	2	1	150
General Public-Adults	Participant Interview (Att. 4e)	10	1	1	10
General Public-Adults	Staff Interview (Att. 4e)	5	1	1	5
				Total	**255**

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2017 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this request. The estimated annualized burden cost is $6206.70. This cost represents the total burden hours of general respondents multiplied by the average hourly wage rate ($24.34).

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Burden Hours	Hourly Wage Rate	Respondent Costs
General Public-Adults	Eligibility Screener (Att. 4a)	10	$24.34	$243.40
General Public-Adults	Contact Information (Att. 4b)	5	$24.34	$121.70
General Public-Adults	Baseline Assessment (Att. 4c)	75	$24.34	$1825.50
General Public-Adults	Follow Up Assessment (Att. 4d)	150	$24.34	$3651.00
General Public-Adults	Participant Interview (Att. 4e)	10	$24.34	$243.40
General Public-Adults	Staff Interview (Att. 4e)	5	$24.34	$121.70

Type of Respondent	Form Name	Burden Hours	Hourly Wage Rate	Respondent Costs
				Total $6206.70

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The annual cost to the government for the data collection is estimated to be $695,535 (Exhibit 14.1).

Exhibit 14.1: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, Project Officer (GS-13 0.40 FTE)	$40,810
	CDC Scientist (GS-13, 0.20 FTE)	$20,405
	CDC Project Coordinator (GS-12, 0.40 FTE)	$34,320
	Subtotal, Direct Costs	**$95,535**
Cooperative Agreement Costs	**Annual Cooperative Agreement #PS15-002 Costs**	**$600,000**
	ANNUALIZED COST TO THE GOVERNMENT	**$695,535**

15. Explanation for Program Changes or Adjustments

This is a new information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Our analysis will focus on questions related to the study objectives. Our analysis plans for assessing the pre-post efficacy of the intervention include a tabular analysis to measure baseline variables and assess their distribution in the sample during the follow up time points (4 and 8 months). Specifically, we will measure the change in number of condomless anal sex acts from baseline to 4 and 8 months.

Data collection will occur over a period of 18 months, beginning in January of 2019 (2 months after OMB approval), analyses will be carried out in July 2020 – October 2020 (19 – 22 months after OMB approval), and the final data set and report will be submitted in December 2020 (24 months after OMB approval). We are requesting approval for 18 months of data collection. The project timeline is detailed in exhibit 16.1.

Exhibit 16.2: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol	September 2016 – July 2017
OMB Submission	August 2017
Recruitment	1 month after OMB Approval
Data Collection	2-19 months after OMB Approval
Data analysis finalized and report drafted	19-22 months after OMB Approval
Final de-identified data set submitted to CDC	24 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, contact information, and locations will be removed) qualitative database for this study along with the corresponding data documentation, which will be made publicly available within 30 months of the end of data collection. It is anticipated that the data collected through this study will be shared as summary data tables and restricted use dataset(s). A data use plan for information collected during this study has been developed. The plan describes in detail how data access will be provided and the provisions for protection of privacy, security, intellectual property, or other rights (**Attachment 7**).

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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