

Summary of Proposed Changes in the ICR for Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection

OMB# 0920-1246

Summary of Changes

We are requesting non-substantive modifications to the information collection request (ICR) for Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection OMB# 0920-1246. As a result of the COVID-19 pandemic, we are requesting a change in the OMB-approved data collection method to mitigate risks for transmission of SARS-CoV-2 among participants and research staff. The changes requested for this ICR are non-substantive modifications to include: 1) adding an option to switch from in-person intervention delivery to virtual options via internet-based video conferencing and telemedicine software (eg., Doxy.me and Zoom) and 2) adding a change from in-person data collection of the baseline, 4 and 8 months assessments and in-depth interviews to remote data collection via an internet survey link or telephone for interviews. No changes are requested to survey/data collection instruments and there are no changes to the burden hours calculated for the study. In addition, there is no video recording included in these changes to virtual methods.

Changes to Include an Option for Virtual Intervention Delivery via Internet-based Video Conferencing and Telemedicine Software

The TLC Intervention follows a patient-centered case management and service delivery model and is delivered through a one day per week drop-in “one-stop-shop” milieu (“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. TransSafe provides a social and service milieu in which participants may access services in a barrier-free and affirming environment. Participation in the TLC intervention may include referrals to services known as “TransWorks,” “TransHousing,” “TransLegal,” and “TransHealth”

During COVID-19 restrictions, TLC services, including TransSafe, “TransWorks,” “TransHousing,” “TransLegal,” and “TransHealth” are offered in virtual mode, via telephone, web-based telehealth and teleconference, as well as email communication.

Table 1. Proposed Intervention Delivery Modification to Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection

Doc, Page, Section, Variable	Change Proposed	Reason for Change Proposed
SSA, Page 15, Estimates of Annualized Burden Hours and Costs	<p>Removed: References to in-person intervention delivery and non-restricted recruitment activities due to COVID-19 risks</p> <p>Added: “Transgender women will be recruited actively at the TLC drop-in center, “TransSafe” (or virtual TLC drop-in center or via virtual TLC services, during COVID-19 restrictions) by study staff and staff will visit local gathering places of TW, such as night clubs, pageants/balls and public places, such as local parks, to identify and recruit potential participants as permitted.”</p>	Added to describe virtual intervention delivery and recruitment procedures.
SSB, Page 4, Respondent Universe and Sampling Methods	<p>Removed: References to in-person intervention delivery and non-COVID-19 restricted recruitment activities</p> <p>Added: “Transgender women will be recruited actively at the TLC drop-in center, “TransSafe” (or virtual TLC drop-in center or via virtual TLC services, during COVID-19 restrictions) by study staff and staff will visit local gathering places of TW, such as night clubs, pageants/balls and public places, such as local parks, to identify and recruit potential participants as permitted.”</p>	Added to describe virtual intervention delivery and recruitment procedures.

Changes to Remote Data Collection of Baseline, 4 and 8-month Assessments and In-depth Interviews via an Internet Survey Link or Telephone for Interviews

Study visits will be completed at Chicago House, or Lurie Children's facilities/locations except in cases in which travel to study sites is not possible due to scheduling difficulties, moving from the local area, or due to COVID-19 restrictions, in which case a remote version of computerized questionnaires may be completed. During the COVID-19 pandemic, visits may be conducted in-person, using precautions, or remotely via telephone or web-based telemedicine conference. Chicago House has adopted HIPAA compliant Doxy.me telehealth software for use during the pandemic, which will also be used to conduct remote research visits. TLC intervention

participants will complete computerized assessments through self-administered modes at three separate assessment visits (baseline, 4, and 8 months).

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. The qualitative interviews will be conducted by study consultants beginning in year 2 of the study (after enrollment has begun), either in-person (when COVID-19 stay-at-home orders are lifted) or by telephone (due to COVID-19 stay-at-home requirements), and audio-recorded and transcribed.

Table 2. Proposed Data Collection Modification to Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection

Page, Section, Variable	Change Proposed	Reason for Change Proposed
SSA, Page 6, Purpose and Use of Collection, content change	Removed: references to interviewer administration and in-person visits	Changed to include remote data collection due to COVID-19 pandemic
SSA, Page 7, Purpose and Use of Collection, content change	Added: “via telephone or video teleconference”	Changed to include remote data collection due to COVID-19 pandemic
SSA, Page 8, Use of Improved Information Technology and Burden Reduction	Removed: references to interviewer administration and in-person visits Added: Specific procedures for remote data collection	Changed to include remote data collection due to COVID-19 pandemic
SSA, Page 12, Protection of the Privacy and Confidentiality of Information Provided by Respondents	Added: “There will be no video recording of any aspect of intervention delivery or data collection.”	Added to clarify that remote data collection via video conferencing does not include video recording of participants.

SSA, Page 13, Protection of the Privacy and Confidentiality of Information Provided by Respondents	Added: “During the COVID-19 pandemic, PrEP hair analysis/DBS, Chlam/GC, and Syphilis Health Check will not be collected at any time point. HIV testing will be completed at the baseline visit only.”	Added to clarify that in-person biomarker screenings are suspended due to COVID-19 pandemic.
SSA, Page 17, Plans for Tabulation and Publication and Project Time Schedule	Updated: project time schedule	Changed to reflect OMB Change Request approval time
SSB, Page 5, Procedures for the Collection of Information	<p>Removed: references to in-person data collection.</p> <p>Added: “either in person, over the telephone, or via teleconference prior to enrollment.”</p> <p>Added: “During the COVID-19 pandemic, consent will be conducted in-person with restrictions or remotely via the e-consent module in REDCap.”</p> <p>Added: “Study visits will be completed at Chicago House, or Lurie Children's facilities/locations except in cases in which travel to study sites is not possible due to scheduling difficulties, moving from the local area, or due to COVID-19 restrictions, in which case a remote version of computerized questionnaires may be completed. During the COVID-19 pandemic, visits may be conducted in-person, using precautions, or remotely via telephone or web-based telemedicine conference. Chicago House has adopted HIPAA compliant Doxy.me telehealth software for use during the pandemic, which will also be used to conduct remote research visits.”</p>	Changed to include remote data collection due to COVID-19 pandemic
SSB, Page 6, Procedures for the Collection of Information	Added: “There will be no video recording of any aspect of intervention delivery or data collection.”	Added to clarify that remote data collection via video conferencing does not include video

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