Attachment 7

ChiCAS Data Use Plan

Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender Persons (PS16-003) Data Use Plan

This plan describes the anticipated use and release by CDC of the dataset(s) named below. All CDC data use plans are required to be in compliance with the CDC/ATSDR Policy on releasing and sharing data, available at: http://aops-mas-iis/Policy/Doc/policy385.pdf. This plan is modifiable and does not represent a legal contract between CDC and any other entity.

Dataset Name: HIV prevention among Latina transgender women: Evaluation of a locally developed intervention. Wake Forest University Health Sciences, Grant #1U01PS005137.

Data in this dataset are from one of two grantees supported by PS16-003, "Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender Persons." The purpose of the projects funded under PS 16-003 is to evaluate locally developed or adapted and potentially effective but insufficiently evaluated interventions that are designed to deliver a combination of HIV prevention, HIV care and treatment, and other support services to racial/ethnic minority transgender persons. Combination HIV prevention interventions are defined as a combination of mutually reinforcing biomedical, behavioral, and social/structural intervention components that together either reduce participants' risks for acquiring HIV or improve outcomes along the HIV care continuum.

Custodial Unit/Contact Information: NCHHSTP/DHAP/PRB:

- 1U01PS005137: Carla Galindo, MPH, CHES (fco4@cdc.gov), Project Officer

Study / Program Description: An estimated 1 in 4 transgender women has HIV; although some studies of transgender women have found prevalence as high as 39%. The odds of becoming HIV positive are estimated to be 34.2 times higher for transgender women than other US adult populations. Some subgroups may be particularly affected by HIV, including transgender women of color (including Hispanic/Latina transgender women) and transgender women who engage in sex work. Hispanic/Latina transgender women report high rates of condomless sex, low rates of medically supervised hormone therapy, and limited awareness of, knowledge about, and use of pre-exposure prophylaxis (PrEP).

The project uses a randomized intervention/delayed-intervention comparison group (waitlist) design to test the efficacy of the 2-session, Spanish-language ChiCAS intervention to promote consistent condom use and the use of pre-exposure prophylaxis (PrEP) and medically supervised hormone therapy by Hispanic/Latino transgender women. Eligibility to participate in the study is limited to individuals who: (a) Self-identify as male-to-female transgender or report having been born male and identifying as female; (b) Self-identify as Hispanic or Latina; (c) Are ≥ 18 years of age; (d) Report sex with at least 1 man in the past 6 months; (e) Are HIV negative (based on self-report and verification by rapid HIV testing); (f) Are fluent in Spanish; and (g) Provide informed consent. A total of 100 to 140

Hispanic/Latina transgender women will be randomized into the ChiCAS intervention (n=50 to 70) or a delayed-intervention comparison group (waitlist) (n=50 to 70).

Data on behavioral outcomes that are the focus of the intervention will be collected at baseline and 6 months following completion of the intervention for persons in the intervention condition and at baseline and 6 months later for persons in the waitlist comparison condition (and prior to their participation in the intervention). The efficacy of the ChiCAS intervention will be assessed by comparing changes in outcomes from baseline to 6-month follow-up among ChiCAS participants relative to individuals in the waitlist comparison condition.

Procedure for requesting access to datasets: Persons who request data are required to provide an approved copy of the Publication Guidelines Concept Proposal (under development) and a signed copy of this Data Sharing Agreement (see below) before data will be provided to them. The data sharing agreement must list and be signed by all individuals who will have access to the data or participate in preparing materials for publication before engaging in research and analysis activities with these data.

Data Source: Grant #1U01PS005137. HIV prevention among Latina transgender women: Evaluation of a locally developed intervention.

Population Represented by Datasets: Populations will include Hispanic/Latino transgender women.

Type of Data: Quantitative data from structured surveys for baseline and 6-month follow-up assessments; qualitative data from in-depth interviews with selected study participants to elucidate factors that contribute to or impede participant reports of engaging in the expected intervention outcomes following completion of the intervention: consistent condom use and use of PrEP and medically-supervised hormone therapy; medical record abstractions, and data from biological markers including PrEP and HIV test results. None of the data described here will contain personal identifying information from study participants.

Process for Omitting Identifying Information: Prior to transferring data to CDC, the PS16-003 awardee, Wake Forest University Health Sciences, will electronically delete all personally identifiable information, including intervention study participant names and contact information (addresses, phone numbers, and email addresses), from all data. Also, data collected from medical chart abstractions, including clinic locations, clinic visit dates, and medical test dates, will be de-identified or transformed prior to sending to CDC to further safeguard participant confidentiality in the electronic transmission of these data. CDC will be provided code and transformation keys in separate communications. Therefore, data transmitted to CDC will not contain PII. Wake Forest and CDC staff will not release data containing PII.

All quotations by intervention participants used in publications from qualitative data where the research population contains 40 or fewer participants can only be identified using gender identity, age category (not specific age), and race/ethnicity (if more than one race is provided, use 'multi-race'). For example, quotes will follow this format:

> *"Lorem ipsum dolor sit amet, duo ei dicta theophrastus intellegebat. Est meliore liberavisse cu. An duo populo laboramus, eam iusto appareat no. Eum probatus evertitur in. Ad ius feugiat consectetuer, eu liber maiorum mea. Nec an alia iriure." Hispanic/Latina Transgender Women, 18-24 years old.*

Data Quality Protocol: The grantee, Wake Forest University, will conduct data cleaning on all data sets prior to delivery to CDC. This process will ensure that all PII (including indirect identification data) are deleted from the data, or in the case of medical chart abstraction data, the data are coded or transformed in order to de-identify data.

Data Retention/Disposal Plan: All data will be retained until analysis is complete and for up to three years following study closure by the Wake Forest IRB. At that time, users must delete all data stored on their servers. CDC will store complete de-identified data on a secure server that is accessible through the Division of HIV Prevention, Prevention Research Branch.

Data Analysis Plan: Applicants requesting access to specific datasets created from datasets provided by Wake Forest University at the termination of its CDC-funded study, and after Wake Forest University, its study partners, and CDC have agreed that all required study analyses have been completed and presented, will submit a plan for analysis of the data requested from CDC. The data analysis plan will include a description of the topic(s), expectations or hypotheses that will be assessed based on analysis of the requested dataset, and a description of planned steps for analyzing and presenting the results of the planned data analysis.

Dataset Release Type*: (**BOLD *all that apply***) 1) public-use dataset, 2) **special-use data sharing agreement,** 3) restricted release, 4) no release

*Special-use data sharing agreement:

- Proposed activities involving the use of the data are reviewed and approved by CDC
- The special use dataset will be generated from a subset of the HIV prevention among Latina transgender women dataset used at CDC, with specific data elements to be determined with each individual request

Dataset Release Site: __ CDC/NCHHSTP/DHAP/PRB _____

Dataset Release Timeline: The grantee, Wake Forest University, will make study data from which all PII has been removed, available to CDC for potential release at the termination of the CDC-funded study. Prior to this, staff from the grantee, its study partners, the University of North Carolina, Greensboro and Triad Health Project,

Greensboro, NC, and CDC will review study datasets and analyze data relative to dissemination topics agreed to by all study participants. It is anticipated that the complete dataset will be made available to CDC about April 2023, after the grantee, its partners, and CDC have agreed that all key study analyses have been completed and cleared by CDC for publication.

Data Elements to be released: Baseline and 6-month study assessment questionnaires and participant responses, and in-depth qualitative interview guides and participant responses.

Dataset Release Format: In-depth interview data will be available in text format. Data from baseline and 6-month follow-up assessments will be provided in a SAS, SPSS or Stata file format.

Date This Form Filled / Last Revised: _____February 16, 2018 _____

Data Sharing Agreement for CDC PS16-003 Datasets

This data sharing agreement ensures that CDC's guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity are adhered to. This agreement is subject to change. All changes will be retroactive, and applicants provided with a summary notice of changes made. A signed data sharing agreement is a contract between CDC and the signatory data users.

Dataset Name: The source of all data is Grant #1U01PS005137. HIV prevention among Latina transgender women: Evaluation of a locally developed intervention. The specific analysis topic will be provided by the applicant.

_____

Applicants Who Will Have Access to Data:

_____

_____

List all persons (name, job title, research role, affiliation, email, phone) approved to have access to data and identify the principal person responsible for the analysis and maintenance/security of the data.

Period of Approval to Use Data: From [Date]:_____To [Date]:_____

Restrictions on Use of Data:
I will not use these data except for qualitative and/or statistical analysis and reporting as described in the attached Publication Agreement product proposal.

Any effort to determine the identity of any individual, group or organization whose data appears in the dataset is prohibited. I will not link these data files with individually identifiable data from other data files.

Maintaining Confidentiality and Requirements if Individual Identity is Discovered:
It is of utmost importance that the identity of data subjects cannot be disclosed. All direct identifiers, as well as characteristics that might lead to identification, are omitted from the dataset. If an individual identity is discovered, I will make no use of the identity and will immediately advise Ms. Carla Galindo, 404.639.1902, and no one else, of this discovery.

Requirement to Include CDC Disclaimer in Publications:
All written and oral presentations of results of analyses will include the following disclaimer: "The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention."

Requirement / Request for Copies of Draft and Final Publications:
Copies of draft oral and written presentations will be submitted to the CDC program office at least eight weeks prior to presentation or submission to a publisher so that CDC and program partners can be informed, verify that analysis results are consistent with previous grantee publications supported by the project results, and in the case of discrepancies, review the analysis and results with the applicant that is granted access to the data. CDC and partners may submit comments within this 8-week window. CDC reserves the right to refuse publication.

CDC will be notified upon final publication of a product and provided with a copy and citation information.

Penalties for Violating Agreement:
I understand that if I violate this agreement, penalties may apply in accordance with CDC policies and Federal law.

Compliance with this agreement will be monitored through pre-publication review of presentation products and/or verification of dataset destruction.

Signature of Data User:

_____Date:_____

All approved users must sign and date application

Signature of CIO/Division/Branch Oversight Official:

_____ Date:_____

Signature of approving official